# 2018 Multistate Pharmacy Jurisprudence Examination (MPJE) Review Course



## Federal Law

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# Recommended Reading



- **Guide to Federal Pharmacy Law, 9th Edition** by Reiss & Hall
  - ISBN-10: 0967633281 | ISBN-13: 978-0967633282
- From http://www.apothecarypress.com/.
  - This BEST SELLER is a comprehensive, easy-to-study guide to current federal pharmacy law.
  - It is designed to help you review the most important federal pharmacy statutes and regulations, including the newest changes in the
    - Rescheduling of controlled substances.
    - Medical Marijuana programs.
    - Generic substitution of biosimilars.
    - New DEA rules that permit pharmacies to collect controlled substances for disposal.
    - FDA regulation of compounding.
    - Drug Quality and Secruity Act (DQSA).
    - Do Not Compound list.
    - Medicare changes.
    - Health Savings Accounts
    - Expedited programs for serious conditions … and much more.
  - This book is designed to assist candidates in preparing for pharmacy law examinations in all states.
  - Also includes over 350 federal law practice questions and answers.
- List Price: $59.95

# Recommended Reading



- Drug Enforcement Administration Office of Diversion Control. "Pharmacist's Manual: An Information Outline of the Controlled Substances Act", 2010 Edition. Available at http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf
- RxLaw.org materials
  - "U.S. Federal Pharmacy Laws, 2018 Study Guide" $59.99
  - "Federal & Florida State: Pharmacy Laws & Regulations, 2018 Study Guide" $161.00

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

# Federal Controlled Substances Act

# Question 1

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- Schedule III, IV & V controlled substance RXs may be transmitted to a community pharmacy by which of the following means? Select all that apply.

A. Email
B. Written
C. Oral
D. Fax
E. Electronic

# Answer to Question 1



- A prescription for controlled substances in Schedules III, IV and V issued by a practitioner may be communicated either orally, in writing or by facsimile to the pharmacist and may be refilled if so authorized on the prescription.
- However, on 3/31/10, DEA published in the Federal Register an interim final rule that would allow electronic transmissions of prescriptions of controlled substances (CII-CV).
- This rule gives prescribers the option of e-prescribing CS, permits pharmacies to receive, dispense & archive electronic RXs, reduces paperwork for DEA registrants, & potentially reduces RX forgeries. DEA believes this rule could reduce the number of RX errors caused by illegible handwriting, as well as the number of misunderstood orally ordered RXs.
- The rule became effective on 6/1/10 (See 21 CFR part 1311 at http://www.deadiversion.usdoj.gov/21cfr/cfr/1311/subpart_c100.htm#200).

# Answer to Question 1, cont.



- As set forth in DEA's regulations, before any electronic RX or pharmacy application may be used to transmit RXs for controlled substances, a third-party must audit the application for compliance with the requirements of 21 CFR part 1311. http://www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm
- As of 5/1/17:
  - Allowed in all 50 states
  - See http://surescripts.com/products-and-services/e-prescribing-of-controlled-substances for the list of pharmacies and pharmacy software vendors have completed Surescripts certification and third-party audits for e-prescribing of controlled substances
  - 89.7 % of FL pharmacies enabled for e-prescribing of controlled substances
  - 8.7 % of FL providers enabled for e-prescribing of controlled substances
  - Permissible to e-prescribe CII-V drugs in FL

# Question 2

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- A community pharmacist dispenses a partial supply of a C-II controlled substance. Within what period of time must the pharmacist dispense the balance, otherwise the balance may not be dispensed?
  - A. 24 hours
  - B. 48 hours
  - C. 72 hours
  - D. 7 days
  - E. 14 days

# Answer to Question 2



- **21 USC § 1306.13 Partial filling of prescriptions.** (a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription…

http://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_13.htm

# Question 3



- A new community pharmacy must register itself with the DEA before it can order and dispense controlled substances. What form does such pharmacy use to initially register with DEA?

A. DEA Form 224a
B. DEA Form 41
C. DEA Form 363
D. DEA Form 224
E. DEA Form 222

# Answer to Question 3



- **DEA Form 224** - Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner
  - NOTE: such entities *renew* their DEA permits using DEA Form 224a
  - NOTE: As of January 2017, DEA no longer sends its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

- DEA Form 225 – Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter.
- DEA Form 363 – Narcotic Treatment Programs
- DEA Form 510 – Domestic Chemical

http://www.deadiversion.usdoj.gov/drugreg/index.html?utm_source=DEA+Numbers+-+There

http://www.deadiversion.usdoj.gov/online_forms_apps.html

- A DEA Form 222 is used to distribute drugs listed in Schedules I and II, http://www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_13.htm.
- A DEA Form 41 is used when controlled substances are destroyed by a DEA registrant, http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/.

# Question 4



- What form must a pharmacy complete to report the significant theft or loss of controlled substances to the DEA?

A. DEA Form 225a
B. DEA Form 510
C. DEA Form 106
D. DEA Form 225
E. DEA Form 222a

# Answer to Question 4



- http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf, Page 16: A pharmacy must also complete a **DEA Form 106** (Report of Theft or Loss of Controlled Substances) which can be found online at www.DEAdiversion.usdoj.gov under the Quick Links section. The DEA Form 106 is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved.
- ***NOTE: A DEA Form 225a is used to renew the registration of manufacturers, distributors, researchers, analytical laboratories, importers and exporters. A DEA Form 510 is an application for registration for those entities using domestic chemicals. A DEA Form 225 is an application used for initial registration of manufacturers, distributors, researchers, analytical laboratories, importers and exporters. Any person already holding a DEA Form 222 may requisition additional forms on DEA Form 222a, which is mailed to a registrant approximately 30 days after each shipment of DEA Forms 222 to that registrant, or by contacting any Division Office or the Registration Section of the Administration.
- ***NOTE: If Investigation Finds No Theft or Loss – If, after the initial notification to DEA, the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, a DEA Form 106 does not need to be filed. However, the registrant must notify DEA in writing of this fact in order to resolve the initial report and explain why no DEA Form 106 was filed regarding the incident.

# Answer to Question 4, continued



- Registrant's Responsibility for Identifying "Significant Loss" – Although the CSA regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action…
- When determining whether a loss is significant, a registrant should consider, among others, the following factors:
  - The actual quantity of controlled substances lost in relation to the type of business;
  - The specific controlled substances;
  - Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
  - A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known;
  - Whether the specific controlled substances are likely candidates for diversion; and
  - Local trends and other indicators of the diversion potential of the missing controlled substances.
- Breakage and Spillage – The breakage or spillage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, or spillage or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. When this disposal occurs, it must be reported to DEA on a DEA Form 41 (Registrants Inventory of Drugs Surrendered).

# Question 5



- Which of the following statements about controlled substance (CS) medications is **CORRECT**? Select all that apply.
  - A. Partial refilling of CIII-V RXs is not permitted.
  - B. Pharmacies placing emergency kits containing CS medications in LTCFs are responsible for the proper control & accountability of such kits within the facility.
  - C. RXs for CIII-V drugs filled by central fill pharmacies for community pharmacies must not be refilled.
  - D. Any community pharmacy that accepts electronic RXs written for CS medications must register as an online pharmacy.
  - E. Physicians are legally permitted to prescribe methadone (CII) for pain.

# Answer to Question 5



- A pharmacist may partially dispense a prescription for schedules III-V controlled substances provided that each partial filling is recorded in the same manner as a refilling, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and no dispensing occurs beyond six months from the date on which the prescription was issued. (p. 42)
- LTCFs need not register with DEA to house emergency kits containing CS so long as there are safeguards in place to minimize access to the drugs, and only limited amounts are provided. Records of placement of kits in DEA must be maintained & available for inspection. Medications in these kits are administered only by authorized personnel. (p. 72)
- The [community] pharmacy transmitting the RX information [to a central fill pharmacy] must… [f]or C III-V RXs, indicate in the information transmitted the number of refills already dispensed and the number of refills remaining… (p. 50)

# Answer to Question 5, continued



- The following are exempt from the Ryan Haight Act's definition of an "online pharmacy" so long as their activities are limited solely to the exemptions provided … Any registered pharmacy whose delivery, distribution, or dispensing of CS by means of the Internet consists solely of filling RXs that were electronically prescribed in a manner authorized by the CSA… (p. 45-46)

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

- Federal law does not restrict the prescribing, dispensing, or administering of any CII-CV narcotic medication, including methadone, for the treatment of pain, if such treatment is deemed medically necessary by a registered practitioner acting in the usual course of professional practice. Confusion often arises due to the regulatory restrictions concerning the use of methadone for the maintenance of detoxification of opioid addicted individuals. http://www.deadiversion.usdoj.gov/faq/prescriptions.htm#rx-8

# Question 6



- Phil's Pharmacy is closing after nearly 50 years in business. Which of the following steps must Phil's take upon terminating its DEA registration?
  - I. Return all unused DEA Forms 222 to the DEA.
  - II. Send the DEA registration certificate to the state board of pharmacy.
  - III. Shred all controlled substance records on the day of termination.

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

# Answer to Question 6



- Termination of Registration – A pharmacy that discontinues business activities either completely or only regarding controlled substances must return its DEA registration certificate and unused official order forms (DEA Form 222) to the local DEA Registration Specialist (Appendix J). In addition, DEA may ask for the location of where inventories, prescriptions, and other required controlled substance records will be stored during the requisite two-year retention period. (p. 9)

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

# Question 7

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- Phil's Pharmacy, an independent community pharmacy, plans to transfer its business operations (including its controlled substances records and inventory) to a national chain pharmacy on 8/31/18, as the chain has just agreed to purchase Phil's. What is the latest date upon which Phil's may inform DEA of the proposed transfer (presuming DEA has not informed Phil's otherwise)?

A. 5/31/18
B. 6/30/18
C. 7/31/18
D. 8/17/18
E. 8/24/18

# Answer to Question 7



- Transfer of Business – A pharmacy registrant that transfers its business operations to another pharmacy registrant must submit in person or by registered or certified mail, return receipt requested, to the Special Agent in Charge in his/her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information:
  - The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);
  - The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);
  - Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed); and
  - The date on which the transfer of controlled substances will occur. (p. 10)

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

# Question 8

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- On 8/31/18, the date Phil's Pharmacy will transfer the controlled substances (CS) in its possession to the chain pharmacy purchasing Phil's, an inventory of such CS must be taken. Which of the following statements about this inventory is **CORRECT**?
  - I. The chain pharmacy must initiate a DEA Form 222 to transfer all CII drugs.
  - II. Phil's is responsible for the accuracy of information contained in the record of this inventory.
  - III. A copy of the record of this inventory must be sent to the DEA.

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

# Answer to Question 8



- **Transfer of Business** – On the day the controlled substances are transferred, a complete inventory must be taken and a copy of the inventory must be included in the records of both the person transferring the business and the person acquiring the business. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. It is not necessary to send a copy of the inventory to the DEA unless requested by the Special Agent in Charge.
- To transfer schedule II controlled substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.
- All controlled substance records required to be kept by the registrant-transferor shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee. (p. 10)
- http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

# Question 9

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- According to federal law, which of the following categories of controlled substances may a community pharmacy disperse among the inventory of non-controlled drugs? Select all that apply.

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

# Answer to Question 9



| | Schedule II | Schedules III & IV | Schedule V |
|---|---|---|---|
| *Registration* | Required | Required | Required |
| *Receiving Records* | DEA Form 222 | Invoices, readily retrievable | Invoices, readily retrievable |
| *Prescriptions* | Written[1] prescriptions[2] | Written, oral, or fax | Written, oral, or fax |
| *Refills* | No | No more than 5 within 6 months | As authorized when prescription is issued or if renewed by a practitioner |
| *Maintenance of Prescriptions* | Separate file | Separate file or readily retrievable | Separate file or readily retrievable[3] |
| *Distribution Between Registrants* | DEA Form 222 | Invoices | Invoices |
| *Security* | Locked cabinet or dispersed among non-controlled pharmaceuticals | Locked cabinet or dispersed among non-controlled pharmaceuticals | Locked cabinet or dispersed among non-controlled pharmaceuticals |
| *Theft or Significant Loss* | Report to DEA and complete DEA Form 106 | Report to DEA and complete DEA Form 106 | Report to DEA and complete DEA Form 106 |

- Note: All records must be maintained for 2 years, unless state law requires a longer period.

1. Written prescriptions include paper prescriptions and electronic prescriptions that meet DEA's requirements for such prescriptions.
2. Emergency prescriptions require a signed follow-up prescription within seven days. Exceptions: A facsimile prescription serves as the original prescription when issued to residents of Long Term Care Facilities, hospice patients, or patients with a diagnosed terminal illness, or for immediate administration (21 C.F.R. § 1306.11(e), (f) and (g)).
3. The record of dispensing can also be a schedule V logbook, if state law allows.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf - See Appendix A p. 61

# Answer to Question 9, continued



The DEA requires pharmacies to keep Schedules II, III, IV and V controlled substances in a locked cabinet *or* dispersed through the non-controlled stock to deter theft.

- Federal law does not mandate that drugs in Schedules II – IV be stored in a locked cabinet… yes, even CIIs!
- State laws are often stricter in this area; &, therefore, the stricter state law must be followed.

An electronic alarm system is also recommended (not required).

- Note that community pharmacies do not possess Schedule I medications (e.g., marijuana) because these drugs have no accepted (i.e., legal) medical use.

# Question 10



- Which of the following statements about controlled substances prescription (RX) records is **CORRECT**?
  - I. All RX records must be readily retrievable for DEA inspection.
  - II. RXs written for CII drugs must be filed separately from all other RXs.
  - III. RXS written for CIII, CIV or CV drugs must be filed separately from all RXs written for noncontrolled drugs.

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

# Answer to Question 10



- Prescription Records – Pharmacies have two options for filing paper prescription records and one option for electronic prescription records. If there is a conflict between federal and state requirements for filing prescriptions, DEA recognizes that the pharmacy must choose a filing system that would comply with both federal and state law. All prescription records must be readily retrievable for DEA inspection. Controlled substance prescriptions must be filed in one of the following ways:
- Paper Prescriptions Records Option 1 (Three separate files):
  - 1. A file for schedule II controlled substances dispensed.
  - 2. A file for schedules III, IV and V controlled substances dispensed.
  - 3. A file for all noncontrolled drugs dispensed.

# Answer to Question 10, continued



- Paper Prescriptions Records Option 2 (Two separate files):
  - 1. A file for all schedule II controlled substances dispensed.
  - 2. A file for all other drugs dispensed (noncontrolled and those in schedules III, IV and V). If this method is used, a prescription for a schedule III, IV or V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high. If a pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy with a red "C" is waived.
- ***NOTE: In both filing options, RXs for CII drugs are filed separately. Also, RXs for CIII-CV drugs may either be filed separately from RXs for noncontrolled drugs (in the 3-file system) or they may be filed with them as long as they are readily retrievable (in the 2-file system).
- http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 20); 21 CFR § 1304.04 (h) http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_04.htm

# Question 11

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- Which of the following statement(s) regarding inventory records of controlled substances is **CORRECT**? Select all that apply.
  - A. A pharmacy has complied with the CSA if it inventories a newly-scheduled or rescheduled drug within 30 days of the change.
  - B. Inventories for controlled substances must be completed annually.
  - C. Exact counts must be made only in those instances where a container holds 1,000 or more tablets/capsules.
  - D. Inventory records of CII drugs must be kept separate from the inventory records of CIII-V drugs.
  - E. Record must be made of whether the inventory was conducted at the beginning or close of business.

# Answer to Question 11



- The registrant is required to take a biennial inventory (every two years) of all controlled substances on hand. The biennial inventory may be taken on any date which is within two years of the previous inventory date. There is no requirement to submit a copy of the inventory to DEA.
- [Pharmacies must make a] count of the substance - if the substance is listed in CII, an exact count or measure of the contents or if the substance is listed in C III-V, an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case, an exact count of the contents is required.
- When a drug not previously listed as a controlled substance is scheduled or a drug is rescheduled, the drug must be inventoried as of the effective date of scheduling or change in scheduling.
- The CSA also requires that all inventory records be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection. In addition, the inventory records of schedule II controlled substances must be kept separate from all other controlled substances.
- The C.F.R. requires that the inventory include … [w]hether the inventory was taken at the beginning or close of business…

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 22)

# Question 12



- A pharmacy orders oxycodone, 5 bottles (100 tablets/bottle) using a DEA Form 222. Which of the following statements about the supplier of this drug order is **CORRECT**?

  I. The supplier may fill the order with 5 bottles of 500 tablets if it is out of bottles of 100 tablets.

  II. The supplier keeps Copy 1 of the DEA Form 222 & forwards Copy 2 to the DEA.

  III. The supplier must not fill the order if it appears that an alteration was made to the form.

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

# Answer to Question 12



- Title 21 C.F.R. § 1305.15(a)(1) requires that, for orders using the DEA Form 222, an order must not be filled if the order is not complete, legible, or properly prepared, executed, or endorsed, or if the order shows any alteration, erasure, or change of any description.
- DEA policy DOES NOT PRECLUDE the substitution of identical products differing in packaging size from those initially ordered, provided that the actual quantity received does not exceed the amount initially ordered and that the National Drug Code number reflected is that of the actual product shipped. For example, a distributor may substitute five bottles of 100, 2 milligram tablets for one bottle of 500, 2 milligram tablets or any variation thereof.
- ***NOTE: From Title 21 C.F.R. §1305.13 Procedure for filling DEA Forms 222. (d) The supplier must retain Copy 1 of the DEA Form 222 for his or her files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 24)

# Question 13



- Sally Shrink is a psychiatrist who prescribes controlled substances (typically for anxiety); thus, she is registered with the DEA. Which of DEA numbers below could be Sally's DEA number?
  - A. GS4235067
  - B. FS4961783
  - C. SS3388318
  - D. MS3388318
  - E. PS4235067

# Answer to Question 13



- Registrant type (first letter of DEA Number):
  - A/B/F/G – Hospital/Clinic/Practitioner/Teaching Institution/Pharmacy
  - M – Mid-Level Practitioner (NP/PA/OD/ET, etc.)
  - P/R – Manufacturer/Distributor/Researcher/Analytical Lab/Importer/Exporter/Reverse Distributor/Narcotic Treatment Program

http://www.deadiversion.usdoj.gov/drugreg/

# Answer to Question 13, continued



- DEA Number Check: 1st digit should be either A, B, F or G for prescribers (like MDs [including psychiatrists, ophthalmologists], veterinarians, podiatrists or dentists)
  - M for midlevel practitioners like optometrists, nurse practitioners & physician assistants
- 2nd digit *typically* is the 1st letter of the registrant's last name
- The 3rd through the 8th positions should contain numbers that are used to calculate the number in the 9th position, the check digit
  - GS4235067
    - Add the 1st, 3rd & 5th digits: 4 + 3 + 0 = 7
    - Add the 2nd, 4th & 6th digits & multiply the sum by 2: [(2 + 5 + 6) x 2 ] = 26
    - Add the 2 results: 7 + 26 = 33 -7th digit should be a 3, but here it is a 7; not valid!
  - **FS4961783**
    - Add the 1st, 3rd, & 5th digits: 4 + 6 + 7 = 17
    - Add the 2nd, 4th, & 6th digits & multiply the sum by 2: [(9 + 1 + 8) x 2 ] = 36
    - Add the 2 results: 17 + 36 = 53 **-7th digit should be a 3, here it is; valid!**
- The far right-hand digit of this check number should be the same as the 9th digit of the DEA number. In this example, both numbers are 3, so the DEA number is a valid number

# Question 14



- Select all that apply. A pharmacy may retain facsimiles of RXs written for CII drugs (in lieu of original RXs) in certain instances, such as when an RX is written *for any CII drug* for a patient: Enrolled in a certified hospice care program.

A. Residing in a long-term care facility.
B. Undergoing home infusion.
C. Of a community pharmacy, generally.
D. Of a community pharmacy, but only in emergency situations.

# Answer to Question 14

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CFR - Code of Federal Regulations Title 21, Sec. 1306.11 Requirement of prescription.

...(e) A prescription...written for a Schedule II **narcotic** substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription...

(f) A prescription... written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription...

(g) A prescription... written for a Schedule II **narcotic** substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare ... which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription...

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1305&showFR=1

# Answer to Question 14, continued



- In order to expedite the filling of a RX, a prescriber may transmit a schedule II RX to the pharmacy by facsimile. The original schedule II RX must be presented to the pharmacist and verified against the facsimile at the time the controlled substance is actually dispensed. The pharmacist must make sure the original document is properly annotated and filed with the records that are required to be kept. (pp. 34-35)
  - A prescriber may fax over an RX to a pharmacy so that the pharmacist can get started on it; but, before dispensing, the RX must be presented to the pharmacy. The faxed RX alone is not sufficient.
- In a bona fide emergency, a practitioner may telephone a schedule II RX to the pharmacist who may then dispense the RX. The prescribing practitioner must provide a written and signed RX to the pharmacy within seven days… (p. 40)
  - The DEA has stated that a prescriber may fax over an emergency CII RX to the pharmacy (in stead of or in addition to phoning it in). Pharmacy Law Desk Reference (2007), p. 75
    - The pharmacist must still determine the legitimacy of it before dispensing.
  - The pharmacy needs a hard copy of the RX for the emergency supply within 7 days. Again, the faxed RX alone is not sufficient.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

# Question 15

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- The labels of RXs for certain categories of controlled substances must contain the following warning, ***"CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."*** What categories?
  - A. Schedule II drugs only
  - B. Schedule II & III drugs only
  - C. Schedule II, III & IV drugs only
  - D. Schedule II, III, IV & V drugs only
  - E. Schedule I, II, III, IV & V drugs

# Answer to Question 15



Code of Federal Regulations, Sec. 290.5 Drugs; statement of required warning.

- The label of any drug listed as a "controlled substance" in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." This statement is not required to appear on the label of a controlled substance dispensed for use in clinical investigations which are "blind."

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=290&showFR=1

# Answer to Question 15, continued



- Required Information for Prescription Labels: The pharmacist dispensing a prescription for a controlled substance listed in schedules II, III, IV, or V must affix to the package a label showing date of filling, the pharmacy name and address, the serial (prescription) number, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law. If a prescription is filled at a central fill pharmacy, the central fill pharmacy must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy.
- Federal Food and Drug Administration regulations require that the label of any drug listed as a "controlled substance" in schedules II, III, or IV of the CSA must, when dispensed to or for a patient, contain the following warning: CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed. In addition, a pharmacist who receives a prescription for a controlled substance must dispense that prescription to the patient or a member of the patient's household. To provide the controlled substance to anyone other than the patient or a member of the patient's household is distribution, not dispensing.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 40)

# Question 16



- A pharmacist who fills an oral morphine sulfate RX in an emergency situation does not receive a "cover" RX from the prescriber in the requisite period of time. The pharmacist must:
  - I. Notify the regional DEA office.
  - II. Notify the state board of medicine.
  - III. Call the patient & request that he/she obtain a written RX to cover the oral order.

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

# Answer to Question 16



- In a bona fide emergency, a practitioner may telephone a schedule II prescription to the pharmacist who may then dispense the prescription. The prescribing practitioner must provide a written and signed prescription to the pharmacy within seven days and meet the below requirements:
  1. The drug prescribed and dispensed must be limited to the amount needed to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription order. ***NOTE: FL law only permits a 72-hour supply
  2. The prescription order must be immediately reduced to writing by the pharmacist and must contain all information, except for the prescribing practitioner's signature.
  3. If the prescribing individual practitioner is not known to the pharmacist, he/she must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner using his or her telephone number as listed in the telephone directory and/or other good faith efforts to insure his or her identity. (p. 40)

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

# Answer to Question 16 continued



4. Within seven days after authorizing an emergency telephone prescription, the prescribing practitioner must furnish the pharmacist a written, signed prescription for the controlled substance prescribed. The prescription must have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven day period. Upon receipt, the dispensing pharmacist must attach this written prescription to the oral emergency prescription which had earlier been reduced to writing by the pharmacist. By regulation, the pharmacist must notify the local DEA Diversion Field Office… if the prescriber fails to provide a written prescription within seven days. Failure of the pharmacist to do so will void the authority conferred on the pharmacy to dispense the controlled substance without a written prescription of a prescribing practitioner… (p. 41)

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

# Question 17

46

- Which of the following statements about the partial-filling of RXs written for CII drugs for patients who are terminally ill &/or reside in a long-term facility (LTCF) is **CORRECT**?
  - I. The pharmacist must record on the RX whether the patient is "terminally ill" or an "LTCF patient."
  - II. The ID of the pharmacist who partially fills the RX must be noted on either the back of the RX or in the electronic dispensing records.
  - III. RXs for such patients may be partially filled for up to 60 days from the date of issue.

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

# Answer to Question 17



- An exception to the partial fill rule (i.e., balance must be filled within 72 hours) has been made for patients in Long Term Care Facilities (LTCF) and patients who have been diagnosed with a terminal illness.
- A prescription for a schedule II controlled substance written for a patient in a [LTCF] or for a patient with a medical diagnosis documenting a terminal illness, may be filled in partial quantities to include individual dosage units… Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient.
- The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" must be deemed to have been filled in violation of the CSA. For each partial filling, the dispensing pharmacist must record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in an LTCF or terminally ill patients are valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication. (p. 41)

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

# Question 18



- On May 15, 2018, a patient presented an RX written for Synalgos-DC® #30 to a community pharmacy. The patient indicated that he would like to get 15 tablets now & return for the remaining 15 in one week. The pharmacist should:
  - A. Call the prescriber to get permission to dispense 15 tablets.
  - B. Dispense 15 tablets as requested by the patient.
  - C. Advise the patient that the full 30 tablets must be supplied at one time.
  - D. Fill the RX as requested by the patient, but advise the patient that the balance must be filled within 72 hours.
  - E. Inform the patient that she can only partially dispense this drug if she doesn't have enough on hand to fill the entire RX.

# Answer to Question 18



- Synalgos-DC (Dihydrocodeine combination product 90 mg/du) is listed as a Schedule III drug - http://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf
- ***NOTE: RXs for schedules III-V drugs may be partially filled for any reason (unlike partial fills of CII drugs, which may only be partially filled if the pharmacy is unable to supply [i.e. not enough drug on hand to fill the order; patient is unable to pay for the entire order]).
- Partial Dispensing – A pharmacist may partially dispense a prescription for schedules III-V controlled substances provided that each partial filling is recorded in the same manner as a refilling, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and no dispensing occurs beyond six months from the date on which the prescription was issued. http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 42)

# Question 19

50

- Which of the following statements about the sale of a codeine-containing CV product at retail without an RX is **CORRECT**? Select all that apply.

A. A supervised intern may dispense the product to the customer/patient.

B. Not more than 240mL or 48 dosage units of this product may be sold to the same purchaser in any 48-hour period.

C. All purchasers must provide a valid photo ID, regardless of whether or not the pharmacist knows him/her.

D. The purchaser must be at least 21 years old.

E. A pharmacy technician may ring up the sale & collect payment for the product.

# Answer to Question 19



- Dispensing Without a Prescription – Dispensing a controlled substance without a prescription is outlined in 21 C.F.R. § 1306.26. The regulation states that a controlled substance listed in schedules II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:
- Such dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his or her professional and legal responsibilities, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist);
  - ***NOTE: The term pharmacist also includes other persons allowed to dispense by state law under the direct supervision of a pharmacist, such as an intern.
- Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance, nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance, may be dispensed at retail to the same purchaser in any given 48-hour period;
  - Opium containing products: ≤ 240 cc. or 48 dosage units
  - Non-opium containing products (like codeine): ≤ 120 cc. or 24 dosage units

# Answer to Question 19, continued



- The purchaser is at least 18 years of age and the pharmacist requires every purchaser of a controlled substance under this section not known to him or her to furnish suitable identification (including proof of age where appropriate);
- A bound record book (which must be maintained in accordance with the recordkeeping requirement of 21 C.F.R. § 1304.04) for dispensing of controlled substances is maintained by the pharmacist, which contains the name and address of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser;
- The prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law; and
- Central fill pharmacies may not dispense controlled substances at the retail level to a purchaser.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 42)

# Question 20



- A central fill pharmacy filling RXs written for controlled substances pursuant to a contract with a retail pharmacy:
  - A. Does not have a corresponding responsibility to ensure that RXs it receives are written for legitimate medical purposes, as it is the retail pharmacy's responsibility to do so.
  - B. May prepare both initial & refill RXs for patients of the retail pharmacy.
  - C. Must maintain the original RX for 2 years from the date of the last refill.
  - D. Shall only use its employees to deliver filled RXs to the retail pharmacy, & not use common carriers (e.g., FedEx)
  - E. Can accept RXs phoned in by the retail pharmacy.

# Answer to Question 20



- A ***"central fill pharmacy"*** fills prescriptions for controlled substances on behalf of retail pharmacies with which it has a contractual agreement to provide such services or with pharmacies who share a common owner…
- Central fill pharmacies are permitted to prepare both initial and refill prescriptions, subject to all applicable state and federal regulations. Only a licensed pharmacist may fill the prescription. Both the retail and central fill pharmacists have a *corresponding responsibility* to ensure that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and otherwise in the manner specified by DEA regulations.
- Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. Prescriptions for controlled substances listed in schedules II, III, IV, or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (pp. 50-51)

# Answer to Question 20, continued



- The retail pharmacy transmitting the prescription information must:
  - Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;
  - Ensure that all information required to be on a prescription is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
  - Maintain the original prescription for a period of two years from the date the prescription was last refilled;
  - Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the retail pharmacy employee accepting delivery;
  - For schedules III-V prescriptions, indicate in the information transmitted the number of refills already dispensed and the number of refills remaining (refills for schedule II prescriptions are not permitted).

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (pp. 50-51)

# Answer to Question 20, continued



- The central fill pharmacy receiving the transmitted prescription must:
  - Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and the DEA registration number of the retail pharmacy transmitting the prescription;
  - Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription; and
  - Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e. private, common, or contract carrier). Central fill pharmacies must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (pp. 50-51)

# Answer to Question 20, continued



- Central fill pharmacies must comply with the provisions of the C.F.R. when selecting private, common, or contract carriers to transport filled prescriptions to a retail pharmacy (and likewise for retail pharmacies retrieving filled prescriptions from a central fill pharmacy) for delivery to the ultimate user.
- For electronic prescriptions, the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal must be added to the electronic prescription record.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (pp. 50-51)

# Question 21

58

- Which of the following drugs may be used outside of opioid treatment programs for maintenance or detoxification treatment?
  - I. Suboxone®
  - II. Subutex®
  - III. Methadone

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

# Answer to Question 21



- Opioid (Narcotic) Addiction Treatment Programs – The Narcotic Addiction Treatment Act of 1974 and the Drug Addiction Treatment Act (DATA) of 2000 amended the CSA with respect to the use of controlled substances in the medical treatment of opioid addiction. These laws established the procedures for approving and licensing practitioners involved in the treatment of opioid addiction as well as improving the quality and delivery of that treatment to the segment of society in need.
- Practitioners wishing to prescribe and dispense FDA approved schedule II controlled substances (i.e., methadone) for maintenance and detoxification treatment must obtain a separate DEA registration as a Narcotic Treatment Program via a DEA Form 363 which may be completed online at www.DEAdiversion.usdoj.gov. In addition to obtaining this separate DEA registration, this type of activity also requires the approval and certification by the Center for Substance Abuse Treatment (CSAT) within the Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services as well as the applicable state methadone authority.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (pp. 52)

# Answer to Question 21, continued



- Note also that the certification requirement may be waived per the Drug Addiction Treatment Act of 2000. Under DATA, qualified office-based physicians may prescribe (and pharmacists may dispense) Schedule III, IV, or V narcotic drugs (or combinations of such drugs) approved by FDA for the treatment of opioid addiction.
  - Suboxone® & Subutex® may be prescribed by qualified office-based practitioners for the treatment of opioid addiction without certification because these drugs are listed in Schedule III.
    - NOTE: Methadone is a CII drug
- In order to qualify for the waiver, physicians must hold a current state medical license, a valid DEA registration number, and meet conditions set forth in the Act. DATA waived practitioners may treat 30 or 100 patients at any one time, dependent on individual authorization from CSAT. Upon authorization by CSAT, DEA will issue a new DEA certificate of registration bearing (1) the DEA registration number, (2) a unique identification number, and (3) the corresponding business activity to identify whether the physician is authorized to treat 30 or 100 patients. Pursuant to 21 C.F.R. §1301.28(d), the practitioner is required to include the identification number on all records when dispensing and on all prescriptions when prescribing Schedules III, IV, or V narcotic controlled drugs for use in maintenance or detoxification treatment. The listing of the identification number on a prescription is in addition to all other information required on a valid prescription to include the practitioner's DEA registration number (see Section IX, Valid Prescription Requirements).

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (pp. 52)

http://www.deadiversion.usdoj.gov/drugreg/faq.htm

# Question 22

61

- A pharmacy registered as a dispenser need not also register as a distributor as long as the total number of dosage units of controlled substances *distributed* by the pharmacy does not exceed a particular percent of controlled substances *dispensed* by the pharmacy in a calendar year. What is that percent?

A. 5
B. 10
C. 20
D. 25
E. 50

# Answer to Question 22



- A pharmacy registered to dispense controlled substances may distribute such substances (without being registered as a distributor) to another pharmacy or to a registered practitioner for the purpose of general dispensing by the practitioner to patients, provided that the following conditions are met:
  1. The pharmacy or practitioner that will receive the controlled substances is registered under the CSA to dispense controlled substances;
  2. The distribution is recorded by the distributing practitioner … [&] the receipt is recorded by the receiving practitioner…
  3. If the pharmacy distributes a schedule II controlled substance, it must document the transfer on an official order form (DEA Form 222) or the electronic equivalent…
  4. **"Five Percent Rule" - total number of dosage units of all controlled substances distributed by a pharmacy may not exceed five percent of all controlled substances dispensed by the pharmacy during a calendar year.** If at any time the controlled substances distributed exceed five percent, the pharmacy is required to register as a **distributor**.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 54)

# Question 23

63

- Which of the following drugs may lead to moderate or low physical dependence or high psychological dependence? Select all that apply.

A. Ketamine
B. Oxandrolone
C. Amobarbital
D. Glutethimide
E. Lysergic acid diethylamide

# Answer to Question 23



- *21 USC § 812 (a) The findings required for each of the schedules are as follows:*
  - *(1) SCHEDULE I.*
    - *(A) The drug or other substance has a high potential for abuse.*
    - *(B) The drug or other substance has no currently accepted medical use in treatment in the United States.*
    - *(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.*
  - *(2) SCHEDULE II.*
    - *(A) The drug or other substance has a high potential for abuse.*
    - *(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.*
    - *(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.*
  - *(3) SCHEDULE III.*
    - *(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I & II.*
    - *(B) The drug or other substance has a currently accepted medical use in treatment in the United States.*
    - *(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.*

# Answer to Question 23, continued



- *(4) SCHEDULE IV.*
  - *(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.*
  - *(B) The drug or other substance has a currently accepted medical use in treatment in the United States.*
  - *(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.*
- *(5) SCHEDULE V.*
  - *(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.*
  - *(B) The drug or other substance has a currently accepted medical use in treatment in the United States.*
  - *(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.*

- Note that the schedules of controlled substances are based on the potential for abuse, the recognition of a medical use & the possibility of physical or psychological dependence.
- Ketamine & Oxandrolone (an anabolic steroid) are CIII non-narcotic drugs; Amobarbital & Glutethimide are CII stimulants; Lysergic acid diethylamide (LSD) is CI.

http://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm

# Question 24



- For how long, generally, is a pharmacy's DEA registration effective?

A. 6 months
B. 1 year
C. 2 years
D. 3 years
E. 5 years

# Answer to Question 24



- Under the CSA, only certain parties are permitted to possess controlled substances legally. These parties must be registered with the DEA, or they must be exempt from registration.
  - For example, a pharmacist who meets the licensure requirements of the state where the pharmacist is practicing, may dispense controlled substances to patients as long as the pharmacist practices in a pharmacy that is registered with the DEA. The pharmacist need not personally be registered with the DEA.
- 21 USC § 822 *(a) Annual registration.*
  - *(1) Every person who **manufactures or distributes** any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain **annually** a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.*
  - *(2) Every person who **dispenses**, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.*

http://www.deadiversion.usdoj.gov/21cfr/21usc/822.htm

- Note: A pharmacy registration must be renewed every three years utilizing DEA Form 224a http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf. (p. 8)

# Question 25



- A dentist wishes to order Tylenol with Codeine #3 to have on hand to administer to her patients. How may the dentist order this medication?
  - I. Purchase the drug from a DEA-registered distributor
  - II. Order the drug electronically using CSOS
  - III. Present an RX to the pharmacy for the drug, indicating "For Office Use Only"

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

# Answer to Question 25



- **Ordering Schedules III-V Controlled Substances –** The registrant must keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate. These receipts must also contain the name of each controlled substance, the finished form, the number of dosage units of finished form in each commercial container, and the number of commercial containers ordered and received. In addition, these receipts must be maintained in a readily retrievable manner for inspection by the DEA.
  - ***NOTE: Practitioners order CIII-V drugs the same way pharmacies do, typically using the computer system to enter the order.
  - To purchase or distribute controlled substances in Schedules I or II, a DEA Form 222 must be used.
  - The DEA permits, but does not require, Schedule I and Schedule II drugs to be ordered from a supplier electronically. The Controlled Substance Ordering System (CSOS —Pronounced like "sea sauce") allows ordering electronically as long as specific criteria have been met.
    - NOTE: CIII-V drugs & non-controlled drugs may be ordered using CSOS!
- A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (pp. 23, 26-27)

# Question 26



- Which of the following drugs is considered a Scheduled Listed Chemical Product?
  - I. Pentobarbital
  - II. Phendimetrazine
  - III. Phenylpropanolamine

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

# Answer to Question 26



- Scheduled Listed Chemical Product (SLCP) – An SLCP is defined as a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 6)

- For more information about these drugs, including sales limit, logbook requirements, etc. See http://www.deadiversion.usdoj.gov/meth/cma2005_general_info.pdf .
- *** NOTE: Pentobarbital is a CII stimulant and phendimetrazine is a CIII non-narcotic.

# Question 27



- The drug products regulated by the federal Combat Methamphetamine Epidemic Act of 2005 are restricted to sale of what quantity (per patient) in one day?

A. 1.2g
B. 2.4g
C. 3.6g
D. 4.8g
E. 6.0g

# Answer to Question 27



- The Combat Methamphetamine Epidemic Act of 2005 created a new category of products called "scheduled listed chemical product (SLCP)." It includes any product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug that contains ephedrine, pseudoephedrine, or PPA (includes salts, optical isomers, and salts of optical isomers) (21 U.S.C. § 802(45)). This applies to nonprescription drug products only, not prescription drug products…
- Other requirements of the law include:
  - Requirement of regulated sellers to place the products behind the counter or in locked cabinets.
  - Requirement of regulated sellers to check the identity of purchasers and maintain a log of each sale that includes the purchaser's name and address, signature of the purchaser, product sold, quantity sold, date, and time.
  - Requirement of regulated sellers to maintain the logbook for at least two years.
  - Requirement of regulated sellers to train employees in the requirements of the law and certify to DEA that the training has occurred.
  - Places a quantity limit of each of the chemicals that may be sold to an individual in a day to **3.6 grams** of the chemical (base) without regard to the number of transactions.
  - For nonliquids, product packaging is limited to blister packs containing no more than 2 dosage units per blister. Where blister packs are not technically feasible, the product must be packaged in unit dose packets or pouches.
  - For individuals, purchases in a 30-day period are limited to 9 grams, of which not more than 7.5 grams may be imported by means of a common or contract carrier or the U.S. Postal Service.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 55)

# Answer to Question 27, continued



- On October 14, 2008, the President signed the Methamphetamine Production Prevention Act. The Act amended the existing language in 21 U.S.C. 830(e)(1)(A) by revising clauses (iv) through (vi). The purpose of this Act was to facilitate the creation of electronic logbooks. Several options were provided for obtaining signatures of purchasers and recording transactions at the time of the sale.
- Specifically, the requirements now state that a regulated seller of scheduled listed chemical products may not sell such a product unless the purchaser:
  - Presents a government issued photographic identification; and
  - Signs the written logbook with his or her name, address, time and date of the sale, or signs in one of the following ways:
    - In the case of an electronic logbook, the device must capture the signature in an electronic format.
    - In the case of a bound paper book, a printed sticker must be affixed to the book at the time of sale adjacent to the signature line. The sticker must display the product name, quantity, name of purchaser, date and address, or a unique identification that can be linked to that information.
    - In the case of a printed document, the document must include a clear line for the purchaser's signature and include product name, quantity, name and address of purchaser, and date and time of sale.
- The logbook must be maintained by the regulated seller for not fewer than two years after the date on which the entry is made (21 U.S.C. 830(e)(1)(A)(vi)).

http://www.deadiversion.usdoj.gov/fed_regs/rules/2011/fr1201.htm

# Question 28

75

- An individual practitioner may issue multiple Schedule II prescriptions for the same patient, written on the same day, subject to which of the following restrictions? For this question, presume that the prescriber intends for one of these RXs to be filled immediately.
  - I. The total quantity prescribed must not exceed a 60-day supply.
  - II. In the space for the "date", the prescriber must write the date that each RX is to be dispensed rather than write the date of issuance.
  - III. On all but the first RX, the prescriber must indicate the earliest date on which the RX may be dispensed.

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

# Answer to Question 28



- The DEA does permit the issuance of multiple prescriptions on the same day, all dated on the date of issuance, with instructions to the pharmacist to dispense the medications at a future time.
- ***21 CFR § 1306.12*** *Refilling Prescriptions; Issuance of Multiple Prescriptions*
  - *(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.*
  - *(b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:*
    - *(i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;*
    - *(ii) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription…*
- Note: a practitioner cannot post-date a prescription for a CII medication!

http://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_12.htm

# Question 29

77

- Which of the following statements about the transfer of RXs written for controlled substance medications from one pharmacy to another is **CORRECT**?
  - I. An RX may be transferred one time only from one pharmacy to another if the two pharmacies do not share a real-time online database.
  - II. The transfer of prescriptions may occur between two pharmacy technicians.
  - III. Information from CIII-CV RXs may not be transferred unless expressly authorized by the prescriber.

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

# Answer to Question 29



- **Transfer of Schedules III-V Prescription Information** – A DEA registered pharmacy may transfer original prescription information for schedules III, IV, and V controlled substances to another DEA registered pharmacy for the purpose of refill dispensing between pharmacies, on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization.
- ***NOTE: From 21 CFR §1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.
- … (b) Transfers are subject to the following requirements:
  - (1) The transfer must be communicated directly between two licensed pharmacists.
- ***NOTE: No requirement to get permission from the prescriber to transfer an RX.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 37-38)

# Question 30



- What information must a controlled substance prescription contain? Select all that apply.
  - A. Patient name and address
  - B. Practitioner's name, address, and DEA number
  - C. Drug name and strength
  - D. Directions for use
  - E. Date of issue

# Answer to Question 30



**Prescription Requirements**

- A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (for example, an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).
- A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number. The prescription must also include:
  - drug name
  - strength
  - dosage form
  - quantity prescribed
  - directions for use
  - number of refills (if any) authorized
- A prescription for a controlled substance must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual (secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature.
- The practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state.

http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm

# Question 31

81

- Which of the following statements about the destruction of controlled substances is **CORRECT**?
  - I. A DEA Form 41 must be executed in order for a pharmacy to transfer its outdated CS to a reverse distributor for destruction.
  - II. Pharmacies may send their outdated CS directly to the DEA without first notifying the DEA that it is doing so.
  - III. Retail pharmacies may collect CS from patients using either collection receptacles or mail-back programs as long as they have modified their DEA registrations to become collectors.

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

# Answer to Question 31



- Disposal of Controlled Substances – A pharmacy may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. The pharmacy should contact the local DEA Diversion Field Office (Appendix K) for an updated list of DEA registered reverse distributors. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA. The DEA procedures established for the disposal of controlled substances must not be construed as altering in any way the state laws or regulations for the disposal of controlled substances.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 14)

# Answer to Question 31, continued



- **Reverse Distributors Authorized to Dispose Controlled Substances** – A pharmacy may forward controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. When a pharmacy transfers schedule II controlled substances to a reverse distributor for destruction, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the pharmacy. When schedules III-V controlled substances are transferred to a reverse distributor for destruction, the pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred. The DEA registered reverse distributor who will destroy the controlled substances is responsible for submitting a DEA Form 41 (Registrants Inventory of Drugs Surrendered) to the DEA when the controlled substances have been destroyed. A DEA Form 41 should not be used to record the transfer of controlled substances between the pharmacy and the reverse distributor disposing of the drugs.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 14)

# Answer to Question 31, continued



- ***From letter from DEA dated, September 9, 2014, announcing that final regulations have been passed regarding the collection of CS from ultimate users, available at https://www.deadiversion.usdoj.gov/drug_disposal/dear_registrant_disposal.pdf
- Collection from Ultimate Users – Authorized collectors may collect pharmaceutical controlled substances from ultimate users using one of the following methods: collection receptacles, or mail-back programs. The following categories of registrants may modify their registration to become collectors if they are authorized to handle schedule II controlled substances: manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies. These registrants may modify their registrations to become authorized collectors online at http://www.DEAdiversion.usdoj.gov. There is no fee to modify a registration for this purpose. Authorized collectors may maintain collection receptacles at their registered locations; and they may operate a mail-back program as long as they have an on-site means of destruction for the mail-back packages. Retail pharmacies and hospitals/clinics with an on-site pharmacy may manage collection receptacles at long-term care facilities.

https://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_registrant.pdf

# Answer to Question 31, continued



Title 21 Code of Federal Regulations. DISPOSAL OF CONTROLLED SUBSTANCES

- **§1307.21 Procedure for disposing of controlled substances.**

a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on **DEA Form 41**, and submit three copies of that form to the Special Agent in Charge in his/her area; or
2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:
   i. The name and address of the person;
   ii. The name and quantity of each controlled substance to be disposed of;
   iii. How the applicant obtained the substance, if known; and
   iv. The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

1) By transfer to person registered under the Act and authorized to possess the substance;
2) By delivery to an agent of the Administration or to the nearest office of the Administration;
3) By destruction in the presence of an agent of the Administration or other authorized person; or
4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons…

http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol9/pdf/CFR-2011-title21-vol9-part1307.pdf

# Question 32



- Which of the following records may a DEA registrant keep at a centralized location?
  - I. Shipping and financial records (but not executed DEA Forms 222)
  - II. Records of inventories of controlled substances
  - III. Prescriptions

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

# Answer to Question 32



- A registrant desiring to maintain shipping and financial records (but not executed official order forms) at a central location rather than the registered location must submit written notification of his/her intention by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the local DEA Diversion Field Office in which the registrant is located.
- ***NOTE: All other records (including inventory records and prescriptions) must be kept at the place of registration

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 20)

# Question 33

88

- Which of the following professionals may prescribe controlled substances using the DEA number of their employer hospital?
  - I. (Medical) Interns/(Residents)
  - II. Staff physicians
  - III. Physician assistants

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

# Answer to Question 33



- Practitioner's Use of a Hospital's DEA Registration Number – Practitioners (e.g., intern, resident, staff physician, mid-level practitioner) who are agents or employees of a hospital or other institution, may, when acting in the usual course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in which he or she is employed, in lieu of individual registration, provided that:
  - The dispensing, administering, or prescribing is in the usual course of professional practice.
  - The practitioner is authorized to do so by the state in which they practice.
  - The hospital or institution has verified that the practitioner is permitted to administer, dispense, or prescribe controlled substances within the state.
  - The practitioner acts only within the scope of employment in the hospital or institution.
  - The hospital or institution authorizes the practitioner to administer, dispense, or prescribe under its registration and assigns a specific internal code number for each practitioner.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 32)

# Question 34

90

- Schedule III, IV & V controlled substances may be refilled:
  - I. Not more than 6 times.
  - II. Not more than for a 5-month period.
  - III. Only if authorized by the prescriber.

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

# Answer to Question 34



- Schedules III and IV controlled substances may be refilled if authorized on the prescription [by the prescriber]. However, the prescription may only be refilled up to five times within six months after the date of issue. After five refills or after six months, whichever occurs first, a new prescription is required.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 35)

# Question 35



- Which of the following statements about an automated dispensing system (ADS) owned by a pharmacy, but housed in a long term care facility (LTCF), is **CORRECT**?
  - I. Drugs housed in the ADS are counted as pharmacy stock.
  - II. Pharmacy personnel must be onsite at the LTCF to program & control the ADS.
  - III. LTCF staff may remove drugs from the ADS with or without an RX.

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

# Answer to Question 35



- **Use of Automated Dispensing Systems by Retail Pharmacies at Long Term Care Facilities** – If state law or regulations permit, the DEA will allow a retail pharmacy to register at the site of the LTCF and store controlled substances in an Automated Dispensing System (ADS) as outlined in 21 C.F.R. § 1301.27. In an ADS, a pharmacy stores bulk drugs in the machine in separate bins or containers. The pharmacy programs and controls the ADS remotely. Only authorized LTCF staff are allowed access to its contents, which are dispensed on a single-dose basis at the time of administration pursuant to a valid prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs are not considered dispensed until the system provides them, drugs in the ADS are counted as pharmacy stock. A registered retail pharmacy that possesses additional registrations for ADS machines at LTCFs may keep all records required for those additional registered sites at the retail pharmacy or other approved central location.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 52)

# Question 36

94

- Which of the following actions is/are appropriate for a pharmacy to take when mailing a narcotic drug filled pursuant to a valid RX?
  - I. Place the warning, “Narcotic: Do not open while in transit” on the outer wrapping.
  - II. Package the drug container in a plain paper outer wrapping.
  - III. Label the inner container to show the name and address of the pharmacy.

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

# Answer to Question 36



- United States Postal Service regulations permit mailing of any controlled substance, provided it is not outwardly dangerous and will not cause injury to a person's life or health, and if the following preparation and packaging standards are met:
- The inner container of any parcel containing controlled substances is marked and sealed as required by the provisions of the CSA and its implementing regulations, and is placed in a plain outer container or securely wrapped in plain paper.
- If the controlled substance consists of prescription medicines, the inner container is also labeled to show the name and address of the pharmacy, practitioner, or other person dispensing the prescription.
- The outside wrapper or container is free of markings that would indicate the nature of the contents.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf (p. 54)

# Federal Law, Generally

# Question 37

97

- Which of the following statements about Risk Evaluation & Mitigation Strategies (REMS) is/are **CORRECT**?

  I. REMS are not required for generic products.

  II. REMS shall only be required during the drug preapproval process.

  III. REMS may be required for a single drug or a class of drugs.

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

# Answer to Question 37



- REMS are required risk management plans that use risk minimization strategies beyond the professional labeling to ensure that the benefits of certain prescription drugs outweigh their risks.
- REMS: Key Points
  - FDA can require a REMS if the agency determines that safety measures are needed beyond the professional labeling to ensure that a drug's benefits outweigh its risks
  - Drug sponsors develop REMS programs, FDA reviews and approves them
  - FDA can require a REMS before or after a drug is approved
    - After approval – when new safety information is learned
  - REMS can be required for a single drug or a class of drugs
  - Healthcare professionals and distributors may need to follow specific safety procedures prior to prescribing, shipping, or dispensing the drug
  - Each REMS has specific safety measures unique to the safety risks associated with a particular drug or class of drugs (i.e., no two REMS are exactly alike)

http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf

# Answer to Question 37, continued



- A REMS for a New Drug Application (NDA) or Biologics Licensing Applications (BLA) may contain any of the following elements:
  - Medication Guide or Patient Package Insert
  - Communication Plan
  - Elements To Assure Safe Use (ETASU)
  - Implementation System
- REMS for ANDA (generic) products may contain the following:
  - Medication Guide
  - Elements to Assure Safe Use (ETASU)
  - Implementation System

http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf

# Question 38

100

- How can drug products be switched from prescription status to OTC status?
  - I. Manufacturer submits a supplemental NDA
  - II. Petition for reclassification is filed
  - III. Via the OTC Review Process

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

# Answer to Question 38



- Ways in which a drug may be switched to OTC from prescription:
  - The manufacturer may request the switch by submitting a supplemental application to its approved NDA (i.e. SNDA)
  - The manufacturer may petition the FDA
  - The drug may be switched through the OTC drug review process
    - Generally applies to all manufacturers' products at the same time
- Sometimes when the manufacturer requests their product to become OTC via supplemental information to their NDA, their product may become OTC and the same ingredient can still be prescription by another company; although this is fairly rare.

Abood RR, Burns KA. *Pharmacy Practice and the Law*, 8th Edition.

# Answer to Question 38, continued



- **3. What is the OTC drug review?**
  - The OTC drug review was established to evaluate the safety and effectiveness of OTC drug products marketed in the United States before May 11, 1972. It is a three-phase public rulemaking process (each phase requiring a *Federal Register* publication) resulting in the establishment of standards (monographs or non-monographs) for an OTC therapeutic drug category.
- **4. What is the first phase of the OTC drug review?**
  - The first phase was accomplished by advisory review panels. The panels were charged with reviewing the ingredients in nonprescription drug products to determine whether these ingredients could be generally recognized as safe and effective for use in self-treatment. They were also charged with reviewing claims and recommending appropriate labeling, including therapeutic indications, dosage instructions, and warnings about side effects and preventing misuse.
  - According to the terms of the review, the panels classified ingredients in three categories as follows:
    - Category I: generally recognized as safe and effective for the claimed therapeutic indication;
    - Category II: not generally recognized as safe and effective or unacceptable indications;
    - Category III: insufficient data available to permit final classification

# Answer to Question 38, continued



- **5. What is the second phase of the OTC drug review?**
  - The second phase of the OTC drug review was the agency's review of ingredients in each class of drugs, based on the panel's findings, on public comment, and on new data that may have become available. The agency, in turn, publishes its conclusions in the *Federal Register* in the form of a tentative final monograph. After publication of the tentative final monograph, a period of time is allotted for objections to the agency's proposal or for requests to be submitted for a hearing before the Commissioner of FDA.
- **6. What is the third phase of the OTC drug review?**
  - The publication of final regulations in the form of drug monographs is the third and last phase of the review process. The monographs establish conditions under which certain OTC drug products are generally recognized as safe and effective.

# Answer to Question 38, continued



**Prescription to OTC Switch**

- 16. What is prescription to OTC switch?
  - Prescription to OTC switch refers to over-the-counter marketing of a product that was once a prescription drug product, for the same dosage form, population, and route of administration.
- 17. How is a prescription to OTC switch accomplished?
  - **An efficacy supplement should be submitted to an approved NDA for a prescription product** if the sponsor plans to switch the drug product covered under the NDA to OTC marketing status in its entirety without a change in the previously approved dosage form or route of administration. An NDA 505(b)(1) should be submitted if the sponsor is proposing to convert some but not all of the approved prescription indications to OTC marketing status. An original NDA (505)(b)(1) or 505(b)(2) needs to be submitted if the sponsor plans to market either a new product OTC whose active substance, indication, or dosage form has never previously been marketed OTC.

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069917.htm

# Answer to Question 38, continued



- FDA's review of OTC drugs is primarily handled by CDER's Office of Drug Evaluation IV. The Nonprescription Drug Advisory Committee meets regularly to assist the agency in evaluating issues surrounding these products. This committee has played a major role in the growth of prescription to OTC switches in recent years.
- Because there are over 300,000 marketed OTC drug products, FDA reviews the active ingredients and the labeling of over 80 therapeutic classes of drugs, for example analgesics or antacids, instead of individual drug products. For each category, an OTC drug monograph is developed and published in the *Federal Register*. OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling. Many of these monographs are found in section 300 of the *Code of Federal Regulations*.
- Once a final monograph is implemented, companies can make and market an OTC product without the need for FDA pre-approval. These monographs define the safety, effectiveness, and labeling of all marketing OTC active ingredients.
- New products that conform to a final monograph may be marketed without further FDA review. Those that do not conform must be reviewed by the New Drug Application process. **A drug company may also petition to change a final monograph to include additional ingredients or to modify labeling.**

http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm

# Question 39

106

- What is the name of the voluntary system for healthcare professionals to report ADRs to FDA?
  A. MEDMARX
  B. STEPS
  C. MEDWATCH
  D. VAERS
  E. CLIA

# Answer to Question 39



- MedWatch, the FDA's safety information and adverse event reporting program, plays a critical role in the agency's postmarketing surveillance--the process of following the safety profile of medical products after they've begun to be used by consumers.
- Through MedWatch, a voluntary program, health professionals report adverse reactions, product problems, and use errors related to drugs, biologics, medical devices, dietary supplements, cosmetics, and infant formulas.

MedWatch: Managing Risks at the FDA by Michelle Meadows; FDA Consumer, Vol. 37, September-October 2003.

MedWatch*Learn* Case Studies for students & health professionals at http://www.accessdata.fda.gov/scripts/MedWatchLearn/health-professionals.htm

# Question 40



- FDA categorizes drug recalls into classes based on the likelihood of the drug causing adverse health consequences to its users. FDA recalls drug XYZ because it believes it is reasonably probable that XYZ will cause adverse health consequences or death. Into what category will this recall be placed?

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

# Answer to Question 40



- Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.
- FDA classification of recalls.
  - A Class I recall applies when there is a reasonable probability that the product will cause serious adverse health consequences or death.
  - A Class II recall applies when the product may cause temporary or medically reversible adverse health consequences, but the probability of serious adverse consequences is remote.
  - A Class III recall applies when a product is not likely to cause adverse health consequences.

https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129337.htm (Link updated 2018!)

# Question 41



- Big Pharma, Inc. wants to change the salt of its existing blockbuster medication from acetate to carbonate. Through which mechanism is Big Pharma likely to proceed in order to gain FDA approval for this change?
  - A. Full NDA
  - B. 505(b)(2)
  - C. ANDA
  - D. IND
  - E. Any of the above mechanisms are appropriate

# Answer to Question 41



- 21 U.S. Code § 355 - New drugs at http://www.law.cornell.edu/uscode/text/21/355
- Under the FDCA, there is a mechanism for approval of a new drug that does not require extensive and expensive clinical trials, and is not the traditional generic approval route. Once known as a "Paper NDA," but now known by the section number that authorizes it, the 505(b)(2) approval permits the sponsor of a new drug to obtain approval if safety and efficacy can be shown through published studies or other evidence not created by the sponsor. As a practical matter, of course, this route will not be available for patented completely new molecular entities, because there will have been no reported studies of them due to their newness. But for slight modifications of existing drugs (a different salt or ester, for example), this is an approval that may be permitted.

  Abood RR, Burns KA. Pharmacy Practice and the Law, 8th Edition.
- Following are additional examples of applications that may be accepted pursuant to section 505(b)(2) of the [Food, Drug & Cosmetic] Act… Active ingredient. An application for a change in an active ingredient such as a different salt, ester, complex, chelate, clathrate, racemate, or enantiomer of an active ingredient in a listed drug containing the same active moiety… http://www.fda.gov/downloads/Drugs/Guidances/ucm079345.pdf (pp. 4-5)

# Question 42



- From what potential violation of the FDCA does the IND provision provide an exemption?

A. Adulteration
B. Compounding
C. Introduction into interstate commerce of an unapproved new drug
D. Misbranding
E. Current Good Manufacturing Practices

# Answer to Question 42



- Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA.

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm

# Question 43

114

- Mrs. Jones is a patient for whom child-resistant medication vial closures are inappropriate. Under the Poison Prevention Packaging Act, who may make a blanket request that all medications be dispensed in nonchild-resistant closures?

A. The prescriber only
B. The patient only
C. The pharmacist only
D. Either the prescriber or the patient only
E. Either the prescriber or the pharmacist only

# Answer to Question 43



- Q. May an individual request that all of his/her prescriptions be filled in conventional (nonspecial packaging)?
  - A. Yes, the law does not preclude a pharmacist from relying on a specific request from a patient to have all of his/her medications placed in nonspecial packaging. May pharmacists choose to have this request in writing, i.e., **a blanket waiver**…
- Q. If the pharmacist is aware that one of his/her customers prefers conventional packaging for his/her prescriptions, can the pharmacist make this decision without the customer's specific request?
  - A. No. The pharmacist may advise the customer that he/she has the option of having the prescription dispensed in noncomplying packaging, but the choice must be that of the customer.
- Q. May a pharmacist dispense a prescription drug in a noncomplying package in response to a standing order from a physician that it be so dispensed?
  - A. This can be done only when it applies to refills of a prescription where the physician has prescribed noncomplying packaging *for that prescription*. However, a drug dispensed to the same person on a different prescription of the same or another prescriber must be dispensed in special packaging, unless the prescription directs the use of noncomplying packaging or the purchaser requests it.

http://www.cpsc.gov//PageFiles/113945/384.pdf (p. 11).

- Bottom line -- A physician may request that a prescribed medication not be dispensed in child-resistant closures, & this request will be honored as long as it is made for each prescription to which it applies (i.e., no "blanket requests"). However, patients may request that all dispensed drugs not be placed in child-resistant containers.

# Question 44

116

- Two products are listed in the Orange Book. One product is rated as AB and the other is rated as AA. They are the same molecular entity. What can be concluded based on the Orange book about the equivalence of the two products?

A. They are therapeutically equivalent.
B. They are bioequivalent.
C. They are rated as bioequivalent.
D. They are not rated as therapeutically equivalent.
E. They are not therapeutically equivalent.

# Answer to Question 44



*Orange Book* – Terminology

- Bioequivalence
  - Products display comparable bioavailability
- Pharmaceutical equivalents (PEs)
  - Products that contain same active ingredients, identical in strength and same dosage form
- Therapeutic equivalents (TEs)
  - PEs that can be expected to have the same clinical effect and safety
- PEs that are bioequivalent are considered to be TEs!

# Answer to Question 44, continued



- Most importantly for pharmacists, the "Orange Book" lists bioequivalence evaluations for drugs of which there is more than one product.
- A reference standard is noted (usually the innovator product, but not always), and each generic product is compared with that reference standard.
- Each product for which an evaluation has been made is given a two letter code, with the first letter of the two letters being either "A" or "B."
  - Only the first letters are significant for making comparisons.
- If two products both have a code beginning with "A," then the two products are rated as bioequivalent. No other combination has meaning. In other words, an "A" rated product cannot be compared with a "B" rated product, and two "B" rated products cannot be compared with each other.
- Simply because products are not both "A" rated does not necessarily mean they are "bad" products; it may mean that they are not shown to be equivalent. Perhaps they really are equivalent, but just have not been shown to be.
  - NOTE: No B-rated generic products after 1984
  - NOTE: Substitution with B-rated product does not violate federal law, but might violate state law

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm

# Question 45

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- Big Pharma Labs is the first to place a new drug on the market. At the time, there were no other drugs with this active ingredient on the market. Years later, a generic manufacturer makes a drug that is bioequivalent to that drug. Big Pharma's product would be best described in the Orange Book as:
  - I. The reference listed drug (RLD).
  - II. AB1 rated.
  - III. B rated.

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

# Answer to Question 45

120

- A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart.
  - NOTE: For a generic to have been approved, it must have proven that it is bioequivalent to the RLD; thus, it could not be rated as "B".
  - Both the RLD & the generic will be rated as A; however, we do not know whether there is more than one RLD on the market, warranting an AB1 rating.

http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm

# Introduction to Question 46



From http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm

| Trade Name | Applicant | Potency | TE Code | Appl No | Product No |
|---|---|---|---|---|---|
| UNITHROID | STEVENS J | 0.025MG | AB1 | 21210 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB1 | 76187 | 001 |
| LEVOXYL | KING PHARMS | 0.025MG | AB1 | 21301 | 001 |
| SYNTHROID | ABBOTT | 0.025MG | AB1 | 21402 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB1 | 21342 | 001 |
| | | | | | |
| SYNTHROID | ABBOTT | 0.025MG | AB2 | 21402 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB2 | 76187 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB2 | 21342 | 001 |
| UNITHROID | STEVENS J | 0.025MG | AB2 | 21210 | 001 |
| | | | | | |
| LEVOXYL | KING PHARMS | 0.025MG | AB3 | 21301 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB3 | 21342 | 001 |
| UNITHROID | STEVENS J | 0.025MG | AB3 | 21210 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB3 | 76187 | 001 |
| | | | | | |
| LEVOTHROID | LLOYD | 0.025MG | AB4 | 21116 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB4 | 76187 | 001 |

# Question 46

122

- Which of the following levothyroxine 0.025 mg products are rated as equivalent to one another?
  - I. Levothyroxine Sodium (Mylan) & Levothroid (Lloyd)
  - II. Unithroid (Stevens J) & Levothroid (Lloyd)
  - III. Synthroid (Abbott) & Levothroid (Lloyd)

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

# Answer to Question 46



- ***Levothyroxine Sodium***. Because there are multiple reference listed drugs of levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character TE codes may be potentially confusing and inadequate for these drug products. Accordingly, FDA provides the following explanation and chart of therapeutic equivalence evaluations for levothyroxine sodium drug products.
- ***NOTE: Levothroid by Lloyd is rated as AB4 & is only equivalent to Levothyroxine Sodium by Mylan. According to FDA, levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levothroid (Lloyd NDA 021116) tablets.
- Thus, either no other studies have been conducted or have failed to demonstrate that any other levothyroxine 0.025 mg tablets are equivalent to Lloyd's Levothroid.
  - Accordingly, in those states that follow the Orange Book for purposes of generic substitution, pharmacists can only substitute Levothroid 0.025 mg with Mylan's levothroxine sodium 0.025 mg.

See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm

# Update to Question 46 (2018)



- Lloyd's Thyro-Tabs tablets (NDA 021116) (previously known as Levothroid) is currently listed in the Discontinued Drug Product List section of the Orange Book and Mylan's levothyroxine product (ANDA 076187) has been selected as the reference standard for ANDA applicants to use to establish bioequivalence to Thyro-Tabs. If an ANDA that uses Mylan's levothyroxine product as its reference standard is approved, the ANDA will receive an AB4 rating. The ANDA applicant also may obtain an AB rating for its product to the other reference listed drugs (i.e., Unithroid, Synthroid, and Levoxyl) by submitting supplements that demonstrate that the generic product is bioequivalent to these other reference listed drugs and satisfies all other therapeutic equivalence criteria with respect to these reference listed drugs. See Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA to Teri Nataline, Principal Consultant, Lachman Consultant Services, Inc., Docket No. FDA-2015-P-0403 (May 27, 2016).

https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#_ftn9

# Question 47

125

- In the package insert, there is a section that describes any situation in which the drug should not be used because the risk of use clearly outweighs the benefit. What is that section called?

A. Warnings
B. Precautions
C. Prohibitions
D. Contraindications
E. Limitations

# Answer to Question 47



- From 21 CFR §201.57 … (5) ***Contraindications***: This section must describe any situations in which the drug should not be used because the risk of use (e.g., certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit. Those situations include use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by the drug and for whom no potential benefit makes the risk acceptable. Known hazards and not theoretical possibilities must be listed (e.g., if severe hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication). If no contraindications are known, this section must state "None."

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=201.57

- ***NOTE: Within the regulation, see the distinction between "contraindications" which describe situations in which the risk of use of a drug outweighs any possible benefit, and "warnings and precautions" that describe how a drug is to be used to minimize risks.

# Question 48

127

- The federal agency that regulates the advertising of OTC drugs is:

A. The Centers for Medicare and Medicaid Services (CMS)
B. The Food and Drug administration (FDA)
C. The Federal Trade Commission (FTC)
D. The Drug Enforcement Agency (DEA)
E. Center for Drug Evaluation and Research (CDER)

# Answer to Question 48



- Accurate and complete information is vital to the safe use of drugs. While drug companies have traditionally promoted their products directly to physicians, more and more they are advertising directly to consumers.
- Advertising of OTC drugs is regulated by the Federal Trade Commission, but [FDA's consumer watchdog, Center for Drug Evaluation and Research (CDER)], oversees the advertising of prescription drugs.
- Advertisements for a drug must contain a truthful summary of information about its effectiveness, side effects, and circumstances when its use should be avoided.
- In addition to its efforts to improve the information that accompanies OTC drugs, CDER monitors a voluntary program that seeks to provide consumer information for prescription drugs in the pharmacy. The center watches this program closely to ensure that it meets its goals for quantity and quality of information.

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143462.htm

# Question 49

129

- Please select the best answer. Prescription drug products containing estrogen *must* be dispensed with the following piece of literature:
  - A. Package insert.
  - B. Patient package insert.
  - C. Medication guide.
  - D. REMS.
  - E. Pamphlet about the importance of routinely taking the drug written by the dispensing pharmacy.

# Answer to Question 49



- *21 CFR§ 310.515 (a) Requirement for a patient package insert. FDA concludes that the safe and effective use of **drug products containing estrogens** requires that patients be fully informed of the benefits and risks involved in the use of these drugs. Accordingly, … each estrogen drug product restricted to prescription distribution, including products containing estrogens in fixed combinations with other drugs, shall be dispensed to patients with a **patient package insert** containing information concerning the drug's benefits and risks. An estrogen drug product that does not comply with the requirements of this section is **misbranded** under section 502(a) of the Federal Food, Drug, and Cosmetic Act…*
- Note that this is simply one example of the special labeling required by FDA for specific drugs. This labeling is directed to patients, rather than to health care professionals.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=310.515

# Question 50



- Which device requires FDA premarket approval?

A. Crutch
B. Liquid bandage
C. Tongue depressor
D. Oxygen mask
E. Replacement heart valve

# Answer to Question 50



*21 USC § 360c (a) Classes of devices. (1) There are established the following classes of devices intended for human use:*

- *(A) Class I, general controls.*
  - *… (ii) (I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and (II) does not present a potential unreasonable risk of illness or injury…*
- *(B) Class II, special controls.*
  - *A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance …*
- *(C) Class III, premarket approval. A device which because--*
  - *… (ii) (I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or (II) presents a potential unreasonable risk of illness or injury, is to be subject, … to premarket approval to provide reasonable assurance of its safety and effectiveness …*

NOTE: Class III medical devices require premarket approval. That requirement places them on essentially the same footing as new drugs.

http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partA-sec360c.htm

# Answer to Question 50, continued



- How to Locate Classification Regulations: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm
- Sec. 870.3925 **Replacement heart valve.**
  - (a)Identification. A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.
  - **(b)Classification. Class III (premarket approval).** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=870.3925
- Sec. 890.3150 Crutch.
  - (a)Identification. A crutch is a device intended for medical purposes for use by disabled persons to provide minimal to moderate weight support while walking.
  - (b)Classification. Class I (general controls). http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=890.3150
- Sec. 880.5090 Liquid bandage.
  - (a)Identification. A liquid bandage is a sterile device that is a liquid, semiliquid, or powder and liquid combination used to cover an opening in the skin or as a dressing for burns. The device is also used as a topical skin protectant.
  - (b)Classification. Class I (general controls). http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=880.5090
- Sec. 880.6230 Tongue depressor.
  - (a)Identification. A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues.
  - (b)Classification. Class I (general controls). http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=880.6230
- Sec. 868.5580 Oxygen mask.
  - (a) *Identification.* An oxygen mask is a device placed over a patient's nose, mouth, or tracheostomy to administer oxygen or aerosols.
  - (b) *Classification.* Class I (general controls). http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=868.5580

# Question 51



- Tamper-evident packaging refers to which of the following?
  - A. Packaging that contains an indicator or barrier that if missing can reasonably be expected to alert the consumer to the possibility that tampering has occurred
  - B. A permanent barrier to the product that only the consumer can remove after purchase
  - C. A permanent barrier that the store removes before the consumer purchases
  - D. An alarm that notifies the retailer that a product has been tampered with
  - E. A statement on the outside of the package that alerts the consumer to the possibility of tampering

# Answer to Question 51



- *21 CFR § 211.132 (b)Requirements for tamper-evident package. (1) Each manufacturer and packer who packages an OTC drug product (except a dermatological, dentifrice, insulin, or lozenge product) for retail sale shall package the product in a tamper-evident package, if this product is accessible to the public while held for sale. A tamper-evident package is one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of successful tampering and to increase the likelihood that consumers will discover if a product has been tampered with, the package is required to be distinctive by design or by the use of one or more indicators or barriers to entry that employ an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture)… A tamper-evident package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-evident feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display. (2) In addition to the tamper-evident packaging feature described in paragraph (b)(1) of this section, any two-piece, hard gelatin capsule covered by this section must be sealed using an acceptable tamper-evident technology…*

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=211.132

# Question 52

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- Which of the following drug(s) is/are exempt from poison prevention packaging? Select all that apply.

A. Estrogen-containing oral contraceptives in memory-aid packaging
B. Sublingual nitroglycerin
C. Combination colestipol products
D. Anhydrous cholestyramine in any form
E. Bottles of prednisone – in any size & strength

# Answer to Question 52



- **16 CFR 1700.14 - Substances requiring special packaging**
- ...(10) *Prescription drugs*. Any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drug shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except for the following:
- (i) Sublingual dosage forms of nitroglycerin.
- (ii) Sublingual and chewable forms of isosorbide dinitrate in dosage strengths of 10 milligrams or less.
- (iii) Erythromycin ethylsuccinate granules for oral suspension and oral suspensions in packages containing not more than 8 grams of the equivalent of erythromycin.
- (iv) Cyclically administered oral contraceptives in manufacturers' mnemonic (memory-aid) dispenser packages that rely solely upon the activity of one or more progestogen or estrogen substances.
- (v) Anhydrous cholestyramine in powder form.
- (vi) All unit dose forms of potassium supplements, including individually-wrapped effervescent tablets, unit dose vials of liquid potassium, and powdered potassium in unit-dose packets, containing not more than 50 milliequivalents of potassium per unit dose.

# Answer to Question 52, continued



- (vii) Sodium fluoride drug preparations including liquid and tablet forms, containing not more than 110 milligrams of sodium fluoride (the equivalent of 50 mg of elemental fluoride) per package or not more than a concentration of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids and containing no other substances subject to this § 1700.14(a)(10).
- (viii) Betamethasone tablets packaged in manufacturers' dispenser packages, containing no more than 12.6 milligrams betamethasone.
- (ix) Pancrelipase preparations in tablet, capsule, or powder form and containing no other substances subject to this § 1700.14(a)(10).
- (x) Prednisone in tablet form, when dispensed in packages containing no more than 105 mg. of the drug, and containing no other substances subject to this § 1700.14(a)(10).
- (xi) -(xii) [Reserved]
- (xiii) Mebendazole in tablet form in packages containing not more than 600 mg. of the drug, and containing no other substance subject to the provisions of this section.
- (xiv) Methylprednisolone in tablet form in packages containing not more than 84 mg of the drug and containing no other substance subject to the provisions of this section.

# Answer to Question 52, continued



- (xv) Colestipol in powder form in packages containing not more than 5 grams of the drug and containing no other substance subject to the provisions of this section.
- (xvi) Erythromycin ethylsuccinate tablets in packages containing no more than the equivalent of 16 grams erythromycin.
- (xvii) Conjugated Estrogens Tablets, U.S.P., when dispensed in mnemonic packages containing not more than 32.0 mg of the drug and containing no other substances subject to this § 1700.14(a)(10).
- (xviii) Norethindrone Acetate Tablets, U.S.P., when dispensed in mnemonic packages containing not more than 50 mg of the drug and containing no other substances subject to this § 1700.14(a)(10).
- (xix) Medroxyprogesterone acetate tablets.
- (xx) Sacrosidase (sucrase) preparations in a solution of glycerol and water.
- (xxi) Hormonal Therapy Replacement Products that rely solely upon the activity of one or more progesterone or estrogen substances.
- (xxii) Colesevelam hydrochloride in powder form in packages containing not more than 3.75 grams of the drug.
- (xxiii) Sevelamer carbonate in its powder form in packages containing not more than 2.4 grams of the drug.

**Learn this list!**

http://www.gpo.gov/fdsys/pkg/CFR-2012-title16-vol2/pdf/CFR-2012-title16-vol2-sec1700-14.pdf (p. 851)

# Question 53

140

- Which of the following laws required drug manufacturers to prove to FDA the effectiveness of their products before marketing them?
  - A. Durham-Humphrey Amendment of 1951
  - B. Kefauver-Harris Drug Amendments of 1962
  - C. Drug Price Competition and Patent Term Restoration Act of 1984
  - D. Food and Drug Administration Modernization Act of 1997
  - E. Food and Drug Administration Amendments Act (FDAAA) of 2007

# Answer to Question 53



- **Durham-Humphrey Amendment of 1951** defines the kinds of drugs that cannot be safely used without medical supervision and restricts their sale to prescription by a licensed practitioner. It gave the FDA the authority to require that drugs be limited to prescription status when they cannot be used safely over the counter; thus, the law created two classes of drugs, prescription only & OTC.
- **Kefauver-Harris Drug Amendments of 1962** passed to ensure drug efficacy and greater drug safety. **For the first time, drug manufacturers are required to prove to FDA the effectiveness of their products before marketing them.** The new law also exempts from the Delaney proviso animal drugs and animal feed additives shown to induce cancer but which leave no detectable levels of residue in the human food supply

http://www.fda.gov/aboutfda/whatwedo/history/milestones/ucm128305.htm

- **Drug Price Competition and Patent Term Restoration Act of 1984** ("Hatch-Waxman") expedites the availability of less costly generic drugs by permitting FDA to approve applications to market generic versions of brand-name drugs without repeating the research done to prove them safe and effective. At the same time, the brand-name companies can apply for up to five years additional patent protection for the new medicines they developed to make up for time lost while their products were going through FDA's approval process.
  http://thomas.loc.gov/cgi-bin/bdquery/z?d098:SN01538:@@@D&summ2=m&|TOM:/bss/d098query.html

# Answer to Question 53, continued



- **Food and Drug Administration Modernization Act of 1997** reauthorizes the Prescription Drug User Fee Act of 1992 and mandates the most wide-ranging reforms in agency practices since 1938. Provisions include measures to accelerate review of devices, regulate advertising of unapproved uses of approved drugs and devices, and regulate health claims for foods. See also https://www.fda.gov/aboutfda/whatwedo/history/milestones/ucm128305.htm
- **Food and Drug Administration Amendments Act (FDAAA) of 2007** represents a very significant addition to FDA authority. Among the many components of the law, the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA) have been reauthorized and expanded. These programs will ensure that FDA staff have the additional resources needed to conduct the complex and comprehensive reviews necessary to new drugs and devices. Two other important laws were reauthorized: the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). Both of these are designed to encourage more research into, and more development of, treatments for children. Overall, this new law will provide significant benefits for those who develop medical products, and for those who use them. See https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm

# Question 54

143

- A generic manufacturer wishes to obtain approval of a product believed to be bioequivalent to the FDA-approved innovator product. Through what mechanism will the generic manufacturer most frequently obtain this approval?

A. Supplemental NDA
B. Abbreviated NDA
C. Additional NDA
D. Bioequivalency NDA
E. Full NDA

# Answer to Question 54



- A new chemical entity that is developed by a sponsor and is approved as a new drug under an NDA is granted a period of exclusive marketing, and during that time no other manufacturer may market the chemical entity.
- Patent laws protect the new drug's exclusivity for a period of time, and under some circumstances, the FDCA provides additional non-patent exclusivity.
- After all applicable periods of exclusivity have expired, it is possible for another manufacturer to formulate the chemical entity into a product and market the product as a generic equivalent of the innovator product.
- The most frequent way of getting to market as a generic equivalent is through an Abbreviated New Drug Application (ANDA).
- An ANDA relies on the safety and efficacy studies of the innovator product's NDA.
- Through an ANDA, a sponsor of a generic equivalent is required only to show bioequivalence with the innovator product. If such bioequivalence is shown, then the assumption is made that the bioequivalent product must be as safe and effective as the innovator product.

*Abood RR, Burns KA. Pharmacy Practice and the Law, 8th Edition.*

# Question 55

145

- Which of the following would likely cause FDA to consider a pharmacy to be engaged in manufacturing rather than compounding?
  - I. Regularly compounding drugs that are copies of those already manufactured without a medical need to do so
  - II. Compounding drugs to sell to other pharmacies for resale
  - III. Preparing up to a 30-day supply of a particular compounded drug in order to fill valid RXs it receives later

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

# Answer to Question 55



**Drug Quality and Security Act.** Section 503A of the Food, Drug & Cosmetic Act from 1997 remains in effect (without the unconstitutional advertising provisions)

- Under 503A, cGMP, adequate direction for use, and new drug provisions of FDCA do not apply if:
  - a sterile or non-sterile drug is compounded for an identified individual patient and
  - the compound is based on receipt of a valid prescription/order and
  - is compounded by a licensed pharmacist/physician. (Sec. 503A(a)(1))
    - ***NOTE: To stay off of FDA's radar, pharmacies should only compound drugs pursuant to RXs & NOT sell the drugs they compound to a 3rd party
- Pharmacist/physician may compound in limited quantities before receipt of a prescription for individual patient if, based on history of the pharmacist or physician receiving prescriptions for the drug product generated solely within established relationship:
  - between the pharmacist/physician and patient, or
  - between the pharmacist and other practitioner that writes the prescription order (503A(a)(2))

# Answer to Question 55, continued



- In its December 2016 guidance on Section 503A's prescription requirement (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf), FDA provided insight into its approach to enforcement of Section 503A's requirement that compounding eligible for certain FDCA exemptions under 503A may occur only pursuant to a valid prescription or under very limited circumstances prior to receipt of such a prescription. While FDA acknowledged the need for some physicians to maintain office supplies of compounded drugs, it established a relatively strict approach to anticipatory compounding, including compounding for office use. FDA noted that under Section 503A(a)(2) of the FDCA, licensed pharmacists and physicians may compound prior to receipt of a patient-specific prescription only if such compounding is in limited quantity and based on a history of receiving valid prescription orders for the compounded drug within the context of an established relationship with the prescribing practitioner.

# Answer to Question 55, continued



- [FDA does] not intend to consider whether a compounder has exceeded the limited quantity condition in section 503A(a)(2) if:
  - The compounder holds for distribution no more than a 30-day supply of a particular compounded drug product (i.e., units of a compounded drug product that the compounder believes it will distribute over a 30-day period) to fill valid prescriptions it has not yet received; and
  - The amount of the supply of a particular compounded product is based on the number of valid prescriptions that the compounder has received for identified individual patients in a 30-day period over the past year that the compounder selected.

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf

# Answer to Question 55, continued



- Essentially a copy of a commercially available drug
  - Cannot compound regularly or inordinate amounts (as defined by the Secretary)
  - Does not include a compounded drug for an identified individual, which produces in that patient a significant difference between compounded drug and commercially available drug (503A(b)(1)(D); 503A(b)(2)) [e.g., a drug is available commercially as a tablet, but, the pharmacy compounds a lozenge for an elderly patient – this is okay to do!]

See FDA Guidance for Industry (January 2018). https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510154.pdf

# Question 56

150

- According to the Health Insurance Portability and Accountability Act (HIPAA), under which situation should the pharmacist generally provide only the "minimum necessary" information about a particular patient? Select all that apply.
  - A. When responding to a prescriber's request to discuss the treatment of the patient
  - B. When advising the patient about the use of her medications
  - C. When communicating with a PBM about potential coverage for a drug a physician has prescribed for the patient
  - D. When speaking with a software vendor about a glitch in the patient's electronic medical record
  - E. When meeting with the pharmacy's attorneys about an RX that was filled incorrectly, causing injury to the patient

# Answer to Question 56



§ 164.502 Uses and disclosures of protected health information: general rules. https://www.law.cornell.edu/cfr/text/45/164.502

- (a) Standard. A covered entity may not use or disclose protected health information, except as permitted …
  - (1) Covered entities: Permitted uses and disclosures. A covered entity is permitted to use or disclose protected health information as follows:
    - (i) To the individual;
    - (ii) For treatment, payment, or health care operations, as permitted …
- (b) Standard: Minimum necessary.
  - (1) Minimum necessary applies. When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.
  - (2) Minimum necessary does not apply. This requirement does not apply to:
    - (i) Disclosures to or requests by a health care provider for treatment;
    - (ii) Uses or disclosures made to the individual…

NOTE: The minimum necessary rule applies to disclosures involving business associates (BAs) like those in choices C-E. Covered entities contract with BAs & disclosures must not extend beyond what was agreed upon in the contract.

# Answer to Question 56, continued



**Business Associates**: 45 CFR 164.502(e), 164.504(e), 164.532(d) and (e) http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/businessassociates.html

- Background: By law, the HIPAA Privacy Rule applies only to covered entities – health plans, health care clearinghouses, and certain health care providers. However, most health care providers and health plans do not carry out all of their health care activities and functions by themselves. Instead, they often use the services of a variety of other persons or businesses. The Privacy Rule allows covered providers and health plans to disclose protected health information to these "business associates" if the providers or plans obtain satisfactory assurances that the business associate will use the information only for the purposes for which it was engaged by the covered entity, will safeguard the information from misuse, and will help the covered entity comply with some of the covered entity's duties under the Privacy Rule. Covered entities may disclose protected health information to an entity in its role as a business associate only to help the covered entity carry out its health care functions – not for the business associate's independent use or purposes, except as needed for the proper management and administration of the business associate.
- How the Rule Works
  - General Provision. The Privacy Rule requires that a covered entity obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information it receives or creates on behalf of the covered entity. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the covered entity and the business associate.

# Answer to Question 56, continued



- What Is a "Business Associate?" A "business associate" is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. A member of the covered entity's workforce is not a business associate. A covered health care provider, health plan, or health care clearinghouse can be a business associate of another covered entity. The Privacy Rule lists some of the functions or activities, as well as the particular services, that make a person or entity a business associate, if the activity or service involves the use or disclosure of protected health information. The types of functions or activities that may make a person or entity a business associate include payment or health care operations activities, as well as other functions or activities regulated by the Administrative Simplification Rules.
- Business associate functions and activities include: claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; billing; benefit management; practice management; and repricing. Business associate services are: legal; actuarial; accounting; consulting; data aggregation; management; administrative; accreditation; and financial. See the definition of "business associate" at 45 CFR 160.103.

# Answer to Question 56, continued



- Examples of Business Associates.
  - A third party administrator that assists a health plan with claims processing.
  - A CPA firm whose accounting services to a health care provider involve access to protected health information.
  - An attorney whose legal services to a health plan involve access to protected health information.
  - A consultant that performs utilization reviews for a hospital.
  - A health care clearinghouse that translates a claim from a non-standard format into a standard transaction on behalf of a health care provider and forwards the processed transaction to a payer.
  - An independent medical transcriptionist that provides transcription services to a physician.
  - A pharmacy benefits manager that manages a health plan's pharmacist network.
- Business Associate Contracts. A covered entity's contract or other written arrangement with its business associate must contain the elements specified at 45 CFR 164.504(e). For example, the contract must: Describe the permitted and required uses of protected health information by the business associate; Provide that the business associate will not use or further disclose the protected health information other than as permitted or required by the contract or as required by law; and Require the business associate to use appropriate safeguards to prevent a use or disclosure of the protected health information other than as provided for by the contract…

# Question 57

155

- A drug is misbranded if:
  - I. Its labeling is false or misleading.
  - II. It is manufactured by a drug company not registered with the FDA.
  - III. Its manufacturer fails to comply with a REMS requirement.

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

# Answer to Question 57



**21 U.S. Code § 352 - Misbranded drugs and devices**

A drug or device shall be deemed to be misbranded—

- (a) False or misleading label
  - If its labeling is false or misleading in any particular…
- (o) Drugs or devices from nonregistered establishments
  - If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 360 of this title…
- (y) Drugs subject to approved risk evaluation and mitigation strategy
  - If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 355 (p) of this title and the responsible person (as such term is used in section 355–1 of this title) fails to comply with a requirement of such strategy provided for under subsection (d), (e), or (f) of section 355–1 of this title…
- ***NOTE: (bb) False or misleading advertisement or promotion of compounded drug
  - If the advertising or promotion of a compounded drug is false or misleading in any particular…

http://www.law.cornell.edu/uscode/text/21/352

# Question 58

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- All of the following are examples of adulteration, **EXCEPT**:
  - A. The drug contains an unsafe color additive.
  - B. The drug is held under insanitary conditions whereby it may have been contaminated with filth.
  - C. The drug's strength differs from the standard set forth in an official compendium.
  - D. The drug's labeling is false or misleading in any particular.
  - E. The drug is prepared in a facility not following current good manufacturing practices.

# Answer to Question 58



**21 U.S. Code § 351 - Adulterated drugs and devices**

A drug or device shall be deemed to be adulterated—

- **(a)Poisonous, insanitary, etc., ingredients; adequate controls in manufacture**
- (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess ... or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe ...
- **(b) Strength, quality, or purity differing from official compendium**
- If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium.

https://www.law.cornell.edu/uscode/text/21/351

# Question 59

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- A manufacturer of a nutritional shake decides to add calcium to its product. Which of the following statements can the manufacturer make in the product's labeling and still have it considered a dietary supplement and not a drug?

A. "Treats osteoporosis"
B. "You'll feel great"
C. "Cures the common cold"
D. "Prevents colorectal cancer"
E. "Mitigates the incidence of obesity"

# Answer to Question 59



- The labeling on dietary supplements may make structure/function claims, but may not make therapeutic claims.

***21 USC § 343(r)(6)*** … a statement for a **dietary supplement** may be made if

- (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, **or describes general well-being from consumption of a nutrient or dietary ingredient**, (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and (C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.".
- **A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.** If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

http://www.law.cornell.edu/uscode/text/21/343

# Further Explanation of Question 59



- *21 USC § 321 (g) (1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)…*
  https://www.law.cornell.edu/uscode/text/21/321

# Question 60



- The *primary* purpose of a Phase 2 clinical trial is to determine:
  - A. Safety
  - B. Effectiveness
  - C. Toxicity
  - D. Compatibility with other drugs
  - E. Cost

# Answer to Question 60



- Phase 2 studies begin if Phase 1 studies don't reveal unacceptable toxicity. While the emphasis in Phase 1 is on safety, the emphasis in Phase 2 is on **effectiveness**. This phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. For controlled trials, patients receiving the drug are compared with similar patients receiving a different treatment--usually an inactive substance (placebo), or a different drug. Safety continues to be evaluated, and short-term side effects are studied. Typically, the number of subjects in Phase 2 studies ranges from a few dozen to about 300.

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm

# Answer to Question 60, continued



- Phase 1 – Purpose**:** Safety and dosage
  - During Phase 1 studies, researchers test a new drug in normal volunteers (healthy people). In most cases, 20 to 80 healthy volunteers or people with the disease/condition participate in Phase 1. However, if a new drug is intended for use in cancer patients, researchers conduct Phase 1 studies in patients with that type of cancer.
  - Phase 1 studies are closely monitored and gather information about how a drug interacts with the human body. Researchers adjust dosing schemes based on animal data to find out how much of a drug the body can tolerate and what its acute side effects are.
  - As a Phase 1 trial continues, researchers answer research questions related to how it works in the body, the side effects associated with increased dosage, and early information about how effective it is to determine how best to administer the drug to limit risks and maximize possible benefits. This is important to the design of Phase 2 studies.
- Phase 3 – Purpose: Efficacy and monitoring of adverse reactions
  - Researchers design Phase 3 studies to demonstrate whether or not a product offers a treatment benefit to a specific population. Sometimes known as pivotal studies, these studies involve 300 to 3,000 participants.
  - Phase 3 studies provide most of the safety data. In previous studies, it is possible that less common side effects might have gone undetected. Because these studies are larger and longer in duration, the results are more likely to show long-term or rare side effects

http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm

# Federal Law Answer Key



| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | B-E | | 13 | B | | 25 | C | | 37 | B | | 49 | B |
| 2 | C | | 14 | B | | 26 | B | | 38 | E | | 50 | E |
| 3 | D | | 15 | C | | 27 | C | | 39 | C | | 51 | A |
| 4 | C | | 16 | A | | 28 | B | | 40 | A | | 52 | A,B |
| 5 | B, E | | 17 | E | | 29 | A | | 41 | B | | 53 | B |
| 6 | A | | 18 | B | | 30 | A-E | | 42 | C | | 54 | B |
| 7 | D | | 19 | A, E | | 31 | B | | 43 | B | | 55 | C |
| 8 | C | | 20 | B | | 32 | A | | 44 | C | | 56 | C-E |
| 9 | B-E | | 21 | C | | 33 | E | | 45 | A | | 57 | E |
| 10 | C | | 22 | A | | 34 | B | | 46 | A | | 58 | D |
| 11 | D, E | | 23 | A, B | | 35 | A | | 47 | D | | 59 | B |
| 12 | D | | 24 | D | | 36 | D | | 48 | C | | 60 | B |