Last Name:_____

Pharmacy 4054 Pharmacy Law
Exam II

Do not open the test booklet prior to being told to do so.

I, the undersigned student, agree to do my best on the exam and that I have only used resources that were readily available to other students in the class. I agree not to use any unapproved resources, including the exams of those around me, during the test.

Signature of Student
Date: October 26th, 2010

So you got your treat, are you ready for your trick? Good luck.

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Form: 0

Version: 0

1. Drugs that are approved on the accelerated approval track
   A. utilize only data from animals.
   B. utilize only data from animals and end point markers such as heart attacks in humans.
   C. are targeted to be approved by the FDA in about a year after the NDA is submitted.
   D. may not be used by the general population.
   E. rely on surrogate data markers.

2. Which of the following situations requires a prescription to be made when the product being administered is a controlled substance?
   i. A licensed prescriber administers the substance to the patient.
   ii. A licensed prescriber tells a licensed nurse in his office to administer the substance to the patient
   iii. A licensed prescriber tells a licensed pharmacist to administer the medication to the patient.
   A. i only
   B. iii only
   C. i and ii only
   D. ii and iii only
   E. i, ii, and iii

3. A patient is prescribed hydrocodone to manage his addiction to opiate substances by a duly licensed physician with a current DEA license. All required information is present on the prescription and the provider noted the indication on the actual script. Is this a legitimate prescription?
   A. Yes, it was issued in the normal course of business of the physician.
   B. Yes, only if it was signed in indelible ink.
   C. Yes, if the patient was enrolled in a opiate dependence program.
   D. No, this is not a legitimate medical purpose.
   E. No, the doctor may only prescribe methadone for addiction.

4. A physician who is registered to prescribe buprenorphine (Subutex) containing medications and C-II , will have two separate DEA registration numbers.
   A. True
   B. False

5. The Poison Prevention Act requires
   A. all medications be in child resistant containers.
   B. all oral medications be in child proof containers.
   C. most oral medications be in child proof containers.
   D. child resistant containers to allow no more than 20% of children to open them.
   E. child resistant containers to allow no less than 20% of adults to open them.

6. Which of the following are reasons to control a medication substance as defined by the LA Uniform Controlled Dangerous Substances Law?
   i. It has a high street value
   ii. It has an actual potential for abuse
   iii. There is a history of abuse of the medication
   A. i only
   B. iii only
   C. i and ii only
   D. ii and iii only
   E. i, ii, and iii

7. _____ is a noncontrolled dangerous substance which by appearance would lead a reasonable person to believe that it is a controlled dangerous substance.
   A. Non-controlled dangerous substance
   B. Counterfeit controlled dangerous substance
   C. Imitation controlled dangerous substance
   D. Controlled substance analogue
   E. Controlled substance pre-cursor

8. Which of the following would include a drug that had an accepted medical use with moderate to low risk of developing dependence?
   A. Schedule I
   B. Schedule II
   C. Schedule III
   D. Schedule IV
   E. Schedule V

9. Which of the following are actions that are allowed according to the guidance issued by the FDA regarding compounds?
   A. Compounding from bulk ingredients approved or not approved by the FDA.
   B. Using non-commercial-scale equipment.
   C. Compounding medications that were withdrawn from the market for safety reasons.
   D. Receiving but not using medications without assurance from the distributor that the product was made in an FDA approved facility.
   E. Compounding a 2 month supply of a product in anticipation of using it.

10. Which of the following forms would need to be completed if a pharmacy was robbed and Oxycontin (Oxycodone) was stolen?
    A. DEA 41
    B. DEA 106
    C. DEA 222
    D. DEA 104

11. Within which of the following schedules is Diphenoxylate placed?
    A. Schedule I
    B. Schedule II
    C. Schedule III
    D. Schedule IV
    E. Schedule V

12. Schedule II inventories must be completed every _____ per the Federal Controlled Substance Act.
    A. prescription
    B. day
    C. month
    D. year
    E. two years

13. A product containing 300 mg of codeine per 200 mls would be classified as a
    A. Schedule I
    B. Schedule II
    C. Schedule III
    D. Schedule IV
    E. Schedule V

14. Which of the following is **not an example** of a prospective DUR?
    A. Identifying risks from using a medication in a certain population
    B. Looking for duplicate therapies in a patient's regimen
    C. Identifying drugs that impact a patient's disease
    D. Determining if a patient has been taking a medication too long
    E. Reviewing a prescription profile for a patient to look for overuse of a medication

15. A product containing only phenobarbital would be classified as a schedule
    A. I
    B. II
    C. III
    D. IV
    E. V

16. Which of the following forms must be filled out and sent to the wholesaler prior to receiving Schedule III drugs?
    A. DEA 104
    B. DEA 106
    C. DEA 222
    D. DEA 41
    E. None of the above

17. Which of the following **was not** addressed by the Medicare Modernization Act of 2003?
    A. A prescription medication program to pay for some medications
    B. A request for a set of rules to handle electronic prescribing
    C. Changed the way the administration of Medicare claims were handled
    D. Required all Medicare patients to enroll in medication therapy management
    E. Created the Medicare Advantage plans

18. Working on the weekend at your local discount drug emporium, you receive a phone call from a local medical doctor asking you to take an emergency phone order for Percocet (Oxycodone and APAP). The pharmacist must receive a signed prescription from the physician within what time period?
    A. Within 24 hours
    B. Within 72 hours
    C. Within 7 days
    D. Within 1 month
    E. The phoned RX counts as the original.

19. An individual in the State of Louisiana may legally purchase up to ____ grams of pseudoephedrine every _____ days
    A. 1, 1
    B. 2, 10
    C. 5, 15
    D. 9, 30
    E. 12, 30

20. Generics are required to contain between _____ and _____ percent of the active drug moiety of the brand name product.
    A. 95, 105
    B. 92.5, 107.5
    C. 80, 120
    D. 75,125
    E. 90. 110

21. When a prescription for Duragesic (fentanyl) was presented to your pharmacy, you only had seven of the ten patches requested by the prescription. The other 3 patches **must** be provided to the patient within _____ or the patient will lose them
    A. 24 hours
    B. 72 hours
    C. 10 days
    D. 30 days
    E. 6 months

22. Which of the following examples would not qualify a patient for Medication Therapy Management that would be covered by Medicare Part D per the Medicare Modernization Act?
    A. A patient that has heart failure.
    B. A patient that spends very little money on medications with diabetes.
    C. A patient who takes azithromycin for an acute sinusitis (with no other diseases or medications.)
    D. A patient who spends around $10,000 dollars a year on medication.
    E. A patient who spends about $50 dollars a month on 11 medications.

23. Which of the following is not searchable by the FDA upon an **initial** site visit unless substantial evidence of manufacturing was documented at a prior time and the search warrant includes it?
    A. Shelves where medications are stored.
    B. Storefront advertisements (that are currently in view)
    C. Advertisements found in the paper
    D. Records of purchases
    E. Verification of the pharmacy license

24. Which of the following is a valid DEA number(s) for I.P. Freeley MD (a licensed Medical Doctor) of Southeast New Hampshire?
    A. AF 1246847
    B. MF 1246847
    C. NH 1246847
    D. PF 1246847
    E. None of the above

25. While picking up a new prescription from Friendly Pharmacy, Mrs. Nelson requests to receive the package insert. Can the pharmacy provide this information to the patient?
    A. No. The FDCA only allows health care practitioners to view this information.
    B. No. Only prescribers are allowed to provide the package insert to the patient; pharmacies are prohibited from doing so.
    C. Yes. Pharmacies are mandated to provide the package insert with each new prescription.
    D. Yes. Pharmacies are not prohibited from providing the package insert to patients.

26. Drug A is an oral medication supplied in 50 mg tablets. It is to be taken orally twice daily for the management of Inflammatory Bowel Disease. However, it is found that Drug A is very effective at reducing allergic reactions on the skin when applied directly to the skin in a gel formulation. Company A holds the 'use patent' for Drug A and is currently seeking an indication for a gel formulation of the product. Which of the following statements is true?
    A. It is illegal for pharmacies to compound the product since it comes from an oral product.
    B. It is legal for pharmacies to compound the product, but only from bulk ingredients.
    C. It is illegal as the product is already approved for the treatment of Inflammatory Bowel Disease
    D. It is allowable as long as the company does not enforce the patent.
    E. This is a prohibited action according to the Food and Drug Modernization Act of 1997.

27. Which of the following is an example of a 'learned intermediary' with regards to patient counseling?
    A. Pharmaceutical company
    B. Drug Wholesaler
    C. Physician
    D. Patient
    E. Medication Researcher

28. According to the Medicare Modernization Act, _____ percent of beneficiaries in an urban setting must be within ____ miles of a pharmacy that accepts the Medicare Part D plan they have.
    A. 80, 1
    B. 80, 2
    C. 90, 1
    D. 90, 2
    E. 100, 5

29. Which of the following laws significantly weakened the ability of the FDA to regulate dietary supplements?
    A. Prescription Drug Marketing Act of 1987
    B. Nutrition Labeling and Education Act of 1990
    C. Dietary and Supplement Health Education Act of 1994
    D. FDA Modernization Act of 1997
    E. Poison Prevention Act of 1970

30. A product containing only midazolam would be classified as a schedule
    A. I.
    B. II.
    C. III.
    D. IV.
    E. V.

31. A new drug application is being evaluated by the FDA for approval. Which of the following chemical rankings would cause the NDA to be evaluated the soonest?
    A. The active moiety is a new molecular entity
    B. The product is a combination of approved compounds
    C. Basically a duplicate or the same as another product
    D. Previously marketed, new indications sought
    E. The dosage form or formulation is new

32. In the state of Louisiana, a collaborative Drug Therapy Management agreement must occur between a _____ and a _____.
    A. pharmacist, Hospital
    B. health care provider, pharmacist
    C. nurse practitioner, pharmacist
    D. physician, physician assistant
    E. pharmacist, physician

33. Which of the following DEA numbers would be a correct DEA number for a physician registered with the DEA whose name is Ralph Junction?
    A. MD3982128
    B. MJ2958239
    C. RJ9019286
    D. EJ7853826
    E. XJ8203825

34. Which of the following schedules may the Attorney General reschedule a drug or medication to in an emergency situation?
    A. Schedule I
    B. Schedule II
    C. Schedule III
    D. Schedule IV
    E. Schedule V

35. Two different bottles that have the same first five numbers of their national drug code would indicate that
    A. they are the same product.
    B. they are made by the same manufacturer.
    C. they are the same size bottle.
    D. they are for the same class of medication.
    E. they are not related.

36. In US v. Harold Donald Henry, the pharmacist Henry was convicted of dispensing a controlled substance without a prescription after reporting his concerns to the local police upon questioning. Which of the following actions would have limited his amount of guilt?
    A. Contacting the physician to verify the prescription.
    B. Reporting the two individuals to the police prior to dispensing the medications
    C. Dispense the medications but with proper labeling.
    D. Reporting the physician to the police
    E. Keeping records that indicate what the patients said to him

37. Which of the following is true regarding penalties if the HIPAA is violated?
    A. Though there are significant monetary fines, no jail/prison time can be awarded.
    B. Releasing PHI for personal gain is punished by a maximum of $50,000 in fines.
    C. The HIPAA does not address penalties for violating it.
    D. The punishment depends on whether the release of PHI was unintentional or intentional.
    E. The punishment is per institution not violation, so a institution would only be punished once for any number of violations.

38. Which of the following employees of the pharmacy are allowed to sell over the counter pseudophedrine assuming all of other applicable laws are followed?
    i. Pharmacist
    ii. Licensed Pharmacy Technician
    iii. Pharmacy clerk/cashier
    A. i only
    B. iii only
    C. i and ii only
    D. ii and iii only
    E. i, ii, and iii only

39. Which of the following forms must be completed to obtain registration with the DEA?
    A. 41
    B. 106
    C. 222
    D. 224
    E. 301

40. Current Good Manufacturing Practices must be practiced by which of the following pharmacies?
    A. A pharmacy that sells only over the counter medications
    B. A pharmacy that repackages medications for its own use
    C. A pharmacy that repackages medications for other pharmacies
    D. All pharmacies
    E. Pharmacies do not have to follow Good Manufacturing Practices

You have completed the test!