

Name: _____

Student Number: |_|_|_|_|_|_|_|_|_|_|

PHARMACY 543 – PHARMACY LAWS & ETHICS

MIDTERM EXAMINATION 2

November 21, 2003

Questions 1-25 are multiple choice. Please record your answers on Side 2 of a Standard Answer Sheet, Form 1158. Follow the instructions on Side 1. Carefully complete your name and student number (both characters and bubbles). Select the "best" answer from the available choices.

For short answer and ethics questions, please limit your answers to the space provided for each question.

Turn in:

- (1) the Standard Answer Form,
- (2) your answers to the short answer and essay questions, and
- (3) other pages as necessary (see below).

Complete your **name and student number on any sheet you turn in** if you want credit for that work.

Please do not turn in pages that do not need to be graded.

Grading: multiple choice questions are 1 point each (total 25 points); short answer questions total 15 points, and the ethics question is 10 points. Exam total is 50 points.

Asking questions during the exam: you may **NOT** ask questions during the licensure examination, so none will be permitted during the midterm. However, if you believe that a question is technically flawed, please indicate your concern in a comment on the exam page and turn it in with your answer sheets.

So as to not confuse you, terms like **NOT, TRUE, FALSE, EXCEPT** and are presented in **BOLD, ALL-CAPS**.

MULTIPLE CHOICE QUESTIONS

1. Which of the following disciplinary actions may the the Board of Pharmacy **NOT** take when a prescription drug wholesaler is found to have violated a law or rule?
 - a. Refuse to issue a license
 - b. Suspend the license
 - c. Revoke the license
 - d. Impose a monetary fine*

2. A medication error occurs where the patient is known to have consumed the incorrect medication. What should be done to best remediate¹ the problem?
- I Notify the prescriber
 - II Determine if medical attention is warranted
 - III Assure delivery of replacement drugs
- a. I only
 - b. I and II
 - c. II and III
 - d. I, II and III *
3. The currently preferred approach to preventing medication errors is:
- I Assess procedural flaws in the prescription processing system
 - II Redesign systems to eliminate flaws
 - III Censure personnel involved in or responsible for errors
- a. I only
 - b. I and II *
 - c. II and III
 - d. I, II and III
4. Root cause analysis is a method suggested by the Joint Commission on Accreditation of Healthcare Organizations for identifying and preventing medication errors. Which of the following is the most frequent root cause associated with medication errors?
- a. Lack of information *
 - b. Methods of storage
 - c. Staffing levels
 - d. Labeling
5. Which of the following are pharmacists required to report to appropriate state authorities?
- I Child abuse
 - II Diversion of controlled substances
 - III Embezzlement of funds by another pharmacist
- a. I only
 - b. I and II only *
 - c. II and III only
 - d. I, II, and III

¹re-me-di-a-tion. The act or process of correcting a fault or deficiency: remediation of a learning disability. *Random House Dictionary*

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6. Which of the following complaints would be subject to the jurisdiction of the Board of Pharmacy?
- I Pharmacist committed a drug dispensing error
 - II Diversion of controlled substances
 - III Pharmacist overcharged a private pay patient for a prescription
- a. I only
 - b. I and II only *
 - c. II and III only
 - d. I, II, and III
7. How many intern/extern hours are required in Washington State in order to qualify for a pharmacist license?
- a. 500
 - b. 1,000
 - c. 1,500 *
 - d. 2,000
8. What is the term used by the Board of Pharmacy to describe a situation in which the pharmacy department is open fewer hours than the remainder of the store?
- a. Differential hours *
 - b. Special hours
 - c. Waivered hours
 - d. Limited hours
9. Which of the following are associated with an emergency kit that is maintained at a nursing home?
- I The emergency kit is owned by the pharmacy
 - II The contents of the kit are limited
 - III Any controlled substances in the kit must be included in the pharmacy's DEA inventory
- a. I only
 - b. I and II only
 - c. II and III only
 - d. I, II, and III *

10. Which of the following references does the Board of Pharmacy use to determine which drugs require a prescription in Washington?
- a. The Orange Book
 - b. The Blue Book
 - c. The Red Book *
 - d. The Green Book
11. Which of the following controlled substances may a registered Animal Control agency use for the purpose of euthanizing sick animals?
- I Sodium Pentobarbital
 - II Ketamine
 - III Morphine
- a. I only *
 - b. I and II only
 - c. II and III only
 - d. I, II, and III
12. Which of the following are limits related to the over-the-counter (OTC) sale of pseudoephedrine-containing products in Washington?
- I Packages may contain no more than 3 grams
 - II Only 3 packages may be sold in a single transaction
 - III Retailers must report any requests for more than 5 packages
- a. I only
 - b. I and II only *
 - c. II and III only
 - d. I, II, and III
13. The Board of Pharmacy authorized ratio of pharmacists to pharmacy technicians is:
- a. 1 to 1
 - b. 1 to 2
 - c. 1 to 3 *
 - d. 1 to 4
14. To which of the following agencies must you report any losses of controlled substances?
- a. Board of Pharmacy *
 - b. Food and Drug Administration
 - c. Washington State Patrol
 - d. Local Police Department

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15. Which of the following is a correct DEA registration number for John Smart, MD?
- a. AS 1234563*
 - b. AJ 1234564
 - c. MS 1234565
 - d. JS 1234566
16. When you are partially dispensing a controlled substance for a terminally ill patient how many days do you have to dispense the total quantity called for on the prescription?
- a. 3 days
 - b. 7 days
 - c. 60 days*
 - d. 180 days
17. Which of the following items may be changed on a Schedule II prescription?
- I The quantity
 - II The strength
 - III The drug
- a. I only
 - b. I and II only*
 - c. II and III only
 - d. I, II, and III
18. How many times may you transfer a controlled substance prescription from an independent pharmacy to an unrelated pharmacy?
- a. Once*
 - b. Twice
 - c. Three times
 - d. Five times in 6 months

19. Which of the following requirements apply when you are selling a Schedule III controlled substance to a practitioner for use in his/her office?
- I The sale must be recorded on an invoice
 - II Such sales may not exceed 5% of controlled substance sales
 - III A prescription may be issued entitled, "For Office Use Only"
- a. I only
 - b. I and II only *
 - c. II and III only
 - d. I, II, and III
20. Which of the following elements need **NOT** be demonstrated in a tort claim?
- a. Duty
 - b. Causation
 - c. Damages
 - d. Summary judgement *
21. A pharmacist has a duty to:
- I Warn patients or notify the prescriber if the prescription may cause the patient harm
 - II Verify that the patient's prescription drug is not past the expiration date
 - III Assume control of a patient's drug therapy
- a. I only
 - b. I and II only *
 - c. II and III only
 - d. I, II, and III
22. What is the statute of limitations on medical tort claims following "discovery"?
- a. 1 year *
 - b. 2 years
 - c. 5 years
 - d. 7 years

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23. Which of the following is **NOT** an example of sexual harassment?
- I Chain pharmacy requires all pharmacists to wear a smock that coordinates with it's 1890's theme
 - II Female supervisor tells male subordinate that she will make sure he gets a new computer if he escorts her to dinner.
 - III A male colleague whistles and says, "Lady looking good today," while leering at a female colleague.
- a. I only *
 - b. I and II only
 - c. II and III only
 - d. I, II, and III
24. In Seattle, you have legal protection against which of the following types of discrimination:
- I Sexual orientation discrimination
 - II Age discrimination
 - III Socioeconomic discrimination
- a. I only
 - b. I and II only *
 - c. II and III only
 - d. I, II, and III
25. In the State of Washington, which of the following statements about labor laws is true?
- a. Employers can prohibit employees from forming a union.
 - b. Employers can make union membership a condition of employment.
 - c. During a strike, union members may bar entry to the workplace.
 - d. Employees can be required to pay for union representation, even if they do not join the union. *

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SHORT ANSWER QUESTIONS

26. Complete the following table with information required under Washington law on a legend drug label applied to every box, bottle, jar, tube or other container of a prescription which is dispensed at a community pharmacy.

Check either **required** or **not required**. Points 5 points. If an exception exists in RCW or WAC, explain the exception for extra credit; 0.5 points each extra credit.

	Required	Not Required	Exception
Name and Address of the Dispensing Pharmacy	<input checked="" type="checkbox"/>		
Prescription Number	<input checked="" type="checkbox"/>		
Name of Prescriber	<input checked="" type="checkbox"/>		
Prescriber's DEA Number		<input checked="" type="checkbox"/>	
Name and Strength of the Medication	<input checked="" type="checkbox"/>		may be omitted at prescriber's request
Quantity Dispensed	<input checked="" type="checkbox"/>		
Expiration Date	<input checked="" type="checkbox"/>		
Name of the Patient	<input checked="" type="checkbox"/>		
Date	<input checked="" type="checkbox"/>		
Identity of Responsible Licensed Pharmacist	<input checked="" type="checkbox"/>		may be recorded in pharmacy's record system

27. Contrast a pharmacist's obligation to counsel a patient on a new prescription (patient has never received this drug previously) under OBRA90 and current State of Washington. 2 points

OBRA90 – offer to counsel

Washington – must counsel

28. What should a pharmacist do if a patient refuses counseling in Washington? 2 points

Document on prescription or in patient's profile

29. Describe the specific circumstances under which a dialysis program may dispense prescription drugs. 1 point

Any of these: pursuant to a valid prescription; case lots; list developed by BOP

30. Complete the following table contrasting Drug Enforcement Administration regulations (21CFR1306.26) and State of Washington regulations (WAC 246-887-030) governing the dispensing of Schedule V over-the-counter drug products. Indicate "none" if there is no requirement. 5 points

	DEA	State of Washington
Dose form restrictions	none	liquid only
Minimum age of purchaser of Schedule V OTC drugs	18 years old	21 years old
Minimum time until second purchase	48 hours	96 hours
Pharmacist/intern notation on product label	none	name and address of the pharmacy; date of sale; his/her initials
Special counseling requirements	none	show purchaser copy of rule

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ETHICS QUESTION

- 31. A recent article in the *Wall Street Journal* describes US Food and Drug Administration efforts to prevent legend drug importation from Canada through internet web sites and from "storefronts" in the US representing Canadian pharmacies. For instance, the FDA has obtained a court injunction to shut down such a business.
 - a. Describe Washington legal requirements for a business that links Washington consumers with pharmacies located in Canada. 3 points

Prohibited under RCW 18.65.350 & 410 -- Nonresident pharmacies, because WA cannot license Canadian pharmacies

- b. One of the justifications offered for use of foreign mail-order pharmacies is the lower prices available. The FDA counterclaims that it cannot assure the safety of drugs imported, say, from Canada. Evaluate the ethics of FDA's activities to enjoin Canadian "storefront" pharmacies. 7 points

Perspective
Beneficence
Nonmaleficence

Autonomy

Justice

Virtue

Issues of law