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**Pharmacy 543 – Pharmacy Laws & Ethics
FINAL EXAMINATION
December 10, 2007**

Questions 1-40 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.** Multiple choice, one point each – 40 points. Questions 41-51 are short-answer, 20 points. Ethics Question, 51. 15 Points.

Exam total: 75 points.

Legibility: please verify that your written answers can be read by mere mortals, and your name and student number are legible and correct. Please **double-check the student ID number for accuracy.** Errors or omissions may delay or impact your grades.

Turn in:

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

Please **DO NOT** turn in pages that do **NOT** need to be graded.

Asking questions during the exam: you may **NOT** ask questions during the licensure examination, so none will be permitted during the exam. 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** are presented in **BOLD, ALL-CAPS.**

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MULTIPLE CHOICE QUESTIONS

1. A patient well known to your pharmacy makes some comments that you find offensive. You have previously asked the patient not to make that sort of comment. Assume that you are employed in a multi-store organization with a human resources department to whom you have previously forwarded numerous complaints, indicating that the comments have affected your ability to perform your duties. What are likely outcomes from this encounter?
 - I. You could prevail in a lawsuit claiming "negligent infliction of emotional distress"
 - II. You could successfully file a disability claim because of "intentional infliction of emotional distress"
 - III. You are terminated because the patient complained to management
 - a. I only
 - b. III only
 - c. I and II only
 - d. I, II and III

2. In Washington, you could be discharged for all of the following **EXCEPT**:
 - a. Making repeated dispensing errors
 - b. Whistle blowing to DSHS
 - c. Wearing the wrong color of shoes
 - d. Your political orientation

3. Which of the following is **NOT** true in Washington?
- Employer must supply uniforms if required in the workplace
 - "No compete" clauses are recognized by the courts
 - You may be routinely tested for controlled substance use
 - You may be routinely tested by polygraph
4. Qui tam actions may result from violations of:
- The False Claims Act
 - Medicaid billing laws
 - The Lincoln Law
- I only
 - III only
 - I and II only
 - I, II and III
5. Each of the following illustrates fraudulent billing except:
- Reverse-billing unclaimed prescriptions
 - Upcoding
 - Billing for ghost patients
 - Billing for drug samples
6. To sustain a finding of common law fraud, Washington State case findings require 9 elements of fraud. Which of the following are examples of those elements?
- A representation of an existing fact that is false
 - Knowingly offer the falsity as fact
 - Intent that the victim would act on the false fact
- I only
 - III only
 - I and II only
 - I, II and III
7. The Oregon Death with Dignity Act requires that a "terminal disease":
- Be medically confirmed
 - By reasonable medical judgment, will cause death within six months
 - Be a permanent unconscious condition diagnosed by at least two physicians
- I only
 - III only
 - I and II only
 - I, II and III
8. In the Oregon Death with Dignity Act, which of the following is **NOT** a requirement for a patient to be able to utilize the act?
- The patient must be a verifiable resident of the State of Oregon.
 - The patient must have a "terminal disease" as defined by the ODWDA.
 - The patient must be assessed for significant mental health issues
 - The patient must have "intractable pain" of at least 3 months duration.

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9. Dr. Walker has a clinic in Seattle, WA and a clinic in Redmond, WA. Controlled substances are dispensed at both clinics. How many times must Dr. Walker register his clinics with the DEA?
- a. None, clinics do not need to register with the DEA
 - b. Once, it covers both clinics
 - c. Twice, each clinic must be registered
 - d. Three times, one for each clinic and a third time to link the practices
10. The Family Medical and Leave Act (1993) applies to employers with how many (or more) employees?
- a. 15
 - b. 50
 - c. 100
 - d. 200
11. The Belmont Report of 1979 established the "basic ethical principles" of:
- I. Respect for Persons
 - II. Justice
 - III. Virtue
- a. I only
 - b. III only
 - c. I and II only
 - d. I, II and III
12. Chapter 18.64 RCW gives the Washington Board of Pharmacy the authority to discipline **FIRMS** in which of the following ways
- I. Revoke license
 - II. Suspend a license
 - III. Assess a fine
- a. I only
 - b. III only
 - c. I and II only
 - d. I, II and III
13. In the Washington Natural Death Act, if the patient is "qualified", which of the following is **TRUE** about "life-sustaining treatment"?
- I. Serves only to prolong the process of dying;
 - II. Can be refused or withdrawn based on the patient's wishes using an advanced directive;
 - III. Could be artificially administered hydration or nutrition, advanced cardiac life support or CPR, or pain interventions.
- a. I only
 - b. III only
 - c. I and II only
 - d. I, II and III

14. The Gonzalez v. Oregon (2006) Supreme Court case dealt with which of the following issues:
- I. Oregon Death with Dignity Act
 - II. Controlled Substances Act
 - III. Physician autonomy in the use of schedule II drugs
- a. I only
 - b. III only
 - c. I and II only
 - d. I, II and III
15. The following individuals may **NOT** serve as witnesses to a patient's advance directive in Washington:
- I. The priest from patient's lifelong church, to which patient has left a portion of her estate
 - II. A notary from the local savings and loan who periodically visits the patient's long term care facility to notarize wills and other documents for a nominal fee
 - III. A cafeteria worker at patient's Long Term Care Facility who is the patient's cousin
- a. I only
 - b. III only
 - c. I and II only
 - d. I, II and III
16. Which of the following drugs is **NOT** required to be dispensed in Child-Resistant-Containers (CRC)?
- a. Nitroglycerin sublingual tablets 0.4 mg No. 25.
 - b. Aspirin 300 mg with Codeine 8 mg tablets, No. 6.
 - c. Tylenol 325 mg tablets, No. 12.
 - d. Erythromycin 250 mg tablets, No. 10.
17. Which of the following out-of-state practitioner's prescriptions may **NOT** be filled in the State of Washington?
- a. Doctor of Osteopathic Medicine
 - b. Doctor of Veterinary Medicine
 - c. Doctor of Naturopathic Medicine
 - d. Doctor of Dental Medicine
18. Which of the following laws would **NOT** be helpful when you are trying to determine if a health care practitioner may prescribe a particular drug?
- a. The health professional's practice act. (Chapter 18 RCW)
 - b. The Uniform Controlled Substances Act (Chapter 69.50 RCW)
 - c. The Federal Controlled Substances Act
 - d. The Legend Drug Act (Chapter 69.41 RCW)
19. When a pharmacist substitutes a lower cost generic drug in place of a brand name drug, what percentage of the savings must be passed on to the consumer?
- a. 40%
 - b. 60%
 - c. 80%
 - d. 100%

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20. You are working as an intern in a pharmacy with clients who speak only Vietnamese. The tech staff speaks both Vietnamese and English fluently, while the pharmacist and you do not speak Vietnamese at all. Which of the following situations present a violation of state professional requirements for pharmacists and could lead to an assertion negligence per se if the patient was harmed by the prescription as dispensed?
- I. When you ask the pharmacist about counseling on new medications, s/he says s/he does counsel them by telling the technician what to say in English, which the technician translates into Vietnamese and tells the patient. The pharmacist remains back in the dispensing area, preoccupied with filling prescriptions
 - II. You receive a prescription from one of the Vietnamese doctors in the area which is handwritten in English, but still is difficult to read. It may be "Celexa", or it may be "Celebrex" and the numbers are blurred. Examining the prescription carefully, you just aren't sure what the doctor wants. The pharmacist reassures you that he knows the doctor's handwriting well, so the prescription must be Celexa 40mg.
 - III. You tell your preceptor you have a counseling project for one of your classes and take it upon yourself to counsel all the new patients on their meds, using the either of the bilingual technicians as a translator.
- a. I only
 - b. III only
 - c. I and II only
 - d. I, II and III
21. When a physician or other prescriber dispenses a prescription drug directly to a patient, which of the following items may the prescriber omit from the label?
- I. Drug name
 - II. Drug Strength
 - III. Prescriber's name
- a. I only
 - b. III only
 - c. I and II only
 - d. I, II and III
22. How many times may an applicant for a pharmacy license fail the licensing examination before he/she is required to have successfully completed additional preparation as directed and approved by the Board before retaking the examination?
- a. 1 time
 - b. 2 times
 - c. 3 times
 - d. 4 times
23. Which of the following prescription filling activities may a pharmacy assistant **NOT** perform?
- a. Selecting the drug from a shelf
 - b. Counting tablets or capsules
 - c. Pouring the tablets or capsules into the prescription bottle.
 - d. Labeling the prescription bottle.

24. Under the Washington Preferred Drug List program administered by the Health Care Authority which of the following must an **ENDORISING PRACTITIONER** do in order for his/her patient to receive a NON-preferred drug that he/she has prescribed?
- I. Write "DAW" on the prescription
 - II. Call the pharmacy to explain the medical necessity for the prescribed drug
 - III. Call the program (i.e., Medicaid, Uniform Medical Plan, or Labor and Industries) that will pay for the prescription to explain the medical necessity for the prescribed drug.
- a. I only
 - b. III only
 - c. I and II only
 - d. I, II, and III
25. Which of the following items is the Board of Pharmacy **NOT** allowed to regulate?
- I. Pesticides
 - II. Oxygen
 - III. Nitrous Oxide
- a. I only
 - b. III only
 - c. I and II only
 - d. I, II, and III
26. In a small hospital that does **NOT** have 24-hour pharmacy service, who may enter the hospital pharmacy to obtain a medication when the pharmacist is **NOT** present?
- a. A designated registered nurse (RN)
 - b. A designated licensed practical nurse (LPN)
 - c. A designated physician (MD)
 - d. Any hospital employee who is designated by the Hospital Administrator
27. Upon inspection, a pharmacy receives an inspection score of 89. This is also referred to in rule as:
- a. Class A
 - b. Conditional
 - c. Unsatisfactory
 - d. Failed
28. To which of the following persons may you sell sterile needles and syringes without a prescription?
- I. 35 year old diabetic
 - II. 20 year old heroin abuser
 - III. 17 year old hemophiliac
- a. I only
 - b. III only
 - c. I and II only
 - d. I, II, and III

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29. Which of the following are **NOT** required when a pharmacy within another establishment (i.e., a grocery store) wishes to operate under different hours than the parent store?
- a. Prior notification to the Board
 - b. Seven-foot solid partitions around the pharmacy
 - c. Separate pharmacy phone number that may not be answered in the parent store.
 - d. Pharmacist on call during hours when parent store is open for business
30. When a patient requests a prescription for refill and there are no authorized refills remaining and you are unable to reach the prescriber, what amount of drug may you dispense to the patient in such an emergency?
- a. A single dose
 - b. 24 hours supply
 - c. 48 hours supply
 - d. 72 hours supply
31. How much counter space is required for each pharmacist who is working in a pharmacy.
- a. 4.5 square feet
 - b. 6.5 square feet
 - c. 8.5 square feet
 - d. 10 square feet
32. In what type of facility do the rules require that a pharmacist must review the original or a direct copy of a drug order (except in an emergency) prior to dispensing the drug.
- a. Skilled Nursing Facility
 - b. Intermediate Care Facility
 - c. Ambulatory Surgical Center
 - d. Hospital
33. Which class of drugs is the patient required to keep in the original container in which it was dispensed?
- a. OTC drugs
 - b. Legend drugs
 - c. Controlled Substances
 - d. Chemotherapy drugs
34. What is the current ratio of pharmacy technicians to pharmacists that is allowed in Washington State?
- a. 1 to 1
 - b. 2 to 1
 - c. 3 to 1
 - d. 4 to 1

35. Which DEA registrant is allowed to disperse its controlled substances among its other legend drugs?
- A physician
 - A pharmacy
 - A Wholesaler
 - A Manufacturer
36. Which of the following is **NOT** required on your pharmacy's DEA inventory?
- Pharmacy owner's name
 - Name of person who took the inventory
 - DEA registration number
 - Number of commercial packages
37. To whom could you provide a copy of a patient's prescription profile without the competent patient's consent?
- A Centers for Disease Control and Prevention (CDC) officer
 - Designated guardian of a patient receiving treatment for bipolar disease
 - Parent of a 14-year-old receiving treatment of HIV
- I only
 - III only
 - I and II only
 - I, II, and III
38. What is the significance of the United States Pharmacopeia (USP) and pharmacist compounding in Washington?
- Provides a suitable basis for selecting containers and closures to package the compounded product
 - Washington's compounding rules require that active pharmaceutical ingredients meet USP requirements or pharmacist must use professional judgment in selecting alternatives
 - FDA's Compliance Policy Guide requires that active pharmaceutical ingredients meet USP requirements or pharmacist must use professional judgment in selecting alternatives
- I only
 - III only
 - I and II only
 - I, II, and III
39. As a consequence of a patient complaint made to the Board of Pharmacy, you have received a "Notice of Correction". What is the next step following receipt of the Notice, besides (one hopes) your resolving the problem that led to the complaint.
- DEA is informed
 - You have 90 days to pay the fine
 - The case is closed
- I only
 - III only
 - I and II only
 - I, II, and III

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40. Which health professional is authorized to prescribe legend drugs, all CS schedules, and anesthesia drugs?
- a. ARNP
 - b. CRNA
 - c. MD
 - d. ND

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SHORT ANSWER QUESTIONS – 20 points total

Please confine your responses to the space provided – write inside the box – and write legibly.

41. If the Board of Pharmacy finds that a number of shopkeepers have violated the laws and rules concerning the sales of products that contain pseudoephedrine, could the Board promulgate a rule that prohibits the sale of OTC products, in manufacturer's packages, by shopkeepers? Explain.

42. While being interviewed for a potential job, you are asked to undergo a physical that includes blood tests for infectious diseases and substance abuse. Under the Americans with Disabilities Act, at what point in the interview process can these tests be legally required?

43. Explain the potential contribution of secondary wholesalers to the current pharmaceutical counterfeiting problem.

44. Give 2 examples of "economic damages" that can be assessed in a Tort claim:

45. What two federal agencies are responsible for determining the schedule of a drug?

46. Please place each of the following entities in the box that next to the type of law they create:

- A. Washington Legislature
- B. Washington Agency
- C. Federal Legislature
- D. Federal Agency

Indicate the organization or agency from list above	Type of Law Created
	United States Code
	Revised Code of Washington
	Washington Administrative Code
	Code of Federal Regulations

47. Name three pharmaceutical care activities that pharmacists have been required to perform as a result of federal law or rules.

48. If a "patient" uses a false name when attempting to obtain a prescription from a physician under what condition(s) does the doctor-patient (confidentiality) privilege apply?

49. Name two prescription drugs that may be dispensed, in case lots, to kidney dialysis patients by a Medicare certified kidney dialysis center that does NOT have a pharmacy license.

50. What must a pharmacist do when he/she receives an electronic prescription for a Schedule III controlled substance?

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ETHICS CASE – 15 points

Please confine your response to the space provided (inside the box) and write legibly.

See the article by Dooren from a recent *Wall Street Journal*.

A patient comes into your pharmacy and requests that you suggest a cough-cold preparation to replace one she had used successfully in the past. The patient states that the cough-cold product was reformulated by the manufacturer several months ago, and the new formulation is not as effective and tastes bad. You recommend another product, noting that other patients have used it without complaint.

FDA Says Decongestant's Effectiveness Unclear By JENNIFER CORBETT DOOREN December 4, 2007; Page A18 WASHINGTON --

Food and Drug Administration medical reviewers said they aren't really clear how well the over-the-counter decongestant phenylephrine works. Their assessment would be presented to an advisory panel meeting next week to consider boosting the effective dose.

Most of the makers of decongestants and combination cold-and-cough products that used to contain pseudoephedrine replaced it with another decongestant, phenylephrine, to avoid having to move their products behind pharmacy counters in 2006. Earlier this year three professors from the University of Florida in Gainesville petitioned the FDA to increase the effective dose of phenylephrine on the basis that the current 10-milligram dose isn't effective. Rep. Henry Waxman (D., Calif.) has also repeatedly asked the FDA to consider the issue. The FDA will convene an advisory panel of outside medical experts to discuss whether the current dose of phenylephrine is effective. The Florida professors said a 25- milligram dose would likely work better, but said additional studies would be required.

Phenylephrine, which has been available since the 1940s, doesn't last as long as pseudoephedrine, but the questions about phenylephrine's effectiveness largely didn't surface until it became widely used over the past two years. Both decongestants are designed to reduce sinus pressure and nasal secretions.

In large amounts, pseudoephedrine can be used to make the illegal drug methamphetamine, and a federal law requires products containing pseudoephedrine to be stored behind pharmacy counters and requires consumers to show photo identification and sign a log book that documents what they bought and when.

Some manufacturers still make products with pseudoephedrine.

51. Something bad happens that is causally linked to the patient using the product you recommended. Do you have protection from a legal claim by the patient? Why? (2 points)

Evaluate the ethics of this vignette, applying normative ethical principles discussed in class.

Dilemma	(1)
Perspective	
Beneficence	(2)
Maleficence	(2)
Autonomy	(2)
Justice	(2)
Virtue	(2)
Root Cause	(2)