

Name: _____

Student Number |__|__|__|__|__|__|__|

PHARMACY 543 – PHARMACY LAWS & ETHICS
FINAL EXAMINATION
December 8, 2000

Questions 1 – 40 are multiple-choice. Please record 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).

There are ten short answer questions and one ethics essay. Please limit your answers to the space provided for each question.

Turn in only (1) the Standard Answer Form, (2) your answers to the short-answer questions (page 13-14), (3) the ethics essay (page 15), and other pages if necessary (see below). Please complete your name and student number on any sheet you turn in if you want credit for that work.

Grading: multiple choice questions are 1 point each (total 40 points); short essay questions are 2 points each (20 points total); ethics question is 10 points. Exam total is 70 points.

In answering multiple choice questions, select the “best” answer among the choices provided.

Asking questions: you will not be allowed to 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 on the exam and turn it in with your answer sheets. Otherwise, please do not turn in pages for the multiple choice examination questions.

1. When could the Board of Pharmacy **NOT** take action against a registrant/licensee?
 - A. complaint received by the Board of a misfill
 - B. evidence received by the Board of controlled substances diversion
 - C. complaint received by the Board of failure to counsel
 - D. complaint received by the Board of drug price irregularities
 - E. complaint received by the Board of misbranding

2. A licensee is under investigation for an alleged misfill. S/he has been reluctant to answer the Board of Pharmacy's investigator's questions, believing the s/he enjoys Fifth Amendment^a protections. In making a Fifth Amend claim, the pharmacist:
 - A. cannot be found guilty of the matter under investigation
 - B. can expect the Board to interpret the Fifth Amendment claim as an admission of guilt
 - C. commits a criminal act
 - D. is being treated unfairly
 - E. none of the above

^a An amendment to the Constitution of the United States, ratified in 1791, that deals with the rights of accused criminals by providing for due process of law, forbidding double jeopardy, and stating that no person may be forced to testify as a witness against himself or herself.

Name: _____

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

3. A pharmacist is alleged to have diverted drugs from a pharmacy and a complaint is filed with the Board of Pharmacy. An investigation is conducted, the pharmacist is interviewed, a report completed and processed by the Board. The Board issues a Statement of Charges alleging that the pharmacist has committed acts of unprofessional conduct. However, the pharmacist is convinced that s/he did nothing wrong and chooses to ignore the Statement of Charges. What are the consequences of the pharmacist's action?
- A. Board may proceed to formal discipline
 - B. the Attorney General must intervene for future disciplinary proceedings
 - C. the Board must go to court for further disciplinary proceedings
 - D. the Drug Enforcement Administration could revoke the pharmacist's license
 - E. the pharmacist is not obliged to respond to the Statement of Charges

4. A patient is harmed as a consequence of a drug-herbal interaction and complains to the Board of Pharmacy. When contacted by the Board investigator, the patient refuses to waive confidentiality ("whistle-blower" statement).

Which of the following actions may the Board take?

- A. continue the investigation to its conclusion
 - B. refer the complaint to the Attorney General
 - C. close the case
 - D. refer the complaint to the US Food and Drug Administration
 - E. refer the complaint to the Federal Trade Commission
5. A detail person (pharmaceutical manufacturer's sales representative) is under extreme pressure to reach his sales quota for an antibiotic with known resistance problems. He develops a plan offering health care professionals ski lift tickets, housing, meals and travel in exchange for the health care professional's agreement to review promotional materials while riding the ski lift.

Under Washington's Uniform Disciplinary Act, who among the following may participate in the ski plan?

- A. physicians
 - B. dentists
 - C. registered nurses
 - D. the detail person
 - E. a hospital medical director (assume s/he is subject to the Uniform Disciplinary Act)
6. Who among the following health care professionals may **NOT** prescribe a cough-cold preparation containing an opiate (Schedule C-III)?
- A. physicians
 - B. dentists
 - C. Advanced Registered Nurse Practitioner
 - D. pharmacist under protocol
 - E. veterinarian (for use by a dog)

Name: _____

Student Number |__|__|__|__|__|__|__|

7. Who among the following medical sub-specialists may prescribe for emergency contraception?
- A. anesthesiologist
 - B. otolaryngologist^b
 - C. psychiatrist
 - D. obstetrician / gynecologist
 - E. all of the above
8. Which of the following are **NOT** required to be dispensed in a child resistant container/closure system?
- A. sublingual nitroglycerin 0.4 mg #25
 - B. aspirin 83 mg #24
 - C. acetaminophen 325 mg #24
 - D. ibuprofen 200 mg #24
 - E. ferrous sulfate 300 mg #100
9. Who among the following may determine that a prescription should be dispensed in a **NON**-child resistant container/closure system?
- A. the prescriber
 - B. the patient
 - C. the pharmacist
 - D. A and B
 - E. A, B and C
10. Under **NON-EMERGENCY** conditions, to which entities may a hospital pharmacy **NOT** sell prescription drugs?
- A. another related hospital
 - B. a retail pharmacy
 - C. a physician, for personal use
 - D. a hospital employee
 - E. a hospital employee's dependent
11. Which of the following drug products do **NOT** require tamper resistant packaging?
- A. aspirin 325 mg
 - B. acetaminophen 325 mg
 - C. insulin 100 u/mL 10 ml
 - D. ibuprofen 200 mg
 - E. diphenhydramine 25 mg

^b The branch of medicine that deals with diagnosis and treatment of diseases of the ear, nose, and throat.

Name: _____

Student Number |__|__|__|__|__|__|__|__|

12. Which of the following factors could be used as evidence that a pharmacy was “manufacturing” rather than “compounding”?
- I. an existing pharmacist-prescriber-patient relationship
 - II. sales to another health care entity for resale
 - III. preparation of drugs that are duplicates of existing commercially available products
- A. I only
 - B. III only
 - C. I or II only
 - D. II or III only
 - E. I, II and III
13. Which of the following would **NOT** be an acceptable compounded drug?
- A. preparation of preservative-free ophthalmic solution for a patient sensitive to preservatives
 - B. preparation of a lactose-free dose form for a lactose-intolerant patient
 - C. albuterol sulfate – 1.9 mg/5 mL^c
 - D. preparation of an oral liquid for of a product commercially available only as an oral solid for a patient unable to swallow the solid form
 - E. preparation of potassium bromide solution for veterinary use
14. Which of the following would **NOT** be considered “difficult to compound” under Food and Drug Administration Modernization Act (FDAMA)?
- A. sterile solution for parenteral administration
 - B. a sustained-release product
 - C. a transdermal delivery system
 - D. metered dose products for inhalation
 - E. preservative-free oral suspensions available commercially as a capsule
15. Various states have passed initiatives that decriminalize possession and use of marijuana for certain medical conditions. Which law(s) takes precedence in the following examples?
- I. Washington State Medical Marijuana Act, Initiative 692
 - II. DEA Schedule I classification
 - III. An Investigational New Drug Application that uses marijuana, effective under FDA law
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. None of the above

^c A 2 mg/5 mL product is commercially available

Name: _____

Student Number |__|__|__|__|__|__|__|

16. Which of the following is the correct relationship?

- A. federal Congress produced regulations
- B. state Legislature produced statutes
- C. Board of Pharmacy produced statutes
- D. administrative agency produced statutes
- E. US Food and Drug Administration produced statutes

17. What makes a drug a drug under Food and Drug Administration law?

- I. manufacturer's preference
- II. drug is a controlled substance under Drug Enforcement Administration law
- III. manufacturer claim that the drug is a compendial article

- A. I only
- B. III only
- C. I and II only
- D. II and III only
- E. I, II and III

18. WAC 246-878-030 Organization and Personnel states that employees with open lesions may not have contact with compounded products, their components or containers.^d A drug compounded by an individual with an apparent illness or open lesion would be

- A. infectious
- B. adulterated
- C. misbranded
- D. contaminated
- E. hazardous

19. The case label on a drug product indicates that the contents are 10 mg per dose while the product bottles are correctly labeled as 5 mg.

Which class recall would likely be initiated by the manufacturer?

- A. 1
- B. 2
- C. 3
- D. 4
- E. 5

^d WAC 246-878-030 (4) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.

Name: _____

Student Number |__|__|__|__|__|__|__|

20. Which of the following schedules contain drugs with high abuse potential, but with legitimate medical uses?

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

21. Which of the following schedule contains drugs with high abuse potential, but with no recognized legitimate medical use?

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

22. Prescriptions for which of the following drugs could **NOT** be refilled after 6 months following the date on which the prescription was originally issued?

- I. morphine (C-II)
- II. Fioricet^e (not scheduled)
- III. Fiorinal^f (C-III)

- A. I only
- B. III only
- C. I and II only
- D. II and III only
- E. I, II and III

23. A patient arrives from another state with a chronic cough. S/he has been using a codeine-containing cough syrup, obtained over-the-counter.

In which of the following do Washington and DEA laws **NOT** differ with regard to OTC sales of C-V drugs?

- A. dose form (e.g., oral solid, liquid)
- B. age of purchaser
- C. frequency of resale
- D. labeling of product delivered to purchaser
- E. concentration of codeine

^e Fioricet contains acetaminophen, butalbital, and caffeine

^f Fiorinal contains aspirin, butalbital, and caffeine

Name: _____

Student Number |__|__|__|__|__|__|__|

24. A heroin abuser is admitted to the hospital for treatment of bacterial endocarditis thought to be secondary to his substance abuse. The hospital has been providing a daily dose of methadone to prevent the patient from suffering withdrawal symptoms.

Upon discharge, the attending physician issues a prescription for a 7-day supply of methadone with the following sig:

methadone 80 mg po qd

May the pharmacy fill this prescription?

- A. the pharmacy may not fill the prescription
 - B. the pharmacy may fill a 3-day supply
 - C. the pharmacy must change the drug to a mixed agonist/antagonist narcotic, such as Stadol
 - D. the pharmacy must transfer the 7-day supply to the physician for dispensing to the patient
 - E. the pharmacy must transfer the 7-day supply to a nursing home, where the patient will stay until subsequent disposition may be determined
25. An otherwise qualified pharmacist who is hearing-impaired applies for a position in a large community hospital pharmacy. Would having other pharmacists handle duties requiring verbal communication (e.g., telephone calls) constitute "reasonable accommodation" under the Americans with Disabilities Act?
- A. true
 - B. false
26. Would the community pharmacy in Forks, which employs only one pharmacist at a time, be required to hire additional staff to assist the hearing-impaired pharmacist described in Question 25?
- A. true
 - B. false
27. Which of the following describes an enforcement action brought by an individual on behalf of the government?
- A. amicus brief action
 - B. qui tam action
 - C. res ipsa loquitur action
 - D. de minimus action
 - E. voir dire action
28. Which of the following describes dispensing a generic drug but billing for a brand name drug?
- A. unbundling
 - B. purposeful fraud
 - C. upcoding
 - D. unwitting fraud
 - E. illegal kickback

Name: _____

Student Number |__|__|__|__|__|__|__|

29. What are your responsibilities as a staff pharmacist should you discover that the hospital pharmacy director is taking home bottles of 500 Vicodin?
- A. confront the director
 - B. notify the US Food and Drug Administration
 - C. notify the Board of Pharmacy
 - D. notify the Drug Enforcement Administration
 - E. notify the local police
30. Which of the following laws would **NOT** be violated if an employee pharmacist diverted controlled substances for personal use from his/her place of employment?
- A. pharmacy practice act
 - B. Uniform Disciplinary Act
 - C. Uniform Controlled Substances Act
 - D. Legend Drug Act
 - E. Occupational Safety and Health Administration Act
31. Which of the following is **NOT** an element of negligence?
- A. a causal relationship
 - B. breach
 - C. duty
 - D. harm
 - E. intent
32. McKee v. American Home Products (1989) found that Washington pharmacists do not have a duty to warn patients of possible hazards associated with prescriptions dispensed to them. What changes have taken place since this decision that render the finding no longer applicable?
- I OBRA90
 - II Board of Pharmacy changes in patient counseling rules
 - III court decisions in other states, e.g, Hooks v. SupreX, Baker v. Arbor Drugs
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III

Name: _____

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

33. An 18 year old female purchases a phenylpropanolamine-containing diet preparation at the recommendation of a pharmacist who is aware that the product's New Drug Application has been withdrawn. The patient asks the pharmacist about the drug's safety and effectiveness, and the patient is sufficiently reassured that she purchases the drug. She uses the product, suffers a stroke, and is considering legal action.

Is the pharmacist protected from liability under RCW 18.64.275⁹?

- A. yes
 - B. no
34. You receive a request from a patient to transfer a prescription from another pharmacy licensed in Washington. Which of the following are **NOT** required to lawfully accomplish the prescription transfer?
- A. write **TRANSFER** on the face of the prescription
 - B. note the date of the last refill on the prescription
 - C. note the number of remaining refills on the prescription
 - D. note the address of the original pharmacy on the prescription
 - E. note the name of the pharmacy technician transferring the prescription on the prescription

⁹ RCW 18.64.275 Limitations on liability for dispensing of prescription. (1) A pharmacist who dispenses a prescription product in the form manufactured by a commercial manufacturer pursuant to a prescription issued by a licensed practitioner is not liable to a person who was injured through the use of the product, based on a claim of the following:

- (a) Strict liability in tort; or
- (b) Implied warranty provisions under the uniform commercial code Title 62A RCW.

(2) The limitation on pharmacist's liability as provided in subsection (1) of this section shall only apply if the pharmacist complies with recordkeeping requirements pursuant to chapters 18.64, 69.41, and 69.50 RCW, and related administrative rules.

(3) A pharmacist who dispenses a prescription product in the form manufactured by a commercial manufacturer issued by a licensed practitioner is liable to the claimant only if the claimant's harm was proximately caused by (a) the negligence of the pharmacist; (b) breach of an express warranty made by the pharmacist; or (c) the intentional misrepresentation of facts about the product by the pharmacist or the intentional concealment of information about the product by the pharmacist. A pharmacist shall not be liable for the product manufacturer's liability except as provided in RCW 7.72.040. [1991 c 189 § 1.]

Name: _____

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

35. A pharmacist is identified as having diverted Dilaudid (C-II) injection for personal use and has refused to surrender his/her license or enter the Washington Recovery Assistance Program for Pharmacists (WRAPP).

What options does the Board of Pharmacy have?

- I. summary suspension of the pharmacists license
 - II. revoke the license
 - III. direct the pharmacist to participate in WRAPP
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III
36. Under Washington law, for how long must a pharmacy retain prescription records?
- A. 1 year
 - B. 2 years
 - C. 3 years
 - D. 4 years
 - E. 5 years
37. What information **MUST** be recorded when making a drug product substitution in Washington?
- A. Drug Code (NDC) number
 - B. the manufacturer's place of business
 - C. FDA's Orange Book -- Therapeutic Equivalence Code
 - D. documentation of the 60% pass-through savings
 - E. manufacturer's name and lot number of the dispensed product
38. From which of the following health care practitioners licensed to practice in Oregon may a Washington pharmacy **NOT** accept a prescription for a legend drug?
- A. advanced registered nurse practitioner
 - B. dentist
 - C. physician
 - D. podiatrist
 - E. veterinarian

Name: _____

Student Number |__|__|__|__|__|__|__|

39. It is policy for Clever-Name Pharmacy^h to have the technician ask any patient with a new prescription if the patient has **EVER** taken the drug before. If the patient responds, "yes", then the pharmacist does not provide counseling.

Is this policy consistent with Washington Board of Pharmacy rules?

- A. yes
- B. no

40. Recall Hypothetical 3: Mr. Melanchol comes to your pharmacy for a prescription for Prozac. You are familiar with this patient and know that he keeps his interactions with people to a minimum and never asks questions. Now you realize that what you thought was introverted behavior may have been depression. You want to take the opportunity to provide support and encouragement to him during counseling, but the phone is ringing off the hook and there are 10 people standing around in the pharmacy counseling alcove....

Which of the following would satisfy Washington patient counseling requirements?

- A. dispense the drug, including the information leaflet printed along with the prescription label
- B. dispense the drug, but call the patient later, providing detailed counseling
- C. call the patient's physician, advising that you were unable to provide counseling
- D. call the community mental health center and ask them to provide the counseling
- E. call the patient's spouse and ask her to provide the counseling

^h Profs. Brushwood and Williams have historically used Acme Pharmacy as the object of their attention in lectures, writings, etc. They have received a complaint from Acme Pharmacy.

Name: _____

Student Number |__|__|__|__|__|__|__|

Name: _____

Student Number |__|__|__|__|__|__|__|

For short answer questions, please be brief. Confine your response to the space provided within the question.

41. You are in the OTC section of a community pharmacy and notice that one of the acetaminophen products is **NOT** packaged with a child resistant container/closure (CRC) system.
- A. Under what circumstances may an over the counter drug be sold without a CRC?
- B. Describe any special labeling required for OTC drugs sold without CRCs.
42. May a pharmacist compound an over-the-counter drug product requested by a patient? Explain your answer.
43. Clever-Name Pharmacy has developed a practice supplying a compounded product that the pharmacist believes to be superior to a conventional treatment for the patient's condition. The pharmacist convinces the patient to switch from the commercial to compounded product. No well-controlled trials have demonstrated the efficacy/safety of the compounded product. Has the pharmacist violated Food and Drug Administration Modernization Act or Washington law regarding compounding? Explain you answer.
44. A pharmacist compounds a cyclosporin eye drop and sells it to his community veterinarian for use at the Veterinary Clinic. The veterinarian uses the drop on a patient and provides the remainder to the animal owner to continue therapy at home. According to Washington compounding law, is this permissible? Explain your answer. (Can be answered with two words)
45. Arizona Ice Tea manufacturers a product line they identify as "Rx Elixirs".ⁱ Has Arizona Ice Tea violated Washington law in naming this product? Explain your answer.

ⁱ For instance: "Rx Stress Relief Elixir - A soothing blend of naturally decaffeinated Black & Green teas. Enhanced with Panax, ginseng, Kava-Kava, Chamomile, and Valerian root. Fortified with Vitamins and minerals"

Name: _____

Student Number |__|__|__|__|__|__|__|

46. What should a pharmacist in the state of Washington do if he/she is presented with a prescription for Emergency Contraception from a member of a medical subspecialty who is operating outside of his/her profession's scope of practice?
47. Explain why ephedrine 25 mg is legend in Washington, but not federally.
48. The Washington Board of Pharmacy requires several steps in initiating a Collaborative Drug Therapy Management Agreement. Name three of these steps.
49. OBRA-90 imposed a counseling requirement for Medicaid patients. If a pharmacist counsels a Medicaid patient thoroughly in accordance with WAC 246-869-220 Patient Counselling Regulation, have they violated OBRA-90?
50. "RCW 71.05.630 Treatment records -- Confidential -- Release. (1) Except as otherwise provided by law, all treatment records shall remain confidential."

For this RCW (not including the STD confidentiality, Mental Health confidentiality, or the Rehabilitation Program confidentiality regulations), give three BRIEF examples of when, in the course of a usual day, this law allows a pharmacist to release otherwise confidential records.

Name: _____

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

Consider the following from Wednesday's San Francisco *Chronicle*.

Suit says Kaiser Permanente pill program jeopardizes patients Kravets D, 12/6/00, Associated Press

(12-06) 19:48 PST SAN FRANCISCO (AP) -- A public interest group sued Kaiser Permanente on Wednesday, accusing the state's largest HMO of jeopardizing patients' health by prescribing double dose-sized pills they must cut in half.

The Superior Court lawsuit covers Kaiser's 6 million California patients but not 2 million others nationally. It asks the court to order a stop to the practice.

"Kaiser's mandatory pill-splitting policy is an outrageous example of an HMO endangering its own patients to increase its own profits," said Arthur Bryant, an attorney for Trial Lawyers for Public Justice, representing six patients and a doctor.

Kaiser said patients were not endangered by the 7-year-old policy and that pill-splitting was voluntary. Of the 1,000 medications it dispenses in pill form, only seven qualify for splitting, said Kaiser spokeswoman Beverly Hayon.

Those are for conditions such as high blood pressure and depression, and include some antibiotics, she said.

"We encourage patients to split those kinds of pills. It is voluntary but at the discretion of the physician," she said.

She said this is done to counter the skyrocketing price of prescription drugs. Drug companies often charge the same for varied doses of medication.

"Why not buy the larger dosage and essentially get two for one?" Hayon asked.

The American Medical Association, the American Society of Consultant Pharmacists and the American Pharmaceutical Association oppose mandatory pill-splitting. Research shows that dosages may vary greatly, resulting in overdosing and underdosing.

Question 1 (2 points): Assume that this action was brought in Washington. Would the pharmacy's liability be any different if the pharmacy split the pill rather than the patient? Why?

Question 2 (8 points) Apply normative ethics principles/theories in evaluating the pill splitting case. Please underline each principle/theory so I can find them, and be sure to explain each principle/theory in the context of the case.