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Pharmacy 543 – Pharmacy Laws & Ethics
FINAL EXAMINATION
December 13, 2002

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 you name and student number (both characters and bubbles). **Select the best answer from the available choices.** 40 points. Questions 41-55 are short answer. Please limit your responses to the space provided for each question. 30 points. Question 56 is an ethics & law question. 10 points. Exam total: 80 points.

Legibility: please verify that your name and student number are legible and correct and that your answers are legible.

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.

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** are presented in **BOLD, ALL-CAPS**.

Multiple Choice Questions

1. Which of the following is **NOT** one of the powers and duties assigned to the Board of Pharmacy?

   a. Regulate the practice of pharmacy
   b. Enforce the laws assigned to it
   c. Establish qualifications for licensing of pharmacists
   d. Conducting disciplinary hearings
   e. Regulating the distribution of drugs by all health professionals

2. For which of the following violations are you **LEAST** likely to have your pharmacist license revoked?

   a. Obtaining the license by fraud
   b. Conviction of a felony related to pharmacy
   c. Selling drugs without a prescription
   d. Permitting a technician to function unsupervised
   e. Committing a serious dispensing error

3. Which of the following are excluded from the definition of "drug" or "device" in the Pharmacy Act (18.64RCW)?

I. Surgical Instruments
II. Gas and Oxygen therapy equipment
III. Medicated animal feed

a. I Only
b. III Only
c. I and II only
d. II and III only
e. only

4. Which of the following firms does the Board of Pharmacy license?

I. Hospital pharmacies
II. Shopkeepers
III. Itinerant Vendors

a. I Only
b. III Only
c. I and II only
d. II and III only
e. I, II and III only

5. Currently, you may not obtain a pharmacist license by reciprocity in the State of _____.

a. Arkansas
b. California
c. Florida
d. Hawaii
e. New York

6. For how many years must pharmacy records must be maintained?

a. 1 year
b. 2 years
c. 3 years
d. 4 years
e. 5 years

7. In Washington, the maximum number of pharmacy technicians that one pharmacist may supervise at one time is:

a. One
b. Two
c. Three
d. Four
e. Five

8. Which of the following drugs may be dispensed in full case lots by a Medicare-approved kidney dialysis center?

I. Heparin injection
II. Sodium Chloride injection
III. Epogen® (Epoetin alfa)

a. I only
b. III Only
c. I and II only
d. II and III only
e. I, II and III only

9. When a pharmacist dispenses a manufacturer prepared product and the patient is harmed, the pharmacist may be held liable for the injury under which of the following conditions?

I. The pharmacist was negligent
II. The pharmacist made an express warranty that was breached
III. The pharmacist intentionally misrepresented facts about the product

a. I only
b. III Only
c. I and II only
d. II and III only
e. I, II and III only

10. Which of the following is **NOT** a violation of the Uniform Disciplinary Act for a pharmacist?

a. False advertising
b. Incompetence involving injury to a patient
c. Failing to report a case of child abuse
d. Conviction of a misdemeanor
e. Failure to cooperate with a Board investigation

11. In Washington, a physician or other prescriber may own a pharmacy under which of the following conditions?

I. The ownership is disclosed to the patients
II. Patients are informed about alternative pharmacies
III. The pharmacy charges 60% less than the closest pharmacy

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III only

12. In a Pharmacy Board disciplinary hearing a pharmacist may **NOT** successfully assert his/her Fifth Amendment Right to refuse to testify in order to avoid self incrimination.

a. True
b. False

13. Which of the following laws contain the most comprehensive listing of persons who may prescribe, dispense or administer drugs in Washington?

a. Pharmacy Practice Act
b. State Food Drug and Cosmetic Act
c. Federal Food Drug and Cosmetic Act
d. State Controlled Substance Act
e. State Legend Drug Act

14. Under current Washington law which of the following formats is required to assure that the pharmacist knows when to substitute a therapeutically equivalent generic drug?

a. "Dispense as Written" on the right hand side and "Substitution Permitted" on the left hand side.
b. "Substitution Permitted" on the right hand side and "Dispense as Written" on the left hand side.
c. A or B – it does not matter which side as long as the words are correct
d. A check box with a caption stating "Dispense as Written"
e. A check box with a caption stating "Substitution Permitted"

15. When a pharmacist dispenses a therapeutically equivalent generic drug pursuant to the prescriber's instructions, how much of the savings between the brand name product and the generic must the pharmacist pass on to the patient?

a. 20 percent
b. 30 percent
c. 40 percent
d. 50 percent
e. 60 percent

16. Which of the following drugs is **EXEMPT** from the Child-resistant packaging requirement?

a. A package of 12 Aspirin 325 mg.
b. A bottle of 10 Amoxicillin capsules 250 mg
c. A bottle of 25 Sublingual nitroglycerin
d. A bottle of 100 Nitrobid Capsules
e. A bottle of 100 Conjugated Estrogen tablets 0.625 mg

17. Which of the following is **NOT** required to be packaged in a tamper-resistant package for over the counter sale?

a. Insulin injection, 10 mL
b. Aspirin tablets 325 mg, No. 100
c. Acetaminophen tablets 325 mg No. 50
d. Benadryl capsules 25 mg No. 10
e. Pseudoephedrine tablets 30 mg No. 30

18. Under **EITHER** the Prescription Drug Marketing Act of 1987 or the Robinson-Patman Antitrust law which of the following would **NOT** be considered to be for a hospital's "own use"?

a. Dispensing the drugs for use by hospital inpatients
b. Dispensing the drugs for patients when they are discharged
c. Dispensing the drugs to refill discharged patients' prescriptions
d. Dispensing the drugs to hospital staff family members
e. Dispensing the drugs to hospital staff

19. In Thompson v. Western States, the Supreme Court found that provisions of section 503A of Food and Drug Administration Modernization Act of 1997 (21 USCS 353a), restricting advertising or promoting of compounded drugs, violated First Amendment's free speech guarantees. WAC 246-878-020 (4) states, in part,

Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not solicit business (e.g., promote, advertise, or use salespersons) to compound specific drug products.

What are the practical consequences of the Supreme Court ruling in Washington?

I. Washington pharmacies may now advertise their specific drug compounding services because the WAC is unenforceable.
II. Washington law is more restrictive so nothing changes
III. It will be necessary for the Washington legislature to pass legislation to resolve this mess

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III only

20. In Washington, what is the standard of proof required for an administrative agency in a disciplinary action?

a. Preponderance of the evidence (more likely than not)
b. Clear, cogent and convincing evidence (much more likely than not)

21. The US Food and Drug Administration has issued a Compliance Policy Guide entitled Sec. 460.200 Pharmacy Compounding in June 2002, including its publication in the Federal Register. One of the provisions of the CPG is that, in their compounding activities, pharmacies may not use "... drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility". If you were providing compounded drug products and did not comply with this aspect of the CPG, must you now change your practices to comply?

a. Yes
b. No

22. Under CPG 460.200 FDA could take regulatory action against pharmacies that compound "drugs for third parties who resell to individual patients" or offer "compounded drug products at wholesale to other state licensed persons or commercial entities for resale". Is the CPG more restrictive than Washington law?

a. Yes
b. No

23. 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. the Attorney General must intervene for future disciplinary proceedings
b. the Board must go to court for further disciplinary proceedings
c. the Drug Enforcement Administration could revoke the pharmacist's license
d. the pharmacist is not obliged to respond to the Statement of Charges
e. the Board may proceed to formal discipline

24. 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 **NOT** participate in the ski plan?

I. physicians
II. dentists
III. registered pharmacists

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III only

25. Which of the following is the correct relationship?

I. federal Congress produces regulations
II. state Legislature produces regulations
III. Board of Pharmacy produces regulations

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III only

26. WAC 246-878-030 Organization and Personnel states that employees with open lesions may not have contact with compounded products, their components or containers. A violation that the Board of Pharmacy could allege for 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

27. 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 differ with regard to OTC sales of C-V drugs?

I. dose form (e.g., oral solid, liquid)
II. age of purchaser
III. frequency of resale

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III only

28. Under Washington law, if a generic drug is legally substituted for a brand-named drug and a patient sues for injury believed to be caused by the generic drug, has the pharmacist assumed a greater liability by dispensing the generic drug?

a. yes
b. no

29. What information **MUST** be recorded when making a drug product substitution in Washington?

a. Manufacturer or distributor of the drug product actually dispensed
b. The national drug code number of the drug product actually dispensed
c. The short name code or trade name of the drug product actually dispensed
d. Any of the above
e. None of the above

30. A patient is visiting Washington from British Columbia and requests a product available there known as a "222".[1] You explain that no comparable product is available in the US, but suggest that the patient purchase some Excedrin Extra Strength[2] and some C-V codeine cough syrup, and indicate that the combination is about the same as "222's". You provide the appropriate conversions, point out the differences, have the patient sign the narcotic book. You are:

I. A prince[ss] among pharmacists for having provided such superb pharmaceutical care.
II. In violation of Washington rules by dispensing a cough syrup for an unlabeled use.
III. Subject to disciplinary action for violation of controlled substances rules.

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III only

31. Female employees in a pharmacy that compounds progesterone suppositories complain of menstrual irregularities. With which agency should a complaint be filed?

I. Board of Pharmacy
II. US Food and Drug Administration
III. Washington Industrial Safety and Health Administration

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III only

32. Which of the following persons may **NOT** authorize the dispensing of a prescription in a non-child resistant container?

I. The prescriber
II. The patient
III. The pharmacist

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III

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[1] 222® A.S.A. Brand Name (Aspirin or Acetylsalicylic Acid) w/ 8 mg's Codeine and 15 mg's Caffeine

[2] Acetaminophen 250 mg, Aspirin 250 mg, Caffeine 65 mg per dose

33. When a drug is labeled with an expiration of "November 2004" what day of the month does the drug expire?

a. November 1
b. November 7
c. November 15
d. November 30
e. December 1

34. In advance directives and end-of-life decision-making, one of the deciding elements is whether the patient's interests outweigh countervailing state interests. What are the state's interests?

I. preservation of life and prevention of suicide
II. protection of the interests of innocent third parties
III. integrity of the medical profession

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III only

35. Select examples of "unwitting" Medicaid/Medicare fraud

I. Prescriptions billed but not picked up
II. Price database and algorithm errors
III. Up-coding – billing for a higher code than the service provided

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III only

36. 4. What is a "qui tam" action?

a. Where something is given or taken in return for something else
b. Where a private party, on behalf of the United States, can sue persons who defraud the federal government
c. Where an injury is due to the defendant's negligence when that which caused it was under his or her control or management and the injury would not have happened had proper management been observed
d. Where laws on which a court rested a previous decision are authoritative in all future cases in which the facts are substantially the same

37. How many hours of continuing education credit must a Washington pharmacist obtain each year, in order to renew his/her pharmacist license?

a. 7.5 hours
b. 10 hours
c. 12 hours
d. 15 hours
e. 20 hours

38. If the Board of Pharmacy determines that a pharmacist has committed an act of unprofessional conduct, which of the following actions may the Board take against the pharmacist's license?

I. Order the pharmacist to pay a fine.
II. Suspend the license.
III. Revoke the license

a. I only
b. III only
c. I and II only
d. II and III only
e. I, II and III

39. You fill a Valium 2mg [benzodiazepine anxiolytic] prescription with Valium 10mg. The patient realizes the mistake, does not take any of the pills and returns the prescription for the correct Valium 2 mg the next day. Are you at risk for a negligence suit?

a. Yes, you have a duty to fill the correct drug and strength and you breached that duty.
b. Yes, as long as she files the suit within 2 years.
c. No, the patient was not injured as a result of the mistake
d. Yes, you violated Drug Enforcement Administration regulations

40. How many interns may a pharmacist preceptor supervise if the interns are dispensing?

a. 1
b. 2
c. 3
d. 4
e. 5

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SHORT ANSWER – Please confine your response to the space provided and write clearly.

Please complete the following grid. Indicate which profession may prescribe the indicated drugs in Washington, and any requirements beyond licensure and Drug Enforcement Administration registration, necessary for prescriptive authority. 20 points.

Question	Profession	May Prescribe	Yes|No	Additional Requirements for Prescriptive Authority
Example	Pharmacist	C-II pain med	Yes	Collaborative Drug Therapy Agreement
41.	ARNP			
42.		Legend antiinflammatory		
44.	MD | DO	Accutane (isotretinoin) Capsules, 10 mg[3]		
48.	DPM	Oxycontin (oxycodone HCl) Controlled Release Tablets, C-II		

51. Hepler and Strand have defined "pharmaceutical care" as "the responsible provision of drug therapy by a pharmacist for the purpose of achieving specific outcomes that improve a patient's quality of life".[4] List the three key concepts identified by Dean Fassett, match them with normative ethics principles discussed in class, and explain their significance in pharmaceutical care. (3 points)

[3]The package insert states: Accutane must be prescribed under the System to Manage Accutane Related Teratogenicity (S.M.A.R.T.).

[4] Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm. 1990 Mar;47(3):533-43.

52. You receive a prescription for a patient in a skilled nursing facility who has been abusing acetaminophen. The patient becomes abusive when his bedside supply is taken away, but routinely takes sufficient doses when provided ad libitum (at one's pleasure) that you are concerned about an overdose. The prescriber proposes that you provide capsules labeled "acetaminophen 325 mg" and a sig "Take one or two capsules every four hours as needed for pain" but containing something like ascorbic acid or lactose.

What legal problems do you see with this proposal? (A one-word answer is possible)[1 point]

53. A pharmacist hears that you have taken this class and wants you to explain the difference between compounding and manufacturing. List four major conditions or situations under which a compounded product, such as progesterone vaginal suppositories, could be considered to be manufactured, and thus subject to the GMP (current Good Manufacturing Practices) regulations of the federal Food, Drug and Cosmetic Act. [4 points]

b.

c.

54. On December 3, 2002 the federal Department of Health and Human Services issued a guidance document associated with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) entitled Standards for Privacy of Individually Identifiable Health Information. [45 CFR Parts 160 and 164] The following is excerpted from the Q&A section of the guidance.

Q: Can a patient have a friend or family member pick up a prescription for her?

A: Yes. A pharmacist may use professional judgment and experience with common practice to make reasonable inferences of the patient's best interest in allowing a person, other that the patient, to pick up a prescription. See 45 CFR 164.510(b).[5] For example, the fact that a relative or friend arrives at a pharmacy and asks to pick up a specific prescription for an individual effectively verifies that he or she is involved in the individual's care, and the HIPAA Privacy Rule allows the pharmacist to give the filled prescription to the relative or friend. The individual does not need to provide the pharmacist with the names of such persons in advance.

a. A prescription is presented that obviously calls for a course of therapy for a sexually-transmitted disease. The prescription identifies two individuals (Alpha and Beta) with different last names, and birth dates that would make them "minors" in Washington. Alpha wants to pick up both courses of therapy, pay cash, and indicates that Beta is "too embarrassed" to come into the pharmacy. Continues next page ...

[5]45CFR § 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object. A covered entity may use or disclose protected health information without the written consent or authorization of the individual as described by §§ 164.506 and 164.508, respectively, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the disclosure in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section....

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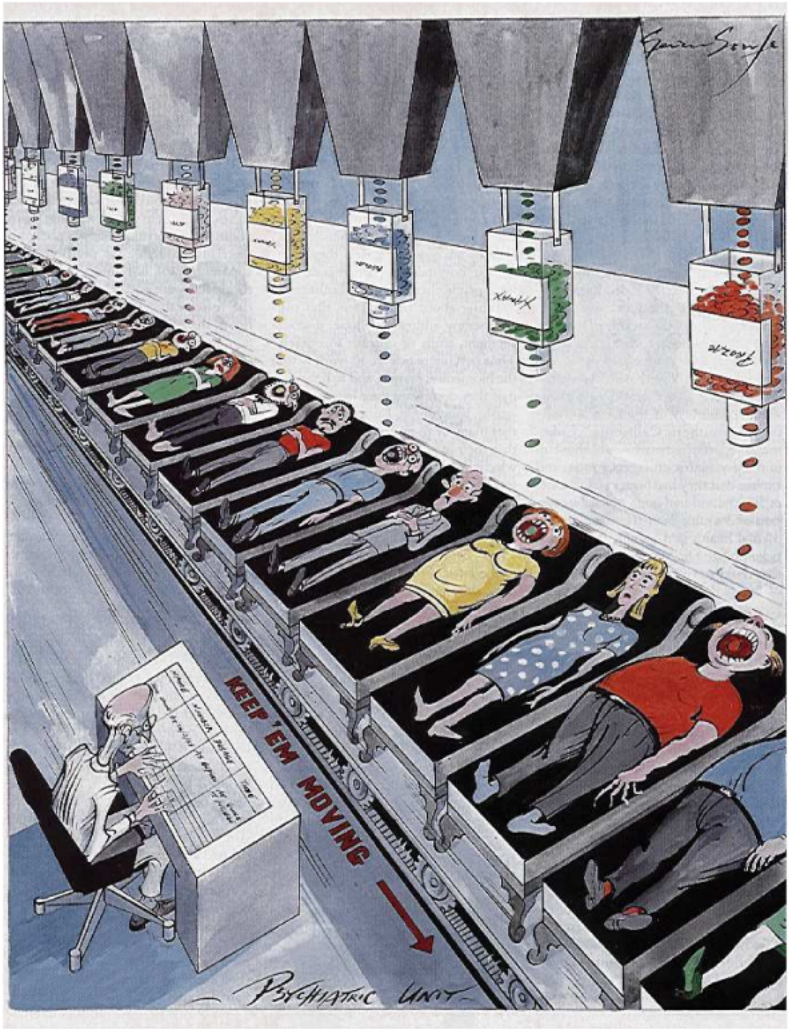
What steps should you take in "delivering" the prescriptions? Assume that the prescription "dispensing" has been accomplished correctly. (1 point)

b. Is Washington law in conflict with HIPAA in this case? Explain. (1 point)



From The New Yorker

55. ROBERT L. COTTAM vs. CVS PHARMACY. SJC-08497 SUPREME JUDICIAL COURT OF MASSACHUSETTS 436 Mass. 316; 764 N.E.2nd 814; 2002 Mass. Abstracted from Lexis-Nexis: We address the issue whether a pharmacy has a duty to warn its customers of the potential side effects of the prescription drugs it dispenses. The plaintiff, Robert L. Cottam, suffered permanent injury when he failed to seek timely medical attention for a [rare] side effect he experienced after taking the prescription drug Trazodone. He had obtained the drug at a CVS Pharmacy (CVS). Cottam filed a complaint in the Superior Court alleging that CVS was negligent in failing to warn him of the side effect and its seriousness. Cottam also claimed negligence in failing to warn by his prescribing physician, Dr. Farrokh Khajavi, and by his therapist, Sheila McHatton. In its answer, CVS denied any negligence and asserted a number of affirmative defenses, including Cottam's own contributory negligence. Both Dr. Khajavi and McHatton settled with Cottam before trial. A jury found CVS fifty-one per cent negligent and Cottam forty-nine per cent negligent, and awarded Cottam damages (after reduction for comparative negligence) in the amount of $ 357,000. Brushwood[6]comments, "... the court held that a Massachusetts pharmacist has no general duty to warn patients of a drug's adverse effects. However, when a pharmacy provides a detailed list of warnings to the patient or by way of advertising promises to provide patients with information, the pharmacy may thereby undertake a duty to provide complete warnings and information."

a. If this had happened in Washington, what would be the pharmacist's duty to warn? (4 points)

b. Evaluate the ethics of the case, next page. (6 points)

[6]Brushwood DB and Kimberlin CL. Voluntary undertaking rule and duty to warn. Am J Healt-Syst Pharm 2002;59:1867

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i. Perspective / why selected
ii. Beneficence
iii. Nonmaleficence
iv. Autonomy
v. Justice
vi. Virtue

SA |__| E |__| Total |___|