Pharmacy 543 – Pharmacy Laws & Ethics Print Name_____
FINAL EXAMINATION
December 14, 2001 Student Number: |___|___|___|___|___|___|___|___|

Questions 1-4# 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.

There are 10 short answer questions and one ethics essay. 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 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 question pages unless you believe that a question is technically flawed (see below).

Grading: multiple choice questions are 1 point each (total 40 points); short answer questions are 4 points each (total 40 points) and the ethics question is 20 points. Exam total is 100 points.

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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1. Under Washington law, compounding is defined as:

   a. the act of combining two or more ingredients in the preparation of a prescription
   b. those activities related to the interpretation and preparation of a prescription and its delivery to a patient
   c. production, preparation, propagation, compounding or processing of a drug or other substance or device or the packaging or repackaging of such substance or device
   d. a. and b.
   e. a., b, and c.

2. Under federal law, a process would be manufacturing as distinguished from compounding when someone engages in

   a. repackaging a drug for resale
   b. changing the container, wrapper or labeling of any drug package to further the distribution of the drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer
   c. compounding commercially available drug products
   d. a. and b.
   e. a., b, and c.

3. The local veterinarian is interested in your preparing various drug products for use in treating animals brought to her for treatment. She is particularly keen about the preparation of topicals for the delivery of drugs to cats, and has the scars to prove it. Can you compound topicals as described and sell them to the vet, knowing that the vet will dispense the topical to the animal's owner for home application?

   a. Yes
   b. No

4. A parent complains that her kid routinely spits up the OTC pediatric cough-cold product recommended on TV. You know the one, where the actor kid runs all over the house trying to hide from the drug-toting mother. She would like you to make something different that the her kid will like. She indicates that she is new in town and that the pediatrician in her previous home town routinely called in an order to the pharmacy. She hasn't been able to get an appointment with the local pediatrician. Which of the following is the most plausible?

   a. You consult your references, find that chocolate covers a lot of bad tastes, mix the cough-cold product with Hershey's syrup 1:1 and tell mom to double the dose. And to shake well.
   b. You tell the mom that doing what she is asking you to do would technically make the compounded product misbranded or adulterated (but you can't remember which).
   c. You tell the mom that doing what she asks would make you liable for any harm that may befall the kid.
   d. b. and c.
   e. None of the above

5. What is the status of the Food and Drug Administration Modernization Act of 1997 with regard to pharmacist compounding.

   a. Only the prohibitions against advertising of specific products have been rescinded, applicable only in the jurisdiction of the 9th Circuit Court of Appeals
   b. The entire section of FDAMA97 regarding pharmacist compounding has been vacated by the 9th Circuit Court of Appeals
   c. The FDA has appealed the 9th Circuit's ruling to the Supreme Court
   d. a. and c.
   e. b. and c.

6. Has the change in legal status of FDAMA97 with regard to pharmacist compounding changed the legality of advertising for compounding specific products in Washington?

   a. Yes
   b. No

7. Recall that Ms. Creamcheese is a 17 year old student at Roosevelt, etc. She comes to the pharmacy with her dad for a prescription for azithromycin 1gm now. Dad hands the prescription in and says how impressed he is that there are new antibiotics that can cure a sinus infection all in one dose.

   When it's time to dispense the medication, Dad is still there, joined by Ms. C, who looks apprehensive. What are your counseling responsibilities? Assume that you have explored allergies, etc., and that you are aware of no reasons preventing Ms. C from taking the azithromycin.

   What should you do? Select the most plausible answer.

   a. The 8 things specified in OBRA90
   b. Orally explain to Ms. C the directions for use and any additional information
   c. You bring Ms. C a large glass of water, and tell her to take the azithromycin, explaining common side effects ...
   d. OBRA90 and Washington law are essentially the same
   e. None of the above

8. Joe has been waiting in line for some time to pick up his prescription for Embarrassing Drug. You are about to start your counseling routine when Joe tells you that he has heard it all before, and, besides, he would prefer if the rest of the store not know about his condition. Knowing Washington law regarding patient counseling as you do, you should do which of the following.

   a. Give Joe the prescription, wish him well and move on to the next patient
   b. Make a notation on the prescription that Joe declined counseling
   c. Tell Joe that the Embarrassing Drug is dangerous and he should listen to your routine
   d. Include the computer printout of instructions in the bag with Joe's Embarrassing Drug. Providing written information is sufficient.

9. Under current Washington law, counseling must be provided to patients receiving refills of legend drugs prescribed for chronic conditions.

   a. Counseling for refills is only necessary when there is a obvious compliance (regimen adherence) problem and upon patient request
   b. In those instances where it is appropriate, the pharmacist shall communicate with the patient adverse effects, over or under utilization, or drug interactions with respect to the use of medications
   c. The pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient from the prescription
   d. b. and c.
   e. None of the above

10. Which federal agency is (agencies are) responsible for promulgating regulations under the Poison Prevention Packaging Act

    a. Environmental Protection Agency
    b. Consumer Product Safety Commission
    c. US Food and Drug Administration
    d. a. and b.
    e. a., b. and c.

11. Which of the following are **FALSE** regarding the requirement for child-resistant closures (CRCs)?

    a. Nitroglycerin sublingual tables must **NOT** be repackaged in a container with a CRC
    b. Ferrous sulfate 300 mg tablets do **NOT** require CRCs because they are dietary supplements, not drugs
    c. Oral contraceptives must be dispensed with CRCs if removed from memory packaging
    d. A specified packaging configuration of OTC drugs need **NOT** have CRCs if labeled for "households without children"
    e. Any unit dose potassium supplement containing no more than 50 mEq potassium per dose does **NOT** require CRCs

12. The Washington implementation of the Legend Drug Act permits the Board of Pharmacy to establish legend status for drugs based upon toxicity or other potentiality for harmful effect of the drug, the method of its use, and any collateral safeguards necessary to its use. The board shall classify a drug as a legend drug where these considerations indicate the drug is not safe for use except under the supervision of a practitioner. Could the Board of Pharmacy assign legend drug status to a substance that the US FDA has **NOT** so identified?

    a. Yes
    b. No

13. Under RCW 69.41.075, the Board of Pharmacy may select a commercially available listing of legend drugs. The currently selected resource is:

    a. The Red Book
    b. The Orange Book
    c. The Yellow Book
    d. The Green Book
    e. The Blue Book

14. Washington law permits substitution generic substitution when authorized by the prescriber. Among the resources upon which a pharmacist may rely in selecting therapeutically equivalent products is the FDA's

    a. The Red Book
    b. The Orange Book
    c. The Yellow Book
    d. The Green Book
    e. The Coloring Book

15. In filling an out-of-state prescription where generic substitution is an option but the source state does **NOT** require a two-line prescription indicating generic substitution authorization, the pharmacist may substitute a therapeutically equivalent generic drug unless otherwise instructed by the practitioner through the use of the words "dispense as written", words of similar meaning, or some other indication.

    a. True
    b. False

16. In establishing negligence, the plaintiff must establish duty, breach, causation and harm. The traditional view of negligence in pharmacist mis-fills focuses on the legal duty to correctly fill a prescription. This traditional view requires that a pharmacist refuse to fill or seek to correct a prescription that contains errors or is illegible.

    a. True
    b. False

17. Which of the following are factors in causing prescription errors?

    a. Illegible handwriting
    b. Poorly transmitted verbal orders
    c. Inadequate staffing
    d. a. and b.
    e. a., b. and c.

18. Which of the following should **NOT** be done when a patient confronts the pharmacist about a prescription error?

    a. Have the technician deal with the patient
    b. Blame the patient
    c. Apologize for the error
    d. a. and b.
    e. a., b. and c.

19. In order to meet federal standards for child resistant packaging a manufacturer must test the container on which of the following groups?

    a. Senior adults over fifty years old
    b. Two year old children
    c. Five year old children
    d. a. and b.
    e. a., b. and c.

20. Which of the following drugs need **NOT** be dispensed in a child resistant container?

    a. Sublingual nitroglycerin tablets
    b. Birth control pills in memory packages
    c. Isosorbide oral tablets 40 mg
    d. a. and b.
    e. a., b. and c.

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

    a. The prescriber
    b. The patient
    c. The pharmacist
    d. a. and b.
    e. a., b. and c.

22. If a prescriber in this State writes the brand name on a prescription, how does a prescriber indicate to the pharmacist that a generic product is to be dispensed?

    a. By signing the prescription on the "Dispense As Written" line
    b. By checking a box that says "Generic OK".
    c. By signing on the "Substitution Permitted" line.
    d. a. and b.
    e. a., b. and c.

23. When a drug is marked 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

24. According to the Robinson-Patman Act as interpreted in Abbott Labs et al. vs. Portland Retail Druggist Association (425 US 1 (1976)), a hospital's "own use" purposes may **NOT** include prescription drugs that it purchased at a special hospital discount for which of the following purposes?

    a. Inpatients of the hospital
    b. Outpatients of the hospital
    c. Hospital employee prescriptions
    d. Hospital discharge prescriptions
    e. Sales to physician staff members for dispensing to their patients

25. Which of the following drug recalls is the most serious?

    a. Class I
    b. Class II
    c. Class III
    d. Class IV
    e. Class V

26. For which of the following drugs must you provide an exact count when you perform your required DEA inventory?

    a. A bottle containing 853 Morphine Sulfate 10 mg Tablets (C-II)
    b. A bottle containing 4,730 Tylenol with Codeine 30 mg Tablets (C-III)
    c. A bottle containing 527 Meprobamate Tablets
    d. a. and b.
    e. a., b. and c.

27. Which of the following is **NOT** a requirement for a controlled substance prescription to be dispensed to a patient.

    a. The prescriber must be registered by the DEA
    b. The prescriber must be licensed or exempt from state licensure
    c. The drug must be within the prescriber's scope of practice
    d. The prescription must be written
    e. The prescription must be for a legitimate medical purpose

28. The pharmacist receives a prescription for 30 Morphine Sulfate Tablets 10 mg but has only 15 tablets in stock, what is the longest time period that the pharmacist has to supply the remaining tablets?

    a. Within 24 hours
    b. Within 48 hours
    c. Within 72 hours
    d. Within 96 hours
    e. Within 120 hours

29. If a Schedule II prescription is phoned in as an emergency, which of the following conditions must be met?

    a. Immediate administration of this drug is necessary
    b. No alternative treatment is available
    c. It is **NOT** reasonably possible for the prescriber to provide a written prescription
    d. a. and b.
    e. a., b. and c.

30. When authorized by a prescriber, what is the maximum number of times that a Schedule III or IV controlled substance may be refilled ?

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

31. When authorized by a prescriber, what is the maximum number of months from the date the prescription was issued that a Schedule III or IV controlled substance may be refilled?

    a. 3 months
    b. 6 months
    c. 12 months
    d. 18 months
    e. 24 months

32. What is the maximum amount of a Schedule V codeine containing cough syrup that may be sold over-the-counter to any person at one time?

    a. 60 mL
    b. 90 mL
    c. 120 mL
    d. 180 mL
    e. 240 mL

33. How many hours of continuing pharmaceutical education must a pharmacist complete each year in order to renew his/her pharmacist license?

    a. 5 hours
    b. 10 hours
    c. 12 hours
    d. 15 hours
    e. 20 hours

34. What controlled substance is authorized for Humane societies and animal control agencies to use for the euthanasia of injured or unwanted animals?

    a. Pentobarbital
    b. Morphine
    c. Potassium Chloride
    d. Phenobarbital
    e. Diazepam

35. A pharmacist receives a Schedule II prescription for Morphine Sulfate 10 mg No. 600 tablets. The prescription states that it is for a terminally ill patient. Assuming that the pharmacist dispenses fifty tablets once each week, how many times may the pharmacist issue partial fills on this prescription?

    a. 0
    b. 5
    c. 10
    d. 12
    e. 15

36. Project 2 years and 3 months from today. You've passed the NAPLEX and MPJE, completed your orientation at CPLS[1] Pharmacies, and have driven to your first work assignment in your new BMW (part of the signing bonus). You spend a busy morning and when you finally get a break, you realize that you've not been asked to counsel anyone, despite the many patients that have picked up prescriptions. When you ask the technician, he indicates that it is CPLS policy to ask the patient if they want to be counseled and, if the patient says "yes", indicate with body language and heavy sighs that they will have to wait. You should:

    a. Keep you mouth shut, because you are on probation and you really like the BMW
    b. Explain Washington law to the technician and ask that he behave accordingly
    c. Complain to CPLS management
    d. Complain to the Board of Pharmacy, because the whistle blower protections will allow you to keep the BMW
    e. Quit, and kiss the BMW goodby

37. The Washington Administrative Code :

    a. Is passed by the Washington State legislature
    b. Takes effect after being signed by the governor
    c. Is promulgated by the appropriate state agency
    d. Is promulgated by federal administrative agencies
    e. Is the same as an RCW

[1]CPLS = Count, pour, lick & stick

38. Which of the following does the Civil Rights Act of 1964 **NOT** address?

    a. Protects race, color, gender, national origin, religion
    b. Covers hiring and firing practices
    c. Covers wages and conditions of employment
    d. Protects against discrimination during pregnancy
    e. Prohibits discrimination against Americans with disabilities

39. Which of the following would **NOT** help a pharmacist prevent medication errors:

    a. Talk with patients about their medications
    b. Involve patients in verifying and clarifying allergies
    c. Give patients written and verbal information about their prescriptions
    d. Memorize patient profiles
    e. Listen to your patients

40. If a family member of your patient were to ask you each of the following health questions about that patient, which of the following would you be able to disclose?

    a. Gender, Date of Birth
    b. That the patient is in an Alcohol Rehabilitative Facility
    c. That the patient has previously had mental health treatment
    d. That the patient had treatment for an STD when he/she was a minor
    e. None of the above information must be confidential

SHORT ANSWER – Please confine your answer to the space provided. 4 points each

41. Recall Ms. Cheesecake. Under what circumstances could you release her medication profile to Dad? Would it make any difference if Ms. C was being treated for a sexually transmitted. disease other than AIDS?

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42. Please complete the following grid.

Indicate which profession may prescribe Schedule II drugs in Washington, and any requirements beyond licensure and Drug Enforcement Administration registration, necessary for prescriptive authority.

Profession	May Prescribe a Schedule II	Additional Requirements for Prescriptive Authority
Example Pharmacist	Yes	Collaborative drug therapy agreement
Advanced Registered Nurse Practitioner		
Doctor of Dental Surgery / Medicine		
Naturopathic Doctor		

43. Daniels in "Normal Functioning and Treatment-Enhancement Distinction"[2] contrasts "medical necessity"and "treatment-enhancement".

    a. Define "medical necessity"

    b. Define and give an example of the "treatment-enhancement distinction"

    c. Give an example of a justice problem arising from the "treatment-enhancement distinction"

44. The focus of the Belmont Report[3] was to "identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles." One of the major contributions of the Commission was to distinguish between "biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other". Explain this distinction.

[2]Daniels N. Cambridge Quarterly of Healthcare Ethics 2000;9:309

[3]The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 197

45. Pharmacies in Washington must have two things to comply with poison control requirements. They are:

    a.

    b.

46. One of the prescription vial manufacturers advertises that its reversible "vial system meets all USP requirements, and when the closure is properly applied in the child-resistant position, it meets the U.S. Consumer Product Safety Commission regulations for child-resistant, senior-friendly packaging." In dispensing legend drugs in Washington, what must be done if a reversible-cap container-closure system is used?

47. For the Board of Pharmacy to take action against a licensee, the alleged violation must be within the Board's jurisdiction. Where is the Board's jurisdiction defined? If revealing a complainant's identity is necessary for a Board investigation, what must happen if the complainant insists on confidentiality?

    a. Jurisdiction

    b. Confidentiality

48. Under Washington's Administrative Procedures Act (APA), an agency's actions may be invalidated through judicial review under 4 conditions. Name two of them. Hint: one was mentioned during student presentations.

    a.

    b.

49. Chiu *et al*. indicate that in "oriental culture, it is common practice not to disclose the truth of the illness, especially from the terminal cancer patient".[4] Contrast their perspective with the "normative" ethics discussed in class.

Select a perspective and one of the normative ethical principals and contrast "truth telling" from a western and Asian perspective.

Perspective:

Normative Ethical Principle(circle one): non-maleficence, beneficence, autonomy, justice, virtue

Contrast:

50. In an article in the current issue of *JAMA*, researchers with the Agency for Healthcare Research and Quality report that inappropriate use of medications by community-dwelling elderly occurs 21.3% of the time.[5] Their main outcome measure was prevalence of use of 33 potentially inappropriate medications. In their study, 2.6% of elderly patients used at least 1 of eleven drugs that should always be avoided by elderly patients [barbiturates, flurazepam, meprobamate, chlorpropamide, meperidine, pentazocine, trimethobenzamide, belladonna alkaloids, dicyclomine, hyoscyamine, propanteline]. (20 points)

a. In Washington, do pharmacists have a legal obligation to intercede[6] to prevent exposure of the elderly to these drugs? Explain. (5 points)

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[4]Chiu et al. Ethical dilemmas in palliative care: a study in Taiwan. J Med Ethics 2000;26:353–357

[5]Zhan C, et al. Potentially inappropriate medication use in community-dwelling elderly. JAMA 2001;286:2823.

[6]in·ter·cede, v.i., -ced·ed, -ced·ing.
1. to act or interpose in behalf of someone in difficulty or trouble, as by pleading or petition: to intercede with the governor for a condemned man.
2. to attempt to reconcile differences between two people or groups; mediate.

b. Take society's perspective and evaluate the ethics of a drug distribution system that evidently routinely exposes elderly patients to known hazards. Be sure to provide a contextually appropriate explanation of each of the terms. (15 points)

- beneficence

- nonmaleficence

- autonomy

- justice

- virtue

Have a safe, happy & restful Holiday