PHARMACY 543 – PHARMACY LAWS & ETHICS **PRINT** Name: _____
MIDTERM EXAMINATION 2
November 16, 2001 Student Number:|__|__|__|__|__|__|__|__|__|

Questions 1-30 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 5 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 30 points); short answer questions are 2 points each (total 10 points) and the ethics question is 10 points. Exam total is 50 points.

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

So as to not confuse you, terms like **NOT, TRUE, FALSE** are presented in bold, all-caps.

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1. Under Title 21 Part 1307, if a pharmacy sells more than ___ percent of total controlled substances dosage procured to another practitioner in a single calendar year, the pharmacy must register as a wholesaler.

   a. 1 percent
   b. 5 percent
   c. 10 percent
   d. 20 percent
   e. 25 percent

2. Morphine, meperidine, and a variety of other controlled substances are manufactured in "Tubex" or "Carpuject" (pre-filled syringe) configuration. If a chart order was written for a 50 mg dose and only 100 mg pre-filled syringes were available, a nurse could "waste" the excess 50 mgs so long as the "wasting" is witnessed and documented.

   a. True
   b. False

3. In transferring a prescription for a Schedule III, IV or V prescription refill, which of the following need **NOT** be reduced to writing by the pharmacist receiving the transferred prescription?

    a. Tthe word "transfer" on the face of the transferred prescription
    b. Date of issuance of original prescription, date of original filling and date of transfer
    c. Mmanufacturer (if a generic was dispensed) of the substance originally dispensed
    d. Prescriber's and pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred
    e. Names of pharmacists transmitting and receiving the prescription transfer

4. Which of the following is **NOT** permitted?

    a. Providing "take home" doses of methadone or LAMM (methadyl acetate) to patients participating in narcotic treatment programs
    b. Providing methadone or LAMM to patients in acute care hospitals for patients otherwise participating in narcotic treatment programs
    c. Prescribing methadone for pain management
    d. Providing methadone or LAMM to patients in extended care facilities for patients otherwise participating in narcotic treatment programs

5. Stating that they were in the neighborhood, Drug Enforcement Administration investigators enter your pharmacy, present their credentials and ask to review your controlled substances records. You should probably:

    a. Show them what they want, making them as comfortable as possible
    b. Close the store or summon your relief pharmacist, knowing that you will be busy observing their activities while in the store
    c. Offer them lunch, as the assistant was just leaving on a lunch run
    d. Ask them to review their procedures and come back when they understand them

6. The Washington Board of Pharmacy may approve intern hours obtained in another state if:

    a. A school of pharmacy in the host state approves the internship
    b. The Board of Pharmacy in the host state approves the internship
    c. UW School of Pharmacy approves the internship
    d. National Association of Boards of Pharmacy approves the internship

7. To receive credit for intern hours "served" in Washington, the intern should:

    a. Adequately perform the practice of pharmacy
    b. "Serve" only under the supervision of pharmacists that satisfy the Board's preceptor certification requirements
    c. "Serve" only in Class A pharmacies
    d. a. and b. only
    e. a., b. and c.

8. Which of the following is **TRUE** regarding Washington pharmacist continuing education requirements?

    a. Completion of 30 contact hours of American Council on Pharmaceutical Education-accredited (ACPE) programs are required every 2 years.
    b. Completion of 15 contact hours of ACPE or Board-accredited programs are required annually
    c. Certificates of completion must be submitted with each annual license renewal
    d. Attendance at continuing medical education programs **CANNOT** be substituted for ACPE or Board-accredited programs

9. Technically, emergency drug kits used in extended care facilities are physical extensions of the supplying pharmacy and remain the property of that pharmacy.

    a. True
    b. False

10. Which of the following is **TRUE** regarding pharmacy services and extended care facilities?

    a. Facilities employing unit-dose drug distribution systems may maintain supplemental dose kits
    b. Doses from the emergency drug kit could be used to replace a missing routine morning dose rather than waiting for the noon delivery
    c. Arrangements must be made for timely pharmacy deliveries of drugs and biologics
    d. a. and c.
    e. a., b., and c.

11. Drug administration in extended care facilities shall be documented as soon as possible after the act of administration, and shall include all of the following **EXCEPT**:

    a. Verification of administration
    b. Verification of drug or biologic identity
    c. Documentation of reasons for ordered doses not taken
    d. Documentation of reasons for administration of, and response to drugs given on an as needed basis (PRN)

12. Pharmacies that are housed in larger "mercantile establishments" with hours that are shorter than the larger establishment must

    a. Have a separate phone line that cannot be answered outside of the pharmacy
    b. Post hours of pharmacy operations
    c. Be enclosed by solid partitions at least seven feet in height, from the floor, which are sufficient to provide adequate security for the pharmacy
    d. a. and c.
    e. a., b., and c.

13. A patient presents a copy of a prescription obtained from another pharmacy that is clearly marked "copy – for informational purposes only". You could fill the prescription if

    a. You verify the authenticity of the copy with a second document, such as the prescription label
    b. The prescriber's nurse approves
    c. The original prescriber provides sufficient information for a new prescription
    d. The pharmacy that provided the prescription copy to the patient approves

14. If the prescriber is not available and in the professional judgment of the pharmacist an emergency need for the medication has been demonstrated, the pharmacist may dispense up to a 7-day supply.

    a. True
    b. False

15. Drugs and sick room supplies legally dispensed by prescription in unit dose forms or in sealed single or multiple dose ampoules or vials may be returned to pharmacy stock if the dispensed articles are sealed containers and meet, in the pharmacist's professional judgement, the standards of the United States Pharmacopeia for storage conditions.

    a. True
    b. False

16. Washington rules specify that pharmacies must have copies of certain reference materials. These include:

    a. The Teal Book (Pharmacy Lawbook), or its contemporary equivalent
    b. The Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations)
    c. The United States Pharmacopeia
    d. a. and b.
    e. a., b., and c.

17. Washington rules specify that pharmacies must have the following to satisfy poison control requirements: The telephone number of the nearest poison control center and at least two one-ounce bottles of syrup of ipecac.

    a. True
    b. False

18. Washington laws and rules specify that the label affixed to a prescription and dispensed in an out-patient setting include certain information. Which of the following is **NOT** always required? [part 1]

    a. Name and address of the pharmacy wherein the prescription is compounded
    b. Corresponding serial number of the prescription
    c. Name of the prescriber
    d. Directions for use
    e. Name of the medicine and the strength per unit dose

19. Washington laws and rules specify that the label affixed to a prescription and dispensed in an out-patient setting include certain information. Which of the following is **NOT** always required? [part 2]

    a. Name of patient
    b. Date prescription is compounded and expiration date of the prescription
    c. Quantity of the prescription
    d. Initials of the licensed pharmacist who has compounded the prescription
    e. "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed."

20. The following statements are true regarding the pharmacist's "standard of care":

    a. The model for the standard of care is the reasonable and prudent pharmacist
    b. The standard of care has evolved from a non-discretionary standard of technical accuracy to a discretionary standard which requires pharmacist to perform a variety of professional functions with due care
    c. The standard of care should reflect the education, training, and circumstances encountered by the individual pharmacist
    d. a. and b. above
    e. a., b., and c.

21. Which of the following is **NOT** an example of economic damages:

    a. Medical expenses
    b. Lost wages
    c. Damages that can be characterized as making the consequences of the harm bearable
    d. Loss of business
    e. All of the above are economic damages

22. You realize once you return home from work that you may have dispensed a higher strength of a cardiac medication to an elderly patient with unstable angina. You contact the evening pharmacist, who pulls the original prescription and verifies that you did in fact dispense the wrong strength. What is the best thing for you to do next to protect yourself from liability?

    a. Call the prescriber first thing the next morning and let him inform the patient
    b. Obtain the patient's home phone number and contact him yourself immediately
    c. Let the evening pharmacist, who is your supervisor, contact the patient and explain the error
    d. Contact the patient first thing in the morning and make sure you provide a replacement medication free of charge
    e. Contact the agent from the company that provides your malpractice insurance and let him handle the problem

23. You are the attorney for the plaintiff, whom you allege was injured when she was dispensed the anti-inflammatory Celebrex (celecoxib) despite a documented allergy in her pharmacy profile to sulfas. (The manufacturer's package insert lists allergy to sulfas as a contraindication for taking Celebrex). Patient developed a severe allergic reaction after one dose of Celebrex and had to be hospitalized. During the course of discovery, you determine from the deposition of the morning pharmacist that the allergy was not discovered because he was at the end of his shift and skipped the step of reviewing the patient's medication profile while verifying the prescription. Moreover, the morning pharmacist left before counseling the patient and in his deposition, the evening pharmacist stated that he assumed that the patient had been counseled when the prescription was dropped off in the morning, so no one provided your client with information about the medication. As part of your case, you assert that the pharmacists' failure to review the medication record and failure to counsel are examples of:

    a. Comparative fault
    b. Proximate cause
    c. Negligence per se
    d. Punitive damages
    e. None of the above

24. The Washington Administrative Code does **NOT** have medication error/quality assurance regulations for which of the following:

    a. Parenteral products for non-hospitalized patients
    b. Extended care facilities
    c. Retail pharmacies
    d. Good manufacturing practice for finished pharmaceuticals
    e. Hospital standards

25. Felicia the Pharmacist works in the ICU at UW Hospital. She has interpreted a physician's order to read 'Potassium 100mEq' instead of '10mEq'. Felicia dispensed the dose and the nurse gave the medication. The hospital has in place a system to address medication errors. The best approach to address such errors and keep them from happening again includes:

    a. Launch an investigation to determine that Felicia was the pharmacist at fault
    b. Convene a committee to discipline or sanction Felicia
    c. Retrain Felicia regarding interpretation of physicians orders
    d. Analyze the error to identify and understand what went wrong; implement system changes
    e. Report her error to the Board of Pharmacy

26. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is an organization that "accredits" hospitals to national standards. Which standards were discussed in class and are intended to promote patient safety:

    a. Ongoing programs to identify risks to patient safety
    b. Patients are informed about the outcomes of care including unanticipated outcomes
    c. Recognize that humans tend to err when relying on memory and observation so have a system in place to strengthen memorization skills
    d. a. and b.
    e. a., b. and c.

27. Mr. Jones has just witnessed his sister die a painful death during which she received care that he is positive he will NEVER want. He writes and signs an Advanced Directive that:

    a. May also be referred to as a 'Living Will'
    b. Generally addresses his desire to refuse specific healthcare interventions
    c. Designates someone to act as a proxy should he lose decision making capacity
    d. Stipulates what forms of medical treatment be provided by caregivers
    e. All of the above

28. A Durable Power of Attorney (DPA) for health care is a legal document where one person assigns another person authority to perform specified actions on behalf of the signer. This DPA differs from an Advance Directive in that it does not specify what medical treatment he desires should he become permanently unconscious or be in a terminal condition.

    a. True
    b. False

29. Mr Jones has now completed writing his Advance Directive and must have it signed by 2 witnesses. Who may **NOT** be one of his witnesses?

a. His son, from whom he is estranged, and is not in the will
b. His best friend
c. His attorney's legal assistant
d. His neighbor
e. A fellow client at his attorney's office

30. The state of Oregon currently has a 'Death with Dignity' act that was approved by 51% of Oregon voters. John Ashcroft, Attorney General has written a memo that will single out Oregon physicians who participate in the 'Death with Dignity' process with their patients. The Attorney intends to have such physicians prosecuted under federal statutes for second degree murder.

a. True
b. False

Short Answer Questions – Please limit your answers to the space provided. Short typically means a few words (not a few paragraphs).

31. List 2 recommendations of the '2000 Department of Health Report' to decrease medication errors.

32. An article in the Wall Street Journal (11/13/01) is titled, "Drugstore Data Could Be Tip-Off to Bioterrorism". The article describes how nation-wide pharmacy chains like Walgreen Co. and Rite Aid Corp. could, in theory, report unusual purchase patterns of over-the-counter drugs for diarrhea, cough-cold, headache, etc. Would reporting of such information to agencies like Washington Department of Health, federal Centers for Disease Control and Prevention, etc., present any confidentiality issues? Briefly justify your answer in the space provided.

33. You are the innocent pharmacy intern. You answer a call from someone wanting to know the price for 25 and 250 Oxy-Contin 40mg (oxycodone sustained release). Provide one example each of when you **must** and **must not** provide pricing information.

    Must:

    Must not:

34. You have a container of outdated C-II drugs. Describe one method for its disposal?

35. The Durham-Humphrey Amendment establishes "legend" status for drugs federally. In Washington, RCW 69.41.075 gives the Board of Pharmacy the authority to classify "legend" drugs. In practice, how does the Board do this? [question can be answered with 2 words]

36. Ethics Question

In 1991, a North Carolina jury awarded $15 million in compensatory and punitive damages to the family of Henry James, a nursing home patient who died a painful death from terminal metastatic prostate cancer. The jury found that a nurse's refusal to administer the opioid analgesics necessary to relieve Mr James's pain, on the rationale that he would become addicted, constituted a gross departure from acceptable care. Significantly, no disciplinary action was forthcoming for either the nurse or the facility. Perhaps because the named defendants were a nurse and a nursing home, and no physician's care was at issue in the case, the implications of the jury's verdict largely escaped the attention of the medical community.

In 1998, William Bergman was admitted to Eden Medical Center in Castro Valley, California, in severe pain. Dr Wing Chin became his physician. Important details surrounding his 5-day hospitalization are in dispute between the Bergman family and those who cared for him. The pain management order throughout his hospital stay was for 2 Vicodin every 4 hours as needed for pain. The hospital records indicate that at some point each day Mr Bergman's pain was rated between 7 and 10 on a 10-point pain intensity scale, 10 being the worst pain imaginable. On the day of his discharge, a pain level of 10 appears in the medical record. Although a definitive diagnosis was not reached, a chest radiograph, combined with a long history of smoking, was strongly suggestive of lung cancer. Mr Bergman declined further tests, wishing to go home and receive hospice care. He died within a week of discharge. In a malpractice action brought by Bergman's family, the hospital settled, and a jury returned a verdict against Dr. Chen of $1.5 million.[1]

Consider the James and Bergman cases and evaluate the five ethics principles and values discussed in class. State your perspective and provide 2-3 sentences for each of the principles and values. Suggested format for each: principle, brief definition, application to case. Limit your answers to space provided.

Perspective:

Principle 1:

Principle 2:

Principle 3:

Principle 4:

Principle 5:

[1]Adapted from Rich BA West J Med 2001;175:151-152.