Student Name _____

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

PHARMACY 543 PHARMACY LAWS & ETHICS
FINAL EXAMINATION
December 14, 1998

Questions 1 – 30 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). If your bubbles are not interpretable by the scanner gizmo, you are liable to lose credit for the multiple choice section of the exam.

Questions 31 – 40 are short answer or essay. Be sure that your name and student number are on all pages that you turn in. Please limit your answers to the space provided for each question.

Turn in (1) the Standard Answer Form and (2) your answers to questions 31-40.

Grading: questions 1 - 30, 1 point each; questions 31 - 40 as indicated [in brackets].

Please select the ***best*** answer from among the responses provided. When a question deals only with federal law it will contain a statement such as "According to federal law..." Some of the questions may include Except and Not to determine if the student knows the exceptions or when some law or rule does not apply. In such instances, **Except** and **NOT** will be shown in **bold face type**.

1. Select examples of purposeful Medicaid/Medicare fraud.

    I. Dispense a generic drug but bill for a brand name drug
    II. Kickbacks
    III. Prescriptions are billed at the time of filling, but never picked up

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

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

    I. Medicare patients paying for services
    II. Price database and algorithm errors
    III. Upcoding -- billing for a higher code than the service provided

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

3. True / False. Under FDA Investigational New Drug regulations, it is illegal to charge for an experimental therapy.

    A. True
    B. False

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

5. Which of the following are possible penalties for violation of the Medicare/Medicaid Anti-Kickback Statute?

   I. Imprisonment of up to five years
   II. Criminal fine of up to $25,000
   III. Exclusion from participation in Medicare and Medicaid for at least five years

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

6. Which of the following is/are true with regard to Washington House Bill 1769 Electronic Transfer of Prescription Information?

   I. Prescription information may be communicated electronically if transmitted to a pharmacy of the patient’s choice.
   II. Transmitting and receiving systems must be approved by the Board of Pharmacy
   III. Transmission of prescriptions for any legend drug permitted, including C-II through C-V

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

7. True / False Prescriptive authority protocols can provide a “work around” for Drug Enforcement Administration restrictions on C-II controlled substances renewals.

   A. True
   B. False

8. Under Washington's Uniform Health Care Information Act (RCW 70.02), disclosure may be made to a third party without the patient's authorization under which of the following circumstances?

    I. To another health care provider when there is a legitimate "need to know"
    II. To penal or custodial institutions where the patient is detained
    III. To a pharmacy benefits management company's agent to distribute refill reminders

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

9. In Washington, a durable power of attorney for health care

    I. Generally addresses withholding or withdrawal of health care interventions
    II. Grants health care decision making authority to specified individuals
    III. Must be witnessed

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

10. Which of the following statements is **TRUE** regarding OBRA-90?

    A. retrospective drug use evaluation is mandated for individual prescriptions
    B. an offer to counsel must be given to all patients who receive new prescriptions
    C. a written record of the pharmacist's evaluation of drug therapy must be made for patients covered under the provisions of OBRA-90.
    D. the pharmacist may delegate counseling responsibilities to specially trained technicians
    E. a written patient information sheet must be given to patients receiving new prescriptions.

11. True / False. With regard to marijuana, any changes in State law will not affect Federal law.

    A. True
    B. False

12. 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

13. Increased FDA scrutiny of pharmacist compounding resulted from:

    I. notorious cases of improper compounding resulting in patient disfigurement and/or death
    II. narrow interpretation of provisions of the Food, Drug and Cosmetic Act by the FDA, especially those that define an “unapproved new drug”
    III. cases of pharmacists engaging in manufacturing activities under the guise of compounding

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

14. Which of the following statements regarding compounding would be considered to be **FALSE** under the provisions of the FDA Modernization Act of 1997?

    A. compounding may be done for patient-specific dosages when a commercially available product does not exist
    B. repackaging of bulk drug substances into unit-of-use packages for resale to other pharmacies is allowable under certain conditions
    C. compounding of batches in anticipation of prescriptions is allowable if a record of routine prescribing of the compound exists
    D. only USP-NF or FDA-listed chemicals may be used in compounding unless an emergency situation exists and there are no alternative therapies available
    E. compounding may be done for patient-specific dosages even if a manufactured product is available if the prescriber indicates that there is a significant need

15. Which of the following states do **NOT** reciprocate pharmacist licenses with Washington?

    A. California
    B. Arizona
    C. Massachusetts
    D. Texas
    E. Rhode Island

16. Which of the following prescriptions is **NOT** required to be packaged in a child resistant container (CRC)?

    A. Tylenol with codeine 30 mg. No. 30. [analgesic]
    B. Ortho-Novum tablets 1/50 in 28 tablet memory pack. [birth control]
    C. Tetracycline capsules 250 mg. No. 40 [antibiotic]
    D. Nitroglycerin sustained release capsules 2.5 mg. No. 100. [antianginal]
    E. Warfarin sodium tablets 5 mg. No. 30 [“blood thinner”]

17. Which of the following are **NOT** authorized practices for hospital pharmacies subject to the Prescription Drug Marketing Act of 1987 (PDMA)?

    A. Prescription drugs may be distributed to the hospital's inpatients.
    B. Prescription drugs may be distributed to hospital's affiliates.
    C. Prescription drugs may be sold to retail pharmacies in an emergency.
    D. Prescription drug samples may be dispensed from hospital pharmacies.
    E. Prescription drugs may be sold to physicians for use in their private practices.

18. 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

19. Which of the following is **NOT** required to be maintained in a licensed pharmacy?

    I. Bottle of ipecac syrup.
    II. Poison Control Center telephone number
    III. Toxicology reference book.

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

20. Which of the following may authorize the dispensing of a prescription drug 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

21. The FDA book entitled "Approved Drug Products with Therapeutic Equivalence" is also called:

    A. The "Red Book"
    B. The "Blue Book"
    C. The "Orange Book"
    D. The "Black Book"
    E. The "Brown Book"

22. Which of the following statements is **TRUE** regarding the key points of the compounding provisions in the FDA Modernization Act of 1997?

    A. compounding must be practiced in the "dyad" relationship, i.e., between the pharmacist and physician
    B. bulk substances used in compounding are those only listed in the USP-NF
    C. for the first time, pharmacists are allowed to compound products that are commercially available without restrictions
    D. a memorandum of understanding between the FDA and each state must be developed to address interstate distribution of inordinate amounts of compounded products and to deal with investigation of complaints about compounded products
    E. advertising or promotion of specific compounded products is allowed

23. Which of the following is the most serious class of drug recall

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

24. Initiative 692 authorized the use of "medical marihuana" for which of the following health conditions?

    I. Attention deficit disorder
    II. Nausea & vomiting due to chemotherapy.
    III. AIDS wasting syndrome

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

25. In Washington, pharmacist prescribing authority (collaborative drug therapy) is best described as:

    A. Independent.
    B. Dependent.
    C. Advanced patient counseling.
    D. Third class of drugs.
    E. Advanced pharmacist practitioner.

26. Which of the following practitioners may **NOT** prescribe Dilaudid [C-II]?

    A. ARNP
    B. MD
    C. PA
    D. DO
    E. DDS

27. You fill Martha Stewart's Valium 2mg [benzodiazepine anxiolytic] prescription with Valium 10mg. She 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. A and B

28. Which of the following is **NOT** true with regard to pharmacist prescriptive authority (collaborative drug therapy) applications:

    I. Board approval must be received by the pharmacist(s) before prescriptive authority activities may be initiated
    II. A signed statement identifying the practitioner authorized to prescribe and the pharmacist(s) who are party to the agreement must be submitted to the Board of Pharmacy
    III. The application must include a description of the diseases, drugs or drug categories involved

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

29. Which of the following are within the Board of Pharmacy's jurisdiction in the investigation and discipline process?

    I. Drug price
    II. Prescription filling error
    III. Failure to counsel

    B. I only
    C. III only
    D. I and II only
    E. II and III only
    F. I, II, and III

30. Which of the following is/are **TRUE** under *WAC 246-869-220 Patient information required*: With each new prescription dispensed the pharmacist must:

    I. for those prescriptions delivered within the confines of the pharmacy -- orally explain to the patient or patient's agent the directions for use and any additional information, in writing if necessary
    II. for those prescriptions delivered outside the pharmacy -- explain by telephone or in writing
    III. When appropriate on refill prescriptions -- communicate with the patient or patient's agent about adverse effects, over or under utilization, or drug interactions

    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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31. Describe a potential consequence of claiming a Fifth Amendment right during a Board of Pharmacy disciplinary investigation. (20 words maximum)[2 points]

32. Under current Federal law, what is the only legitimate access to marijuana? (maximum 5 words)[2 points]

33. Before releasing health care information about a patient that you have been subpoenaed to provide, what must have happened and in what time frame? (maximum 10 words)[2 points]

34. List the four required elements of professional negligence, i.e., what needs to be proven in order for a pharmacist to be considered to be legally negligent.[8 points]

35. Define “safe harbor” in the context of health care fraud. (Maximum 20 words)[2 points]

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36. The Declaration of Helsinki is included in Title 21 Code of Federal Regulations § 312.120 *Foreign clinical studies not conducted under an IND*.

A. Why? (20 word maximum)[2 points]

B. While Title 21 CFR 50.25 *Elements of Informed Consent* and the Declaration of Helsinki have similar goals, they are not equivalent. Give two examples of differences between the two documents. For instance, 21 CFR 50.25 specifies that "a disclosure of appropriate alternative procedures ... that might be advantageous to the patient" must be described while this requirement is missing from Helsinki. [2 points, though no points will be given for the example]

37. Other than fines, debarment (the loss of the right to participate in Medicare or Medicaid) and imprisonment, what impact could conviction of Medicare/Medicaid fraud have on your practice as a pharmacist? (5 word maximum)[2 points]

38. 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 a placebo.

A. What legal problems do you see with this proposal? (A one-word answer is possible)[2 points]

B. What ethical problems do you see with this proposal? Evaluate this problem using normative principles. [10 points]

C. What is a legal and ethical alternative to the proposal?[2 points]

39. 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]

40. What must be true about a patient for him/her to revoke a health care directive or durable power of attorney for health care? (can be answered with one word; 10 words maximum) [2 points]