

Name: \_\_\_\_\_

Student Number: |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|

PHARMACY 543 – PHARMACY LAWS & ETHICS  
**MIDTERM EXAMINATION**  
October 29, 2004

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
- (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.

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

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1. A pharmacy that is registered with the DEA may hire a pharmacist, who had been convicted of a controlled substances felony, if five years have elapsed since the conviction and the pharmacist has had his/her pharmacy license restored.
    - a. True
    - b. False

2. Under the Federal Food, Drug and Cosmetic Act, as amended, which of the following is included in the definition of a drug?
- I. Habit-forming
  - II. Does not achieve any of its principal intended purposes through chemical action
  - III. Intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease
- a. I only
  - b. III only
  - c. I and II only
  - d. II and III only
  - e. I, II and III
3. Which of the following is **NOT** a term used in Qui Tam actions?
- a. Relator
  - b. Kickbacks
  - c. Whistleblower
  - d. False Claims Act
  - e. "He who brings the action as well for the king as for himself"
4. Unbundling is a term used to describe a fraudulent billing practice in which of the following?
- a. Multiple procedures are combined into one billing code
  - b. Prescriptions for larger quantities are filled multiple times with smaller quantities and billed repeatedly
  - c. One procedure is split into many smaller components which are billed individually
  - d. A False Claim Act violation is initiated
  - e. An OBRA-90 mandate is violated
5. Which of the following best describes fraudulent upcoding?
- a. Using ghost patients to bill Medicare
  - b. Forging false referrals
  - c. Changing dates of service
  - d. Providing one service but billing for another, more expensive service
  - e. Fee splitting
6. Which of the following is a Schedule II drug?
- a. Aspirin 325 mg with Codeine 8 mg
  - b. Aspirin 325 mg with Codeine 16 mg
  - c. Aspirin 325 mg with Codeine 32mg
  - d. Aspirin 325 mg with Codeine 65 mg
  - e. Aspirin 325 mg with Codeine 100 mg

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7. Which of the following is **NOT** a schedule III drug?
- a. Hydrocodone 5 mg with Acetaminophen 325 mg
  - b. Marinol (dronabinol)
  - c. Testosterone 10 mg
  - d. Librium (chlordiazepoxide) 10 mg
  - e. Secobarbital suppositories
8. Non-emergency telephoned prescriptions are allowed for drugs in which of the following controlled substances schedules?
- I. Schedule II
  - II. Schedule III
  - III. Schedule IV
- a. I only
  - b. III only
  - c. I and II only
  - d. II and III only
  - e. I, II, and III
9. Which of the following practitioners are considered to be **EXEMPT** from registration with the DEA?
- I. A physician in the U.S. Navy
  - II. A dentist in the U.S. Public Health Service
  - III. An Advanced Registered Nurse Practitioner in the U.S. Army
- a. I only
  - b. III only
  - c. I and II only
  - d. II and III only
  - e. I, II, and III

10. Which of the following methods is acceptable for storage of controlled substances stocked in a community pharmacy?
- I. Substantially constructed locked cabinet
  - II. Dispersed throughout non-controlled drugs
  - III. Locked fishing tackle box
- a. I only
  - b. III only
  - c. I and II only
  - d. II and III only
  - e. I, II and III
11. Which of the following section(s) of a completed DEA order form No. 222 must be retained in the pharmacy records?
- a. Copy 1.
  - b. Copy 2.
  - c. Copy 3.
  - d. Copy 1 and 2
  - e. Copy 2 and 3
12. Which of the following DEA numbers would be a valid number for Mary Smith, MD?
- a. AM 9743382
  - b. AS 5248415
  - c. MS 8804999
  - d. BM 1159347
  - e. MM 4224438
13. On January 1st you dispensed a prescription calling for Vicodin (hydrocodone & acetaminophen) Tablets No. 40 Sig: Take 1 tablet every 4 hours as needed for pain. Refill 4 times. Assuming that you dispensed 40 tablets originally, how many times may you dispense partial refills between January and June if you dispensed 20 tablets at each subsequent refill?
- a. 2 times
  - b. 3 times
  - c. 4 times
  - d. 5 times
  - e. 6 times
14. If you receive a FAXed prescription for 30 Morphine Sulfate tablets for a Hospice patient you may fill it without first obtaining an original signed prescription from an authorized prescriber.
- a. True
  - b. False

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15. Which of the following items on a Schedule II prescription may **NOT** be changed by a pharmacist?
- I. Prescriber's signature
  - II. Name of patient
  - III. Drug
- a. I only
  - b. III only
  - c. I & II only
  - d. II and III only
  - e. I, II and III
16. Which of the following drugs may be dispensed by a pharmacy when prescribed by a physician to maintain an opiate addict?
- I. Suboxone (buprenorphine / naloxone)
  - II. Subutex (buprenorphine)
  - III. Methadone
- a. I only
  - b. III only
  - c. I and II
  - d. II and III
  - e. I, II and III
17. Indicate which of following disclosures is subject to the HIPAA "need to know" principle.
- a. Pharmacist discloses patient's medication record to Child Protective Services as part of investigation of alleged child abuse on the part of patient;
  - b. Pharmacist accesses patient file to assess whether patient has a history of gastric ulcer/gastrointestinal bleed as a DSHS pre-requisite for Drug Utilization Review (DUR) and payment purposes for NSAID's;
  - c. Off-duty pharmacist is in pharmacy to pick up paycheck when close friend's medication is being checked;
  - d. Patient's personal representative (PR) brings form signed by patient that requests copy of medication record;
  - e. None of the above is subject to the "need to know" principle.

18. Which of the following products containing controlled substances are exempt from the usual DEA record keeping requirements?
- I. Laboratory reagents
  - II. Steroid - Estrogen combination drugs
  - III. Steroid Veterinary Implants
- a. I only
  - b. III only
  - c. I and II only
  - d. II and III only
  - e. I, II and III
19. Pursuant to the Washington State Precursor Chemical Control law, a person may make a purchase of up to 15 grams of pseudoephedrine products in a single transaction.
- a. True
  - b. False
20. You're working in your pharmacy minding your own business when an agent for the Board of Pharmacy presents himself to your front counter tech, shows his Department of Health badge, and asks to be let into the pharmacy. What should you instruct your tech to do?
- a. Stall the investigator until you can contact your attorney
  - b. Let him in
  - c. Tell him that he may only come in if he shows her a copy of his search warrant
  - d. "Plead the Fifth" and say nothing to him
  - e. Ask for the consent forms of the patient records he wants to see
21. You apply to work for a pharmaceutical company that primarily manufactures controlled substances. As part of your application for the job, you must sign a form that states that you will consent to periodic urine testing. Under the US Constitution, can this employer ask you to consent to periodic urine testing?
- a. Yes
  - b. No
22. A party who was the subject of a non-permitted disclosure because of negligence on the part of a health care worker may recover actual damages under HIPAA.
- a. True
  - b. False

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23. If the Board of Pharmacy followed the Administrative Procedures Act and published a final rule prohibiting physicians from dispensing controlled substances and the rule was challenged in court by physicians, which of the following reasons could a judge use to overturn the rule?
- I. The Board had exceeded its statutory authority
  - II. The Board made an error of law
  - III. The Board made a procedural error
- a. I only
  - b. III only
  - c. I and II only
  - d. II and III only
  - e. I, II and III
24. The following individuals present to your pharmacy and attempt to access the medication records of one of your patients. To which of these individuals will you **REFUSE** to give the information?
- I. To a police officer who has an unresponsive suspect in custody; a medication vial was found in the suspect's pocket and the officer wants to identify its contents;
  - II. To a friend of the patient who provides care for the patient on occasion and usually picks up the patient's medications;
  - III. To the mother of a patient who is busy with activities for "Senior Week" at Roosevelt High School;
- a. I only
  - b. III only
  - c. I and II only
  - d. II and III only
  - e. I, II and III
25. You work for the Home I.V. team at a county hospital. You are training a patient and family members about administering a dose of vancomycin at home, and you reach up the patient's IV pole to hook the bag up for infusion. Ouch! You stick yourself with an uncapped needle that was left on the pole by the night nurse. Under Washington law, you may request that the patient be tested for HIV and you may access the results of the test.
- a. True
  - b. False

26. Under Washington law, to whom are you **PROHIBITED** from disclosing the HIV test results if you have seen that the results are **POSITIVE**?
- a. To the patient's health insurance discharge planner to set up coverage for anti-retroviral therapy;
  - b. To the other Home I.V. team pharmacist who trains patients on a completely different service;
  - c. To the nursing team who has been caring for the patient in-house and was unaware that patient was even at risk for being HIV positive;
  - d. To patient's mother (patient is an adult), who will be involved in caring for patient and in administering;
  - e. None of the above

	For each of the following actions, select the appropriate court venue.	Administrative	Civil	Criminal
27.	Board of Pharmacy hearing to determine whether a pharmacist's license should be suspended	A	B	C
28.	Trail testimony from pharmacy supervisor regarding the work record of a pharmacist who misfilled a prescription and caused the extended hospitalization and permanent injury of the plaintiff	A	B	C
29.	Arrest warrant issued by the Washington Superior Court for a pharmacist implicated by the DEA in an investigation of a drug diversion scheme	A	B	C

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30. A DEA investigator enters the pharmacy and presents appropriate credentials and notice of the inspection.<sup>1</sup> She states that the purpose of the inspection<sup>2</sup> is to verify the pharmacy's receipt of certain controlled substance shipments. Which of the following records may she inspect without further legal justification (e.g., a warrant)?
- I. Controlled substances records
  - II. Inventory records
  - III. Prescription records
- 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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<sup>1</sup>Sec. 1316.06 Notice of inspection.

The notice of inspection (DEA (or DNB) Form 82) shall contain:

- (a) The name and title of the owner, operator, or agent in charge of the controlled premises;
- (b) The controlled premises name;
- (c) The address of the controlled premises to be inspected;
- (d) The date and time of the inspection;
- (e) A statement that a notice of inspection is given pursuant to section 510 of the Act (21 U.S.C. 880);
- (f) A reproduction of the pertinent parts of section 510 of the Act; and
- (g) The signature of the inspector.

<sup>2</sup>Sec. 1316.05 Entry.

An inspection shall be carried out by an inspector. Any such inspector, upon (a) stating his purpose and (b) presenting to the owner, operator or agent in charge of the premises to be inspected (1) appropriate credentials, and (2) written notice of his inspection authority under Sec. 1316.06 of this chapter, and (c) receiving informed consent under Sec. 1316.08 or through the use of administrative warrant issued under Secs. 1316.09-1316.13, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.





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Ethics Case Evaluation – Please confine your response to the space provided.

36. When pharmacist Neil Noesen refused to fill a customer's prescription for birth-control pills at a Kmart in Menomonie, Wis., he did so on the basis of his religious beliefs. But when he also refused to transfer the woman's prescription to another pharmacy, she went to the police.

Next week, on May 4, Mr. Noesen will appear before a court commissioner in Madison, Wis., to face a disciplinary hearing on charges of unprofessional conduct. The Wisconsin Department of Regulation and Licensing could fine him or revoke his license....

The American Pharmacists Association maintains a two-part policy. "The pharmacist has the right to conscience, and the patient has the right to legally prescribed medication," says spokesman Michael Stewart. A pharmacist who objects to dispensing a particular medication must tell an employer. If one pharmacist refuses to fill a prescription on grounds of conscience, another pharmacist must do it. Some customers may be referred to another pharmacy. Other prescriptions may be delivered by mail.

"In the great majority of cases, the pharmacist's right to conscience is exercised appropriately and seamlessly, so the patient is not even aware that the pharmacist has exercised that right," Mr. Stewart says. "A pharmacist can say, 'Let me get Bob for you, ma'am,' and that's the end of that."

Two states - South Dakota and Arkansas - already have laws protecting pharmacists who refuse to fill birth-control prescriptions on moral or religious grounds. Ten other states, including Wisconsin, are considering such legislation - Indiana, Michigan, Minnesota, Mississippi, Missouri, Ohio, Rhode Island, Vermont, and Washington [?!]....<sup>3</sup>

- a. If you wanted to change your current pharmacy practice circumstances in Washington to reflect your personal beliefs, how could you do so? Provide three different methods. Very short answers are appreciated! (3 points)


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<sup>3</sup>Abstracted from Christian Science Monitor Apr 26, 2004

- b. Evaluate the ethics of this occurrence, using the normative principles discussed in class. (7 points)

Perspective
Beneficence
Nonmaleficence
Autonomy
Justice
Virtue