

Name: _____

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

**PHARMACY 543 – PHARMACY LAWS & ETHICS
MIDTERM EXAMINATION
02 November 2005**

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 2-part ethics question. 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 ethics questions (separate pages), 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 question points are indicated (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**.

Use the following prescription to answer questions 1 thru 5.

1. The pharmacist has only 15 tablets of morphine sulfate 10 mg 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



John D. Powers, M.D.
63 Plymouth Street
Anytown WA 98700
DEA ??123456?

Patient: Mary Johnson
123 Franklin St, Anytown WA
Morphine Sulfate Tables 10 mg No. 30
Sig: 1 q4h prn pain

Substitution Permitted Dispense As Written

2. If the pharmacist has no 10 mg morphine sulfate but has sufficient 5 mg tablets in stock, with the permission of the prescriber, the pharmacist may do which of the following?
- I. Change the Rx to 5 mg and double the quantity and Sig
 - II. Prepare a new prescription for this dosage strength
 - III. The pharmacist is **NOT** allowed to change this prescription
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II, and III
3. If the prescription for Ms. Johnston was phoned in as an emergency, which of the following conditions **MUST** be met?
- I. Immediate administration of this drug is necessary
 - II. No alternative treatment is available
 - III. It is **NOT** reasonably possible for the prescriber to provide a written prescription
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II, and III
4. If the prescription for Ms. Johnson was **NOT** an emergency and was transmitted to the pharmacy, on a Friday afternoon via FAX, the pharmacist could do which of the following?
- I. Fill the prescription as written and dispense to patient
 - II. Dispense up to a 72-hour supply
 - III. Use the FAX copy for reference and dispense upon receipt of the original
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II, and III
5. Which of the following information is **NOT** required to be on the prescription label for Ms. Johnson's prescription?
- A. Pharmacy address
 - B. Doctor's address
 - C. Patient name
 - D. Date of filling
 - E. Transfer caution

End of questions related to this prescription. Continue with the examination.

6. How long from the date of issuance by a prescriber may a Schedule III prescription be filled?
- A. 72 hours
 - B. 5 days
 - C. 30 days
 - D. 60 days
 - E. 6 months

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7. You receive a prescription for Vicodin (Hydrocodone 5 mg / Acetaminophen 325 mg) Tablets No. 100 but you have only 50 tablets in stock. How much time do you have to supply the remaining 50 tablets? Vicodin is Schedule III.
- A. 72 hours
 - B. 96 hours
 - C. 30 days
 - D. 6 months
 - E. 12 months
8. Which of the following DEA numbers would be valid for Albert Schweitzer, MD?
- A. AA 1234561
 - B. AS 1234562
 - C. MS 1234563
 - D. AS 1234563
 - E. AS 1234564
9. A controlled substance prescription issued by a doctor in one of the uniformed services **MUST** include which of the following?
- I. Patient's social security number
 - II. Practitioner's social security number
 - III. Patient's address
- 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 of controlled substance storage may be utilized by a community pharmacy?
- I. Storage in a drawer near the computer
 - II. Dispersed throughout the legend drugs
 - III. In a locked metal cabinet.
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II, and III
11. How many members are on the Washington State Board of Pharmacy?
- A. Three
 - B. Four
 - C. Five
 - D. Seven
 - E. Nine

12. Which of the following items may **NOT** be regulated by the Washington State Board of Pharmacy?
- I. Medicated Animal Feeds
 - II. Medical Gases
 - III. Pesticides
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II, and III
13. Which of the following are **NOT** grounds for disciplinary action against a Washington pharmacist's license?
- I. Being found to be mentally incompetent
 - II. Knowingly violating a State or Federal law
 - III. Allowing an intern to fill and dispense a prescription without checking it
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II, and III
14. Which of the following may enter a hospital pharmacy in the absence of a pharmacist in order to obtain an emergency supply of a medication for a patient?
- I. A Registered Nurse, designated by the hospital
 - II. A Licensed Practical Nurse, designated by the hospital
 - III. A Licensed Physician, designated by the hospital
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II, and III
15. Which of the following medications may a Medicare approved Dialysis Program **NOT** dispense to its patients without being licensed as a pharmacy?
- A. Heparin
 - B. Sodium Chloride for Injection
 - C. Potassium Chloride for Injection
 - D. Magnesium Sulfate for Injection
 - E. Dyalysate

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16. In order to substitute a therapeutically equivalent drug that is **NOT** chemically equivalent to the drug prescribed, a pharmacist **MUST** have which of the following:
- I. Prior consent of the prescriber
 - II. The prescriber's signature on the "Substitution Permitted" line
 - III. The drug is included on the State's Preferred Drug List.
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II, and III
17. Authorization to prescribe, dispense or administer prescription drugs in Washington may be found in which of the following laws:
- I. Legend Drug Act (Chapter 69.41 RCW)
 - II. Uniform Controlled Substances Act (Chapter 69.50 RCW)
 - III. Individual Health Professional Practice Acts (Chapter 18 RCW)
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II, and III
18. The ethical principle of autonomy includes
- I. Competence
 - II. Confidentiality
 - III. Informed Consent
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III
19. Application of the research principle of "respect for persons" includes:
- I. informed consent
 - II. voluntariness
 - III. risk/benefit assessment
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III

20. The U.S. Constitution:
- I. Is the Declaration of Independence
 - II. Requires a 2/3 vote by both houses of Congress to propose amendment, and 3/4 of legislatures of each state to ratify an amendment
 - III. Is the supreme law of the land
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III
21. Administrative Law is the body of law created by administrative agencies. The WAC is such an example.
- A. True.
 - B. False.
22. *Stare Decisis*:
- I. Means that courts follow earlier court decisions, or "precedent"
 - II. Allows courts to distinguish earlier precedent based on different facts
 - III. Is codified in statute.
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III
23. A Washington Board of Pharmacy investigation against a newly licensed pharmacist:
- I. Is **NOT** a legal action
 - II. Could include sanctions such as warnings or license suspension or revocation.
 - III. Is an example of an administrative action.
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III
24. A Medical Device
- I. Is the same as "drug" except it does **NOT** achieve any of its principal intended purposes through chemical action ... and is **NOT** dependent upon being metabolized...
 - II. Could be regulated by FDA's CDRH **BECAUSE** it is similar to an existing (predicate) product
 - III. Is **NOT** listed in a official compendium like drugs are.
- 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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25. A competent adult can create an advance directive under the Washington State Natural Death Act directing the withdrawal of "life-sustaining treatment". Pain therapy is excluded from this statutory definition of "life-sustaining treatment" most likely:
- I. to prevent providers from withdrawing drugs for pain control when patients become incompetent or "terminal".
 - II. to prevent the extra costs of pain management at end of life.
 - III. because pain treatment may hasten death
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III
26. Violations of HIPAA and Washington's RCW 70.02 Medical Records -- Health Care Information Access and Disclosure statute include:
- I. Talking about a patient with another pharmacist **NOT** involved with that patient's care, over lunch in a public place.
 - II. Careless disposal or mishandling of patient records.
 - III. Forwarding of email with patient information to non-secure site.
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III
27. Good Compounding practice presumes a prescriber-patient-pharmacy relationship because
- I. This enhances the financial lucrateness of compounding.
 - II. The regulations require it.
 - III. The pharmacist needs to take extra care to look out for possible compounding-related safety and effectiveness problems.
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II and III
28. Purposeful fraud includes
- I. misrepresentation on a pharmacy license application
 - II. charging for patients that don't exist
 - III. incorrect provider numbers
- A. I only
 - B. II only
 - C. I and II only
 - D. II and III only
 - E. I, II and III

29. Unwitting fraud includes:

- I. prescriptions billed for but **NOT** picked up by a patient
 - II. kickbacks
 - III. unbundling
-
- A. I only
 - B. II only
 - C. I and II only
 - D. II and III only
 - E. I, II and III

30. The "Common Rule", 45 CFR § 46.111 Criteria for IRB approval of research:

- I. Tells pharmacists how to bill the government.
 - II. Provides detailed regulations on how researchers are to conduct research on patients.
 - III. Tells IRBs how to conduct research in their federally funded institutions, and certain ways they need to protect patients.
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- A. I only
 - B. II only
 - C. I and II only
 - D. II and III only
 - E. I, II and III

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Short Answer Questions. (10 points) Confine your answers to the space provided.

31. The [_____] of the provider distinguishes research from innovative therapy.(1)

32. How might FDA's "Orange Book" be appropriately used in Washington pharmacy practice?(2)

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33. Use the following four abbreviations in a sentence that explains their meaning and relationships: CFR, RCW, USC, and WAC. (2)

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34. What is the name of the publication in which a federal agency's promulgation of a "final rule" **MUST** be announced? What is described in the "preamble" of a final rule? (3)

a. Final Rule	
b. Preamble	

See reverse side for next question.

35. A fifteen-year-old patient is receiving prescription drug therapy. Under Washington law what would a pharmacy need to receive to release prescription information to: (2)

Information Released to	Pharmacy MUST receive the following for legal disclosure
Parent	
Health Care Provider	
The Courts	
Law Enforcement Officer	

Ethics Question. (10 points) Read the abstract by Hardin and Yusufaly.

Background: Advance directives are widely promoted as a means to plan for patients' decisional incapacity, yet there is little evidence of their effectiveness. We devised a study to assess physicians' compliance with hypothetical advance directives and further examine their clinical reasoning.

Methods: The study consisted of an analysis of a mailed written survey containing 6 hypothetical cases of seriously ill patients. Each case contained an explicit advance directive with potential conflict between the directive and (1) prognosis, (2) wishes of family or friends, or (3) quality of life. Data were collected on the clinical treatment decisions made by physicians and the reasons for those decisions. Study participants were all internal medicine faculty and resident physicians from a single academic institution.

Results: A total of 47% analyzable surveys (117/250) were

returned. Decisions by faculty and residents were not consistent with the advance directive in 65% of cases. This inconsistency was similar for faculty and residents (68% and 61%, respectively; $P > .05$). When physicians made decisions inconsistent with the advance directive, they were more likely to list reasons other than the directive for their decisions (89%; $P < .001$).

Conclusions: Internists frequently made treatment decisions that were not consistent with an explicit advance directive. In difficult clinical situations, internists appear to consider other factors such as prognosis, perceived quality of life, and the wishes of family or friends as more determinative than the directive. Future work needs to explore the generalizability of these findings and examine how strictly patients desire their advance directives to be followed.

Arch Intern Med. 2004;164:1531-1533

Question: under Washington's Natural Death Act (RCW 70.122 *et seq.*), would the circumstances described in the abstract be actionable¹? Explain. (3 points) Limit your answer to this page.

¹actionable

giving cause for legal action: giving a basis for somebody to take legal action
[Encarta® World English Dictionary, accessed 28Oct05]

Ethics Evaluation. Given the findings in the Hardin & Yusufaly article, explain each of the principles and values below and evaluate a case where a patient has an advance directive in place that requests that nutrition and “heroic measures” be withheld. Assume that the advance directive meets all legal requirements, that the patient is in a permanent vegetative state and that the health care team continues to provide life-sustaining care.

Limit your answers to the space provided for each section. (7 points)

Perspective (1)	
Beneficence (1)	
Non-maleficence (1)	
Justice (1)	
Virtue (1)	
Root Cause (2)	