

Name: _____

Student Number |_|_|_|_|_|_|_|_|_|_|

**PHARMACY 543 PHARMACY LAWS & ETHICS
MIDTERM EXAMINATION
October 29, 1998**

Questions 1 – 20 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). Questions 21-24 are short answer and 25 is an 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 21-25.

Grading: questions 1-20, 60 points; 21-24, 24 points and question 25, 16 points.

Asking questions: you will *not* be allowed to 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 on the exam and turn it in with your answer sheets.

Please select the best answer from among the five 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. How long from the date of issuance by a prescriber may a Schedule III prescription be filled?

- A. 72 hours
- B. Five days
- C. 30 days
- D. 60 days
- E. Six months

2. You receive a prescription for Tylenol with Codeine 30 mg Tablets No. 50. You have only 30 tablets in stock. How much time do you have to supply the remaining 20 tablets?

- A. 72 hours
- B. Five days
- C. 30 days
- D. 60 days
- E. Six months

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3. Which of the following DEA numbers would be valid for Albert Smith, MD?
- A. AA 1234567
 - B. AS 1234563
 - C. MS 1234563
 - D. AS 1234561
 - E. AS 1234569
4. 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
5. Which of the following drugs have resulted in significant changes in the Federal Food Drug and Cosmetic Act after they were found to cause significant health problems?
- I. Elixir of Sulfanilamide
 - II. Thalidomide
 - III. Codeine
- A. I only
 - B. III only
 - C. I and II only
 - D. II and III only
 - E. I, II, and III
6. For which of the following drugs must you provide an exact count when you perform your required DEA inventory?
- I. A bottle containing 457 Morphine Sulfate 10 mg Tablets
 - II. A bottle containing 4,900 Tylenol with Codeine 30 mg Tablets
 - III. A bottle containing 999 Meprobamate Tablets
- 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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7. 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

8. 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, substantially constructed cabinet.

- 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 must be notified of any theft or significant loss of controlled substances?

- A. DEA
- B. FBI
- C. FDA
- D. CPSC
- E. DSHS

10. When centralized record keeping has been authorized, which of the following controlled substance records must be maintained at the registered location:

- I. Prescriptions
- II. Biennial inventory
- III. Completed official order forms

- 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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11. Which of the following controlled substances need **NOT** be counted during a DEA inventory:

- A. Hospital clinic supplies
- B. Patient prescriptions at a nursing home
- C. Drugs in the nursing home emergency kit
- D. Drugs sent to the OR for today's use
- E. Drugs awaiting return to wholesaler

12. The Drug Enforcement Administration placed anabolic steroids in a controlled substance schedule on February 13, 1991. On what day should a pharmacy have inventoried its stock of these drugs?

- A. February 13, 1991
- B. February 20, 1991
- C. February 28, 1991
- D. March 13, 1991
- E. March 31, 1991

13. Which of the following is **NOT** a requirement for controlled substances inventories?

- A. Must be in hand written form
- B. Must include all controlled substances under control of the registrant
- C. Must show when it was done (beginning or end of business)
- D. Must be signed by person taking inventory
- E. Must show an exact count for schedule II drugs

14. DEA order forms may be used to order which of the following drug classes

- A. Schedule II only
- B. Schedule III only
- C. Schedule III and IV only
- D. Schedule IV only
- E. Schedule V only

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Use the following prescription to answer questions 16 - 19

John P. Powers, M.D.
63 Plymouth Street
Anytown, WA 98700
(360) 555-1234
DEA No. xxxxxxxxx
Date _____

Patient: Mary Johnson, 123 Franklin St, Anytown, WA

Morphine Sulfate tablets 10 mg No. 30

Sig: 1 q 4 h prn pain.

Refill

Substitution Permitted

Dispense as Written

15. 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

16. If the pharmacist has no 10 mg morphine sulfate but has sufficient 5 mg tablets in stock, the pharmacist may do which of the following?

- I. Change the Rx to 5 mg and double the quantity and directions for use
- 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

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17. If the prescription for Ms. Johnson 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

18. If the prescription for Ms. Johnson was NOT an emergency and was transmitted to the pharmacy 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 24 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

19. 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. Rx serial number

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

20. How many hours of continuing education must a pharmacist obtain each year in order to renew his/her license in Washington?

- A. 7.5 hours
- B. 10 hours
- C. 12 hours
- D. 15 hours
- E. 30 hours

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21. The Washington Administrative Code states:

WAC 246-840-420 Authorized prescriptions by the ARNP with prescriptive authority.

(1) Prescriptions for drugs shall comply with all applicable state and federal laws.

(2) Prescriptions shall be signed by the prescriber with the initials ARNP.

(3) Prescriptions for controlled substances in Schedules I through IV are prohibited by RCW 18.79.240 (1)(r).

(4) Any ARNP with prescriptive authorization who prescribes Schedule V controlled substances shall register with the drug enforcement administration.

[Statutory Authority: Chapter 18.79 RCW. 97-13-100, § 246-840-420, filed 6/18/97, effective 7/19/97.]

Assuming that you are *unaware* of the above, write out a search phrase that employs wildcards and Boolean operators that could help you determine if an ARNP (advanced registered nurse practitioner) can prescribe controlled substances in Washington.

22. List four federal and/or state agencies that impact on the practice of pharmacy and describe the impact.

1.

2.

3.

4.

23. Describe the public health goals achieved by the Durham-Humphrey Amendment of 1951. How were patients' autonomous rights impacted by this amendment?

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24. The Governor of Washington vetoes a bill. Does this bill have any chance of becoming a law? Explain your answer.

25. A patient with AIDS is well known to you through his ongoing compliance problems and has now failed combination (antiretroviral and protease inhibitor) therapy. His CD4s are below 50 (an indicator of advanced disease) and he has recently lost nearly 20 percent of his normal weight (another indicator of advanced disease). He has heard that it is possible to obtain plasma from an infected-but-well patient, treat the plasma with a disinfecting agent, and infuse the treated plasma into patients such as himself with beneficial but unproven effect.

He has found someone that will collect, manipulate and administer the treated plasma. After the fifth treatment, he develops sepsis (per *Random House Unabridged*: "local or generalized invasion of the body by pathogenic microorganisms or their toxins"). Blood cultures show an organism that is also detected in the administered plasma and in environmental samples obtained at the preparation site. Specimens of plasma collected prior to processing were found to be sterile (no growth).

A. What is the term in FDA law that describes the legal status of the plasma at the time of administration? (One-word answer)(2 points)

B. Assume a perspective and evaluate the ethics of the above case. (14 points)