Name: _____ _____
Last First
Student Number |__|__|__|__|__|__|__|__|

Pharmacy 543 – Pharmacy Laws & Ethics
MIDTERM EXAMINATION
October 27, 2008

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.** Multiple choice, one point each – 30 points. Questions 31-35 are short-answer, 10 points. Ethics question, 10 points.

Exam total: 50 points.

Legibility: please verify that your written answers can be read by mere mortals, and your name and student ID number are legible, correct, and present on any papers you turn in. Please double-check your student ID number for accuracy. Errors or omissions may delay or impact your grade.

Turn in:

(1) the Standard Answer Form,
(2) your answers to the short answer questions (1 sheet 2 sides) and the ethics question (1 sheet 2 sides)
(3) other pages as necessary (see below).

Please DO NOT turn in pages that do NOT need to be graded.

You may NOT ask questions during the exam. However, if you believe that a question is technically flawed, please circle the faulty question number and briefly describe your concern. Turn in that (those) exam page(s) and your concerns will be addressed.

So as to NOT confuse you, terms like **NOT, TRUE, FALSE** are presented in **BOLD, ALL-CAPS**.

MULTIPLE CHOICE QUESTIONS

1. The role of the administrative branch of federal or state government is to:

   a. Enact the law
   b. Interpret the law
   c. Implement the law
   d. Formulate the law

2. The Tenth Amendment to the Constitution gives the states the right to legislate in all areas except those specifically prohibited or given to the US Congress in the Constitution. Which of the following is a **PERMITTED** state legislative activity?

   a. Regulate interstate commerce
   b. Regulate healthcare professions
   c. Raise armies
   d. Coin money

3. "Common law" is:

I. A tradition derived from Napoleonic Law in France
II. Applicable throughout the United States
III. Relies on "precedent" in establishing a standard for future decisions

a. I only
b. III only
c. I and III only
d. I, II and III

4. *Were you to violate a rule in the practice of pharmacy, you could be involved in which of the following proceedings?

I. Criminal
II. Civil
III. Administrative

a. I only
b. III only
c. I and III only
d. I, II and III

5. Which is **TRUE** about federal and state laws when they are in conflict?

I. Federal laws prevail when permitted in the Constitution
II. State laws always prevail
III. State laws prevail if more restrictive

a. I only
c. III only
d. I and III only
e. I, II and III

6. The powers of Washington's Board of Pharmacy include promulgation of rules for all **EXCEPT**:

a. Wholesaling of drugs and medical devices by pharmacists
b. Establish criteria for valid prescriptions
c. Distribution of drugs and medical devices by physicians
d. Establish the qualifications for licensure of pharmacists or pharmacy interns

7. Which of the following is required to be registered with the Drug Enforcement Administration in order to participate in the manufacture, prescribing or dispensing of controlled substances?

I. Pharmacists
II. Pharmacy Technicians
III. Pharmacies

a. I only
b. III only
c. I and III
d. I, II, and III

8. When the Administrator of the DEA has proposed to revoke the DEA registration of a pharmacy, who has the burden of proof that this pharmacy should no longer have the registration?

a. The DEA
b. The pharmacy

9. Which DEA registrants are required to provide the following security measures to protect their controlled substances: alarms, perimeter security, locked cages?

a. Wholesalers
b. Pharmacies
c. Narcotic Treatment Programs
d. Physicians

10. On 12/31/2008 you find that you are running out of pharmacy storage space for prescriptions so you decide to shred some of your older controlled substance prescriptions. The DEA would have **NO** reason to object if you destroyed all prescriptions that had been written earlier than which of the following dates?

a. 12/31/07
b. 06/30/07
c. 12/31/06
d. 06/30/06

11. When performing your required DEA inventory, for which of the following must you record an exact count?

a. Oxycodone 5 mg/APAP 325 mg (C-II)
b. Hydrocodone 10 mg/APAP 650 mg (C-III)
c. Tylenol Elixir with Codeine 12 mg/5ml (C-V)
d. Diazepam 10 mg (C-IV)

12. When the DEA schedules a drug that was previously **NOT** designated as a controlled substance, when is a pharmacy required to inventory the supply of this drug that it has in stock?

a. On the day that the DEA scheduled the drug.
b. Within 30 days of the date of the DEA's action.
c. Within 60 days of the date of the DEA's action.
d. Within 90 days of the date of the DEA's action.

13. You receive a prescription for Hydrocodone 10 mg/APAP 650 mg tablets No. 30. (C-III) You have only 15 tablets in stock. How much time do you have to supply the remaining 15 tablets?

a. 3 days
b. 5 days
c. 7 days
d. 180 days

14. You send a DEA Form 222 to a wholesaler to order drugs but the company does not have one of the requested items in current stock. How long does the wholesaler have to supply this drug?

a. 3 days
b. 7 days
c. 30 days
d. 60 days

15. Which of the following is a valid DEA number for Dr. Evelyn Johnson, pediatrician.

a. AJ 1234564
b. MJ1234563
c. AJ 1234563
d. AE1234563

16. Which federal official has the authority to define, by rule, an "emergency situation" as this term is used in the Controlled Substances Act?

a. The Attorney General
b. The Secretary of Health & Human Services
c. The DEA Administrator
d. The U. S. Surgeon General

17. Which of the following is a requirement for a pharmacist to be able to legally fill a verbal prescription for a Schedule II drug?

I. Immediate administration of the 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 III
d. I, II, and III

18. In which of the following medical conditions is it legal to prescribe a Schedule II stimulant drug in Washington State?

a. Narcolepsy
b. Cerebral Palsy
c. A.I.D.S.
d. Glaucoma

19. A hard copy prescription for a controlled substance must contain all of the following **EXCEPT**:

a. The prescriber's address
b. Date of issue
c. The symbols C-II, C-III, C-IV or C-V
d. The prescriber's DEA number

20. Which of the following is **NOT** a Schedule III drug?

a. Hydrocodone 5mg with Acetaminophen 325 mg tablets
b. Marinol (dronabinol) capsules
c. Testosterone 10 mg tablets
d. Valium (diazepam) 5 mg tablets

21. Which of the following practitioners are considered to be **EXEMPT** from registration by the DEA?

I. A physician in the U. S. Army
II. An Advanced Registered Nurse Practitioner employed by an Indian Tribe
III. A dentist in the U. S. Public Health Service

a. I only
b. III only
c. I and III only
d. I, II, and III

22. You have dispensed the following prescription calling for Hydrocodone 5 mg and Acetaminophen 325 mg tablets, No. 60, Refill 3 times, Sig: Take 1 tablet every 4 hours as needed for pain. (C-III) Assuming that you dispensed 60 tablets originally, how many times, prior to the expiration of the prescription, may you dispense partial refills if you dispensed 30 tablets with each subsequent refill.

a. 2 times
b. 4 times
c. 6 times total 240 - 60 = 180; 180/30=6
d. 8 times

23. A prescriber FAXed a prescription to your pharmacy for Morphine Sulfate Tablets sustained release 10 mg, No. 100, Sig: Take 1 tablet every 12 hours for pain. The prescription is for a hospice patient. You are allowed to fill the prescription as follows:

a. Only a 72-hour emergency supply may be dispensed
b. Only a 7 day supply may be dispensed
c. Only 21 day supply may be dispensed
d. The full quantity may be dispensed

24. The three ethical principles for conducting behavioral research established by the Belmont Report were:

a. Respect for persons, virtue and trust
b. Beneficence, justice and trust
c. Respect for persons, beneficence, justice
d. Beneficence, justice and virtue

25. Justice, in the context of biomedical ethics, refers to:

a. Making decisions that are fair to the patient
b. Ensuring the fair distribution of society's goods
c. Ensuring equal distribution of society's goods
d. Doing things in accordance with existing law

26. When would it be "OK" to administer an experimental therapy to a patient **WITHOUT** her/his consent?

I. The health care provider believes that the patient would refuse therapy if the therapy's potential adverse events were disclosed
II. The therapy to be provided represents standard of care
III. The patient is unconscious and failure to treat would lead to serious harm

a. I only
b. III only
c. I and III only
d. I, II and III

27. To whom of the following could prescription information **NOT** be provided **WITHOUT** a patient's authorization?

a. Medical personnel treating an immediate, life-threatening condition
b. An FDA investigator exploring drug manufacturing problems
c. A county sheriff
d. A researcher operating under an approved Institutional Review Board protocol

28. A Board of Pharmacy investigator presents her credentials and asks to be admitted to the pharmacy to review specified prescription records. What should you do?

a. Stall the investigator until your attorney arrives
b. Admit the investigator
c. Request to see a search warrant
d. Request to see consent forms for the specified prescription records

29. If the Board of Pharmacy promulgated a rule prohibiting physicians from dispensing controlled substances and the rule was challenged by physicians, which of the following reasons might a judge give for overturning the rule?

I. The Board had exceeded its statutory authority
II. The Board had made an error of law
III. The Board made a procedural error

a. I only
b. III only
c. I and III only
d. I, II and III

30. Which of the following are required for compliance with Washington rules when compounding a commercially available prescription drug?

I. Authorization by the prescriber
II. Ingredients are listed in an official compendium
III. Patient agrees

a. I only
b. III only
c. I and III only
d. I, II and III

Short Answer Questions. Answers written outside the provided space will not be graded.

31. Susan Morrison comes to your pharmacy requesting that you fill a prescription for her that she's received previously from a different pharmacy. As the **RECEIVING** pharmacist, please fill in the missing items on the transferred prescription below for a non-controlled substance prescription. (2 points)

Susan Morrison Today's date: 10/27/2008

TRANSFER

Synthroid 25 mcg #30
Sig: Take one tablet by mouth once daily

Dr. Jack Chen

Issue date of original prescription: 8/15/2008
11 refills on original prescription
Originally dispensed on 8/30/2008

Transferor Pharmacist: Mike Cheadle
153 First Avenue
Seattle, WA 98105
DEA number: MC2468759

Number of remaining refills \ Date and location(s) of all refills

32. Your colleague at the pharmacy is confused about what protected health information (PHI) she can disclose to another person without the patient's prior authorization. Help her by giving her two examples of situations where it is permissible to use and disclose PHI under applicable HIPAA rules. (2 points)

a. Treatment \ payment \ health care operations

b.

33. A state passed a law to the effect that a pharmacist could refill a Schedule II prescription two times when the patient requires continual use of the medication. (A) Would you comply with the state law? (B) Explain the legal principle that supports your decision. (2 points)

a. No, Federal law doesn't permit refills (1 pt)

b. Doctrine of preemption (1 pt) unless state law is more restrictive, which it isn't in this case (1 pt)

34. Please complete the following table with the list of the remaining four classes of prescription medications and their respective time limits / expirations in Washington. Follow the example provided. (2 points)

Prescription Medication Class	Washington Time Limit / Expiration
Schedule II	12 months
Schedule III	6 months
Schedule IV	6 months
Schedule V	12 months
Legend drug	12 months

35. Mary Johnson is a patient who you've been seeing in your pharmacy for several years. She enters your pharmacy and hands you a new prescription. You notice that the prescriber has written for oxycodone 10mg, which you do not have available in your pharmacy - you only stock the 5mg strength. You also notice another error on the prescription.

Please update the prescription below according to what is allowed for a pharmacist to change on a Schedule II controlled substance prescription. You may also indicate if something is incorrect that you cannot change (2 points, ½ point will be deducted for each incorrect recommendation)

Date: 10/27/2008

Patient name: Mary Johnson
Patient DOB: 4/24/1956
Patient address: 2868 Oak St. Seattle, WA 98105

Oxycodone 10mg #30
Sig: I tablet PO Q4hrs PRN pain
Refill: 2

Dr. Keith Monroe (signature)
DEA # AM2468759
525 Madison Ave. Seattle, WA 98105

Change strength to 5 mg, quantity to 60 and sig to 2 tablets; eliminate refills

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Ethics Question. Answers written outside the provided space will not be graded.

Evaluate issues of pharmacy practice law regarding the following, abstracted from a January 2008 news release from the US Food and Drug Administration. (2)

The U.S. Food and Drug Administration (FDA) sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called "bio-identical hormone replacement therapy," or "BHRT" products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA is concerned that unfounded claims like these mislead women and health care professionals.

The pharmacy operations improperly claim that their drugs, which contain hormones such as estrogen, progesterone, and estriol (which is not a component of an FDA-approved drug and has not been proven safe and effective for any use) are superior to FDA-approved menopausal hormone therapy drugs and prevent or treat serious diseases, including Alzheimer's disease, stroke, and various forms of cancer.

FDA is concerned that the claims for safety, effectiveness, and superiority that these pharmacy operations are making mislead patients, as well as doctors and other health care professionals. Compounded drugs are not reviewed by the FDA for safety and effectiveness, and FDA encourages patients to use FDA-approved drugs whenever possible. The warning letters state that the pharmacy operations violate federal law by making false and misleading claims about their hormone therapy drugs....

The pharmacy operations compound hormone therapy drugs that contain estriol as well as progesterone and estrogen. No drug product containing estriol has been approved by FDA and the safety and effectiveness of estriol is unknown....

FDA also responded today to a citizen petition from Wyeth, Madison, NJ, asking FDA to take regulatory action against compounding pharmacy operations that produce compounded "BHRT" drugs. Other stakeholders, including health care providers and consumer groups, have also raised concerns about "BHRT" drugs....

confined to WA's practice act and associated rules

- would it be OK if there was a valid prescriber-patient-pharmacist relationship? (Yes)
- advertising restrictions in WA
- compendial status of ingredients
- adequate drug compounding controls 246-878-100

Evaluate the ethical considerations for preparing the medication given the circumstances above. Stay inside the box. (8 points)

Describe the dilemma	
Perspective	
Beneficence	

Non-maleficence	
Autonomy	
Justice	
Virtue	
Root Cause	