Pharmacy 543 – Pharmacy Laws & Ethics
FINAL EXAMINATION
December 12, 2005

Questions 1-40 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 – 40 points. Questions 41-49 are short-answer, 20 points. Ethics question. 15 Points.

Exam total: 75 points.

**Legibility:** please verify that your written answers can be read by mere mortals, and your name and student number are legible and correct. Please double-check the student ID number for accuracy. Errors or omissions may delay or impact your grades.

**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.

Asking questions during the exam: you may **NOT** ask questions during the licensure examination, so none will be permitted during the exam. 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, FALSE** are presented in **BOLD, ALL-CAPS**.

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**MULTIPLE CHOICE QUESTIONS**

1. How many hours of continuing education credit must a 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

2. Which of the following states have more stringent limits on the reciprocity of pharmacist licenses than does Washington State?
   
   I. Florida  
   II. California  
   III. Hawaii  

   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 prescriptions is NOT required to be packaged in a child resistant container (CRC)?

A. Tylenol with codeine 15 mg. No. 10.
B. Ortho-Novum Birth Control tablets 1/50 in 28 tablet memory pack.
C. Doxycycline capsules 250 mg. No. 40
D. Nitroglycerin sustained release capsules 2.5 mg. No. 100.
E. Warfarin sodium tablets 5 mg. No. 30

4. Which of the following methods of controlled substance storage may be utilized by a community pharmacy?

I. Stored together in the "Fast Movers Section".
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

5. For which of the following drugs must you provide an EXACT count when you perform your DEA required controlled substances inventory?

I. A bottle containing 97 Morphine Sulfate 10 mg tablets (Schedule II)
II. A bottle containing 4,750 Aspirin with Codeine 30 mg tablets (Schedule III)
III. A bottle containing 832 Meprobamate tablets (Schedule IV)

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

6. Which of the following is NOT a requirement in order to sell a Schedule V cough syrup in Washington?

A. The purchaser must be at least 18 years old.
B. The drug must be intended for use for its labeled purpose.
C. The pharmacist must initial and date the container.
D. The sale must be recorded in the Schedule V record book.
E. The purchaser must sign the Schedule V record book.

WAC 246.887.030 specifies 21; any answer for this question was accepted

7. Which of the following agencies MUST be notified in case of any theft or significant loss of controlled substances?

I. The Washington State Patrol Narcotics Unit
II. The State Board of Pharmacy
III. The Drug Enforcement Administration

A. I only
B. III only
C. I and II only
8. How many legislators' affirmative votes does it take in order to pass a bill for consideration of the Governor for her signature?
   A. 25
   B. 49
   C. 74
   D. 98
   E. 100

9. Prior to January 2006, when Medicare Part D becomes fully effective, for which of the following types of prescription drugs will Medicare reimburse?
   A. Prescription drugs that must be administered by a licensed health professional only.
   B. Prescription drugs that are on an insurance company's approved formulary only.
   C. Schedule II Controlled Substances only.
   D. Non-controlled drugs only.
   E. Biotech drugs only.

10. Which of the following are characteristics of the Medicare program?
    I. The program is funded by federal funds only.
    II. The program is restricted to persons over the age of 65 and a limited number of other patients
    III. The program is administered by the States
    A. I only
    B. III only
    C. I and II only
    D. II and III only
    E. I, II, and III

11. A hospital that meets which of the following requirements is considered to be in compliance with Medicare requirements?
    I. Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)
    II. Washington State Department of Health (DOH)
    III. American Hospital Association (AHA)
    A. I only
    B. III only
    C. I and II only
    D. II and III only
    E. I, II, and III

12. Which of the following may NOT dispense prescription drug samples?
    A. Retail pharmacies.
    B. Hospital pharmacies
    C. HMO pharmacies
    D. Physician Assistants
E. Advanced Registered Nurse Practitioners

13. In order to obtain a pharmacist license in Washington, how many hours of internship is a student pharmacist required to obtain in addition to the hours that are provided through the school of pharmacy experiential rotations.

A. 100  
B. 200  
C. 300  
D. 500  
E. 1,000

14. Which of the following pharmacists is EXEMPT from the continuing education hours required to renew a pharmacist license?

I. Pharmacists who are renewing their license for the first time.  
II. Pharmacists who have received a waiver from the Board of Pharmacy  
III. Pharmacists licensed by reciprocity who are renewing their license for the first time

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

15. An ARNP wishes to purchase a bottle of Meperidine (Demerol) 50 mg/ml Injection 10 x 1 ml syringes (Schedule II) to be administered to patients in the ARNP's office practice. Which of the following documents should be used to record this transaction?

A. A DEA form 222 signed by the ARNP. 
B. A prescription showing the name of the ARNP as the patient. 
C. A prescription marked, "For Office Use Only". 
D. A prescription showing the name of the ARNP's office staff member. 
E. An invoice signed by the ARNP.

16. Which of the following professional responsibilities are restricted to pharmacists and may NOT be performed by technicians or assistants?

I. Receipt of verbal prescriptions from practitioners.  
II. Consultation with patients about their prescriptions.  
III. Entering original prescription data into a pharmacy computer system.

A. I only  
B. III only  
C. I and II only  
D. II and III only  
E. I, II, and III
17. Which of the following are allowed in Skilled Nursing Facilities?

I. Administration of drugs by non-licensed personnel.
II. Emergency kits.
III. On-site destruction of expired controlled substances.

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

18. When a grocery store is open for longer hours than the pharmacy located therein, the legal Board of Pharmacy term for this situation is which of the following:

A. Extraordinary hours
B. Differential hours
C. Mercantile hours
D. Shopkeeper hours
E. Exceptional hours

19. When a pharmacy operates under the conditions described in question number 18, which of the following activities may be performed?

I. Patients may leave prescriptions in a mail slot or drop box for later pick up.
II. Patients may pick up refilled prescriptions if no counseling is legally required.
III. Technicians may continue to work in the pharmacy until the pharmacist is again on duty.

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

20. A patient enters the pharmacy on a Sunday afternoon requesting a refill of a prescription but when you look it up you determine that there are no authorized refills remaining on the prescription. According to Board of Pharmacy rules you may dispense up to a 72 hour supply of the drug IF the prescription is for which of the following drugs:

I. Atenolol 50 mg Tablets (Legend Drug)
II. Promethazine 6.25 mg with Codeine 20 mg/5 ml (Schedule V)
III. Tylenol 300 mg with Codeine 30 mg Tablets (Schedule III)

A. I only
B. III only
C. I and II only
D. II and III only
E. I, II, and III
21. Which of the following complaints to the Board of Pharmacy would \textbf{NOT} be within the jurisdiction of the Board?

A. The pharmacist incorrectly filled a prescription.
B. A pharmacy assistant diverted controlled substances.
C. The pharmacy failed an inspection.
D. A pharmacy’s controlled substances records are inaccurate.
E. The pharmacy overcharged for a prescription.

22. Which of the following licensees may \textbf{NOT} be fined by the Board of Pharmacy for violations of law or rule?

A. Pharmacists
B. Pharmacy Assistants
C. Pharmacy Technicians
D. Pharmacies
E. Pharmacy Responsible managers

23. Which of the following drugs may be purchased and used by Animal Control Agencies or Humane Societies that are registered with the Board of Pharmacy?

I. Sodium Pentobarbital
II. Sodium Amobarbital
III. Ketamine

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

24. For which of the following medical conditions may Schedule II stimulant drugs \textbf{NOT} be prescribed?

I. Narcolepsy
II. Attention-deficit Hyperactivity Disorder (ADHD)
III. Bipolar Disorder

A. I only
B. III only
C. I and II only
D. II and III only
E. I, II, and III
25. According to the Supreme Court decision in Abbott Labs et al v. Portland Retail Druggists Assn. 425 US 1 (1976) concerning "Own use" provisions, to which of the following may a hospital provide prescription drugs that it has purchased at a discounted price?

I. Inpatients for use in the hospital
II. Emergency room patients
III. Physicians for use in their office practice

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

26. For which of the following purposes may a pharmacy legally sell sterile needles and syringes?

I. Use by Needle exchange programs.
II. Use by Injection Drug Users (IDU) to prevent blood borne diseases.
III. Use by model airplane builders to apply small amounts of glue.

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

27. Which of the following restrictions did the 2005 Washington State Legislature place on the OTC distribution of pseudoephedrine products?

I. No public access (self-service) to obtain the drug.
II. No person may purchase more than 2 packages in a 24-hour period.
III. All purchasers must show photo identification.

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

Please read both questions 28 and 29 before answering them.

28. Which of the following is MORE predictive that a pain patient may be an addict rather than being under-treated?

I. Forging controlled substance prescriptions
II. Injecting an oral formulation
III. Obtaining prescription drugs from non-medical sources

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 is **LESS** predictive that a pain patient may be an addict as opposed to being under treated?

   I. Aggressive complaining about the need for higher doses.
   II. Drug hoarding during periods of reduced symptoms.
   III. Requesting specific drugs for treatment.

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

30. Pharmacy refusal ("conscience") clauses implicate ethical issues of

   I. Patient autonomy
   II. Beneficence
   III. Justice

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

31. Public policy exceptions to the "at will" employment doctrine include:

   I. State Statutory rights protection
   II. Court interpretation of Employer-Employee Contracts
   III. Court interpretation of an Employee handbook

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

32. Pharmacy internship requirements include:

   I. Supervision by a Pharmacist preceptor who is certified by the BOP.
   II. Preceptor report to BOP of intern's profession experience gained.
   III. Yearly submission of Intern Site Evaluation Report to BOP.

   A. I only
   B. III only
   C. I and II only
   D. II and III only
   E. I, II, and III
33. Pharmacist responsibilities to prevent drug diversion include:
   I. Maintain knowledge of presently abused drugs.
   II. Follow established procedures.
   III. Keep accurate notes and records.

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

34. Under Medicare Part D, pharmacists may face much larger exposure to fraudulent claims against the federal government.

   A. TRUE  
   B. FALSE  

35. The doctrine of double effect
   I. distinguishes intended outcomes from unintended outcomes
   II. is based upon the intent of the providers
   III. may shield a health care provider from a criminal homicide charge in a death from overdose.

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

36. A valid health care directive in Washington state requires

   I. That it be in writing.
   II. That it be signed by declarant with 2 witnesses unrelated by blood or marriage.
   III. That it be witnessed by potential heirs of the estate.

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

37. Which of the following statements must be present on labels of prescription drugs dispensed in Washington?

   A. Caution, federal law prohibits dispensing without a prescription.
   B. Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.
   C. Caution: state or federal law prohibits dispensing without a prescription.
   D. Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.
38. Which of the following are potential violations of HIPAA’s privacy rule and Washington’s Uniform Health Care Information Act (RCW 70.02)?

I. Disposal of pharmacy computer system label debris in the trash
II. Dispensing of prescriptions to persons other than the patient
III. Viewing computer screens showing protected healthcare information for patients with whom you do not have a professional relationship

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

39. In Washington, if you were discharged from a job with an employer such as a chain pharmacy because you objected to participating in an activity you believed to be illegal or dangerous, you might be protected under:

I. “Statutory torts”  
II. Duty of fair representation  
III. Wrongful discharge against public policy

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

40. Which federal agency has primary responsibility for tamper-resistant closure requirements?

A. Consumer Product Safety Commission  
B. Environmental Protection Agency  
C. Food and Drug Administration  
D. Department of Health and Human Services
SHORT ANSWER QUESTIONS – 20 points total

Please confine your response to the space provided (inside the box) and write legibly.

41. When transferring a controlled substance prescription from one pharmacy to another over the telephone, DEA and Washington require that certain information be documented. Complete the following chart. (5 points)

<table>
<thead>
<tr>
<th>Pharmacy FROM which controlled substance prescription is transferred</th>
<th>Pharmacy TO which controlled substance prescription is transferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal classification of person implementing transfer</td>
<td></td>
</tr>
<tr>
<td>Information element that must be documented – four each for the FROM and TO pharmacies</td>
<td></td>
</tr>
</tbody>
</table>

42. Name the individuals who are authorized to request NON-child-resistant prescription containers. (1 point)

a. 

b. 

43. A pharmacy intern licensed in Washington State may perform <a.> functions of a pharmacist under the <b.> of a pharmacist. (1 point)

<a.> 

<b.> 

44. Most Health care Providers involved in drug diversion are doing it for _____. (1 point)
45. Provide four examples each of misbranding and adulteration (4 points)

<table>
<thead>
<tr>
<th>Misbranding</th>
<th>Adulteration</th>
</tr>
</thead>
<tbody>
<tr>
<td>label or labeling false or misleading (4 points)</td>
<td>made from bad stuff (4 points)</td>
</tr>
<tr>
<td>labeling not understandable under conditions of</td>
<td>failed to register / no distributor/mfg address</td>
</tr>
<tr>
<td>intended use (4 points)</td>
<td>container/closure system could result in A (4 points)</td>
</tr>
<tr>
<td>mfg in a way that could result in A (4 points)</td>
<td>failure to register / no distributor/mfg address</td>
</tr>
<tr>
<td>following labeling could result in health hazard,</td>
<td></td>
</tr>
<tr>
<td>strength/quantity differs from claim (4 points)</td>
<td></td>
</tr>
</tbody>
</table>

46. "At will" employment means Employer can terminate Employee's job for _____. (1 point)

47. What is the legal basis of the federal government’s objection to Oregon’s Death with Dignity Act, currently under review by the Supreme Court? (2 points)

Controlled Substances Act, as amended, requires that controlled substance only be used for "legitimate medical purposes"; the AG decided that physician assisted suicide as practiced in Oregon was not a legitimate medical purpose; HC providers that facilitated assisted suicide could be subject to criminal trafficking charges, etd., under the CSA.

48. Make up a valid, complete DEA number for an ARNP named Paula K. Johnson. Show your computations for verifying the number. (4 points)

DEA Number | ____|____|____|____|____|____|____|____|____|____|____|

Computations

1+5+4 + 2(3+2+6) = 32; check digit is 2

49. What is the regulatory concern regarding "secondary wholesalers" in the pharmaceuticals industry. (1 point)
ETHICS CASE – 15 points

Please confine your response to the space provided (inside the box) and write legibly.

Rachel Pourchot says she was stunned when a pharmacist refused to fill her Plan B prescription. The 27-year-old St. Louis resident and her long-term boyfriend already use two forms of birth control. But, Pourchot said, she wanted to have Plan B on hand -- just in case she was assaulted or if the other control methods failed. So during a lunch break on a Friday in September, she and a friend went to a Target in Fenton. Pourchot wanted to get a refill of her birth control pills and Plan B. "I just took it for granted that they were going to fill it. It's a federally-approved drug. It was written out by a doctor," said Pourchot, a mental health counselor. A technician said the pharmacy could fill the birth control pills but did not have any morning-after pills in stock, Pourchot said. Then the pharmacist added that she would not fill it anyway and "that is my right," Pourchot recalled. "I didn't think a real pharmacist would say, 'No, I'm not going to do it,'" Pourchot said. A Target spokeswoman disputed that the pharmacist refused to fill the prescription but confirmed that Plan B was out of stock that day.

From: Todd C. Frankel | ST. LOUIS POST-DISPATCH. St. Louis Post - Dispatch. St. Louis, Mo.: Dec 4, 2005. pg. B.1

50. Several legal theories have been presented in class regarding pharmacists’ obligation to dispense valid prescriptions; some relate to a specific interpretation of a federal act. Name the act and the required behavior. (3 points)

<table>
<thead>
<tr>
<th>federal act</th>
<th>required behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Civil Rights Act</td>
<td>reasonable accommodation</td>
</tr>
</tbody>
</table>

51. How effective is the “we are out of that” / “we don’t stock that” claim? Specifically, if a patient was in some way harmed as a consequence of being told “we don’t have that” and forgoing the treatment when indeed you did have the prescribed drug, what actions might be brought by the Board of Pharmacy? (4 points)

See reverse side.
**Ethics Evaluation.** Explain each of the principles and values below. Limit your answers to the space provided for each section. (8 points)

<table>
<thead>
<tr>
<th>Perspective (1)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Beneficence (1)</td>
<td></td>
</tr>
<tr>
<td>Non-maleficence (1)</td>
<td></td>
</tr>
<tr>
<td>Autonomy (1)</td>
<td></td>
</tr>
<tr>
<td>Justice (1)</td>
<td></td>
</tr>
<tr>
<td>Virtue (1)</td>
<td></td>
</tr>
<tr>
<td>Root Cause (2)</td>
<td></td>
</tr>
</tbody>
</table>