

Last Name	First Name

Student Number							

**Pharmacy 543 – Pharmacy Laws & Ethics  
FINAL EXAMINATION  
December 14, 2009**

**Instructions**

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, 45 points.
- Short-answer, 20 points.
- Ethics question, 10 Points.
- Exam total: 75 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 grades.

Turn in:

- (1) the Standard Answer Form ("bubble sheet", "Scantron")
- (2) your answers to the short answer questions (**1 sheet 2 sides**) and the ethics question (**1 sheet 2 sides**)
- (3) this page, only if 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, identify the question and "flaw" below.

Terms such as **NOT, TRUE, FALSE** are presented in **BOLD, ALL-CAPS**.

If you believe that a question is technically flawed, please describe below and turn in this page. Please don't turn in the exam question itself.

Question Number	Describe the "flaw"

Page left intentionally blank

## MULTIPLE CHOICE QUESTIONS

1. What did Initiative 1000 (Death with Dignity) change in WA's Natural Death Act?
  - a. Authorized mercy killing
  - b. Authorized active euthanasia
  - c. Authorized physician assisted suicide
  - d. Authorized deliberate omission of health care to end life
  
2. There is a difference in the number of grams of pseudoephedrine that may be purchased at one time because the State of Washington and the DEA calculate this amount differently. Which of the following is used by the DEA?
  - a. Base
  - b. Salt
  - c. Molecular weight
  - d. Total tablet weight
  
3. Under the Americans with Disabilities Act, which of the following questions would **NOT** be permitted during a pre-employment interview.
  - I. Ability to complete a specified task
  - II. Credit status
  - III. Existence of a medical condition
  - a. I only
  - b. III only
  - c. I and III only
  - d. I, II and III
  
4. The term "at will employment" means that an employer may discharge an employee for which of the following without fear of liability?
  - I. No cause
  - II. Morally wrong cause
  - III. Good cause
  - a. I only
  - b. III only
  - c. I and III only
  - d. I, II and III

5. Which of the following is generally **TRUE** about work environment requirements?
- I. Employer must supply uniform when required in the workplace
  - II. Polygraph testing is allowed
  - III. Drug testing and monitoring is allowed
- a. I only
  - b. III only
  - c. I and III only
  - d. I, II and III
6. Who is responsible for drug storage areas in a hospital pharmacy as specified in Washington law?
- I The Director of Nursing
  - II The hospital's Chief Executive Officer
  - III The Director of Pharmacy
- a. I only
  - b. III only
  - c. I & III only
  - d. I, II and III
7. What frequency of inspections is required for nursing care units and other areas where medications are dispensed, administered or stored in Washington hospitals?
- a. Weekly
  - b. Monthly
  - c. Semi-annually
  - d. Yearly
8. Under which body of law are pharmacists required to report drug diversion?
- I. Drug Enforcement Administration, Department of Justice [21CFR1300 et seq.]
  - II. Whistleblower Complaints in Healthcare Settings [WAC 246-15]
  - III. Pharmacy Licensing [WAC 246-869]
- a. I only
  - b. III only
  - c. I and III only
  - d. I, II and III
9. What is the regulatory concern regarding "secondary wholesalers" in the pharmaceuticals industry?
- a. Sherman Antitrust violations
  - b. Robinson-Patman violations
  - c. Entry point for counterfeit products
  - d. Traceability problems with Type III recalls
10. Which class of medical devices generally requires clinical trials to demonstrate safety

under conditions of intended use?

- a. Class I
- b. Class II
- c. Class III
- d. Class IV

11. Washington's Uniform Health Care Information Act (RCW 70.02) specifies when disclosure of health care information is permitted without patient authorization. Which of the following is a permitted disclosure?

- I. To a person reasonably believed to be providing health care to the patient
  - II. For a research project if approved by an Institutional Review Board
  - III. To provide directory information, unless the patient has instructed the health care provider or health care facility not to make the disclosure
- a. I only
  - b. I and II only
  - c. I and III only
  - d. I, II and III

12. A patient comes to the pharmacy and asks to review his/her prescription records. Which of the following is **TRUE**?

- I. Request must be in writing
  - II. Requested documents must be provided in 15 working days, if possible
  - III. Provider must explain any codes used in the records
- a. I only
  - b. I and II only
  - c. I and III only
  - d. I, II and III

13. Which of the following is **TRUE** about harassment in the workplace?

- I. Employers must establish an anti-harassment policy
  - II. Jokes about other people's cultural practices cannot be considered harassment if they are told in good humor
  - III. Unwelcome physical contact could be considered harassment
- a. I only
  - b. III only
  - c. I and III only
  - d. I, II and III

The following scenario applies to questions 14 - 18.

It's your first week as a pharmacy intern at Billy's Pharmacy and your boss (Billy, the store owner) asks that you pay attention in order to learn how he keeps the store profitable – just as 85-year-old Mae walks in the front door.

Here's what you witness as Mae asks if her Medicaid coupon or Medicare will pay for her flu shot that her primary care doctor, Dr. Krum, sent her to get from Billy.

14. Billy first directs Mae to an OTC cough syrup, telling her that it's good to have some of his private label guaifenesin (generic Robitussin™) syrup on hand during the cold season. The 4 oz. bottle costs Mae \$14.50 cash but you saw on an invoice that Billy only paid \$0.75 per bottle.
15. Billy lets Mae know that neither Medicaid nor Medicare covers flu shots and tells her that she will need to pay \$45 cash. He tells her that he will give her a 2% senior discount, however.
16. While Billy gives Mae her flu shot, you check to see if Mae has any prescriptions to pick up and notice that 3 of her prescriptions are still on the pickup shelf from 35 days ago. You pull Billy aside and ask about those prescriptions and he tells you to go ahead and fill 3 "fresh" prescriptions for Mae and to bill her insurance.
17. After Mae leaves, you witness Billy billing Medicare for the flu shot, the syringe, the gauze, the injection and the "Band-aid".
18. Dr. Krum received a customary "thank you" card from Billy with a crisp \$50 bill inside.

Which of these transactions performed by Billy might be considered "fraud" by a court of law or an insurance company? Match the above observations with the terms below.

Example: billing for a "ghost" patient – patient never seen

Question	Answer	Term
Example	a.	a. billing for goods not provided to the patient b. kickback c. not technically fraud d. Qui tam e. unbundling
14.		
15.		
16.		
17.		
18.		

19. A pharmacy student accepts a job as an intern in a pharmacy. Who is responsible for confirming the certification status of the preceptor?
- The Intern
  - The Preceptor
  - The Pharmacy
  - The Board of Pharmacy
20. When a pharmacist is working in the pharmacy, which of the following may be performed under the Board of Pharmacy rules concerning "Pharmacist Responsibilities?"
- A pharmacy technician consults a patient profile at the request of a physician to determine when the patient received her most recent refill.
  - A pharmacy assistant receives a telephoned request to refill a prescription.
  - A properly supervised pharmacy intern performs the final check on a prescription.
- I only
  - III only
  - I and III only
  - I, II, and III
21. Which of the following are acceptable alternatives to dispensing a medical product pursuant to a valid prescription in Washington?
- If unavailable in pharmacy, obtain and deliver when available
  - Routinely refer patient to another pharmacy if local pharmacist objects to dispensing for moral or ethical reasons
  - Return the prescription to the patient
- I only
  - III only
  - I and III only
  - I, II and III
22. Which of the following are allowed in Skilled Nursing Facilities?
- Emergency kits containing legend drugs.
  - Administration of drugs by non-licensed personnel.
  - On-site destruction of expired controlled substances.
- I only
  - III only
  - I and III only
  - I, II and III

23. Which of the following are **FALSE** about pharmacies located within a larger mercantile establishment which is open to the public for business at times when a pharmacist is not present?
- a. Custodial services may be provided when the pharmacy is closed
  - b. The pharmacy must be enclosed by partitions sufficient to provide adequate security
  - c. Answer phones for recording oral prescriptions must inform the caller as to the time the pharmacy is open
  - d. Pharmacy hours of operation must be displayed at the mercantile establishment's entrance
24. How soon must the Board of Pharmacy be notified about the appointment of a "responsible manager"?
- a. Immediately
  - b. 10 business days
  - c. 14 calendar days
  - d. 1 month
25. Which of the following is/are **TRUE** about electronic prescription transfers?
- I. Must be between two or more pharmacies with a common data base
  - II. The electronic system must provide audit trail capabilities
  - III. The electronic system must assure that the number of authorized refills is not exceeded
- a. I only
  - b. III only
  - c. I & III only
  - d. I, II and III
26. "Adequate facilities" for pharmacies include all of the following **EXCEPT**?
- a. Adequate ventilation including air conditioning
  - b. An 18 inch x 36 inch counter available at all times
  - c. Hot and cold running water in the compounding area
  - d. Refrigerator capable of maintaining 2-8° Celsius
27. Who may determine if patient counseling is required when dispensing a new or refilled prescription?
- I. The patient
  - II. Pharmacy technician
  - III. The pharmacist
- a. I only
  - b. III only
  - c. I and III only
  - d. I, II and III
28. Which of the following is **NOT** a schedule III drug?

- a. Hydrocodone 5mg with Acetaminophen 750 mg
  - b. Marinol 2.5 mg (dronabinol)
  - c. Valium (diazepam) 2 mg
  - d. Pentobarbital suppositories 50 mg
29. Which of the following practitioners are **EXEMPT** from registration with the DEA?
- I. A physician's assistant in the U.S. Air Force
  - II. A pharmacist in the VA (Dept. of Veterans Affairs)
  - III. An ARNP in the US Public Health Service
- a. I only
  - b. III only
  - c. II and III only
  - d. I, II, & III
30. Which of the following DEA numbers would be a valid number for Amy Snow, DO?
- a. AA 1234563
  - b. AS 1234563
  - c. MS 1234564
  - d. BA 1234564
31. How long must a pharmacy retain controlled substances records to comply with DEA regulations?
- a. 6 months
  - b. 12 months
  - c. 18 months
  - d. 24 months
32. Which of the following records is required when a pharmacist sells a Schedule II controlled substance to a physician for use in the physician's office?
- a. DEA form 222 signed by the physician
  - b. DEA form 222 signed by the pharmacist
  - c. A prescription signed by the physician
  - d. An invoice signed by the pharmacist and the physician
33. Which of the following practitioners may prescribe Suboxone (buprenorphine) for a patient in Washington?
- a. A physician (MD)
  - b. A physician Assistant (PA)
  - c. A naturopathic physician (ND)
  - d. An Optometrist (OD)

34. Which of the following prescriptions need **NOT** be dispensed in a child resistant container (CRC)?
- I. Nitroglycerin sublingual tablets 0.4 mg, No. 100
  - II. Emergency contraception
  - III. Isosorbide oral tablets
- a. I only
  - b. III only
  - c. II and III only
  - d. I, II, & III
35. Which of the following persons may authorize the dispensing of a prescription drug in a non-child resistant container?
- I. Patient
  - II. Pharmacist
  - III. Prescriber
- a. I only
  - b. III only
  - c. I and III only
  - d. I, II, & III
36. When a drug is labeled with an expiration date of December 2009, what day of the month does the drug expire?
- a. December 1.
  - b. December 7.
  - c. December 15.
  - d. December 31.
37. Under which of the following circumstances could the Washington State Board of Pharmacy **NOT** take action against a pharmacist?
- a. Allegations that the pharmacist had violated the Federal Food, Drug, and Cosmetic Act.
  - b. Allegations that the pharmacist had violated the Federal Controlled Substances Act.
  - c. Allegations that the pharmacist had violated the Washington State Poison Control Act.
  - d. Allegations that the pharmacist had violated the Washington Consumer Protection laws by overcharging for a prescription.

38. When a pharmacist receives a Statement of Charges from the Board of Pharmacy, which of the following actions should he/she take?
- Ignore the document if it was not served on the pharmacist by a sworn police officer.
  - Respond to the Board within 21 days.
  - Call the Board office to request additional information.
  - Call any attorney who is listed in the Yellow Pages.
39. When a pharmacist is **NOT** available in a pharmacy, that is operating under differential hours, which of the following actions are allowed?
- A pharmacy technician may dispense a refilled prescription that is waiting on the will call shelf.
  - The patient may leave the prescription or refill request in a locked box outside of the pharmacy.
  - The patient may leave the prescription or refill request with the store manager.
  - The patient may phone in a refill request to a phone that may be answered in the open portion of the store.
40. A pharmacist is found to be abusing marijuana and refuses to surrender her license or enter the Washington Recovery Assistance Program for Pharmacists (WRAPP.) Which of the following actions is the Board of Pharmacy allowed to take?
- None because marijuana is not an FDA approved drug product.
  - None because marijuana is not listed in the Uniform Disciplinary Act.
  - None if the pharmacist claims the marijuana is for a medical purpose.
  - Summary suspension of the license.
41. From which of the following practitioners, licensed in Idaho, may a Washington pharmacist **NOT** accept prescriptions?
- dentist
  - osteopath
  - physician assistant
  - veterinarian
42. With which of the following prescribers may a Washington pharmacist **NOT** engage in a Collaborative Drug Therapy Agreement?
- Advanced Registered Nurse Practitioner
  - Physician Assistant - Certified
  - Naturopathic Physician
  - Veterinarian

43. When a pharmacy provides prescription drugs in Med-Packs (compliance packaging), which of the following is **NOT** required on the prescription label?
- a. Names of each of the drugs
  - b. Patient's name
  - c. Patient's address
  - d. Date of issue
44. Which of the following may **NOT** possess, distribute, or dispense prescription drugs that are labeled, "Physician Samples"?
- a. Joe's Community Pharmacy, Inc.
  - b. Merciful Hospital, Inc.
  - c. Our Free Clinic, Inc.
  - d. Gigantic HMO, Inc.
45. Which of the following out of state distributors are **NOT** required to be licensed in Washington?
- a. A wholesaler that only ships to its own branch in Washington.
  - b. A wholesaler that only ships to dental offices in Washington.
  - c. A manufacturer that only ships to 5 pharmacies in Washington
  - d. A wholesaler that only ships to members of one pharmacy chain in Washington

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**Short Answer Questions**  
(20 Points)

46. What would be required for a pharmacist to alter the flavor of an over-the-counter cough-cold preparation? (1)

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47. In Washington state, a hours of pharmacy continuing education are required every b year(s) for pharmacy license renewal. (2)

a.	
b.	

48. Your pharmacy recently underwent an inspection by the Washington Board of Pharmacy and you get a score of 85. (2)

a. How long do you have to obtain a Class A score?	
b. What is the minimum inspection score required for Class A rating?	

49. The Institute for Safe Medication Practices has identified several "look alike sound alike" medications. For example: Aricept (used to treat Alzheimer's disease) and Azilect (used to treat Parkinson's disease) are on the ISMP list. Who is responsible for reviewing and approving brand and generic drug names? (1)

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50. Dr. Jones is an endorsing practitioner for the Washington Preferred Drug List (PDL). She is treating a Medicaid patient and wishes to prescribe a proton-pump-inhibitor that is not on the state PDL for this class of drugs. How can she override the preferred drug substitution? (1)

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51. Which state agency inspects nursing homes for compliance with Medicare Conditions of Participation? (1)

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52. Complete the following table, indicating differences between Medicare and Medicaid. (6)

	Medicare	Medicaid
Source of funding for program (state or federal)		
Who sets reimbursement rates		
Can prices be negotiated with pharmaceutical companies under current law		

53. In the state of Washington, who is required to authorize the use of a compounded product that is substituted for a commercially available product?

54. A device manufacturer has developed a medical laser for "cutting or ablation" of tissues. To obtain FDA approval of this product, the company compared safety and efficacy of the laser with an existing heated wire cautery device (standard in industry at the time). This is an example of what type of device approval?

55. When a physician prescribes Subutex (buprenorphine) to maintain an opiate addict, he/she must obtain a modified DEA registration number from the DEA. How does this number differ from the physician's previous number?

56. If a Washington prescriber writes a prescription for a brand name drug and has signed a prescription on the signature line that is located on the \_\_\_\_\_ side of the prescription he/she has authorized the pharmacist to substitute an equivalent generic drug.

57. Provide an example of individuals or institutions to which a hospital pharmacy may **NOT** sell prescription drugs **EXCEPT** in an emergency?

another hospital with the same ownership, a physician for personal use, a hospital employee, community pharmacy

58. Under Washington law, how long must a pharmacy retain prescription records?

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### Ethics Case

The following was abstracted from the 01Dec2009 Wall Street Journal.

**"CVS Accused of Selling Expired Products"** By Chad Bray

America's largest pharmacy chain CVS/Pharmacy is being sued by Connecticut Officials over allegations that the chain has been selling food and various over-the-counter drugs which have been way past their expiration dates in many of its Connecticut based stores. Connecticut Attorney General Richard Blumenthal said Monday that his office is suing a unit of CVS Caremark Corp. for allegedly selling expired over-the-counter drugs and other products in its stores in Connecticut.

In a statement, Mr. Blumenthal said investigators from his office found expired food, beverages and over-the-counter medications on sale in 20 or more CVS stores in Connecticut in the summers of 2008 and 2009. The lawsuit was filed against CVS Pharmacy Inc. by Mr. Blumenthal's office in cooperation with Connecticut Department of Consumer Protection Commissioner Jerry Farrell Jr.

"Basic business law and ethics give consumers a right to unspoiled food and safe and effective medicine," Mr. Blumenthal said. "I will fight for significant penalties against CVS, sending a powerful message that expiration dates must be respected. Any item past its expiration date should be off shelves, out of stores."

Earlier this month, CVS agreed to pay \$875,000 in penalties, costs and fees to end a probe by New York Attorney General Andrew Cuomo into the sale of expired products in its New York stores. CVS also agreed to commit to policies and procedures designed to prevent expired products from being stocked on its shelves, including training for CVS employees.

59. With regard to over-the-counter drugs, which Act has CVS violated and what single-word term from the Act is used to describe the violation?

a. Act	
b. term	

60. Evaluate the pharmacy practice ethical considerations for the abstracted case. (8)

<b>Describe the dilemma</b>	
<b>Perspective</b>	
<b>Beneficence</b>	
<b>Nonmaleficence</b>	

<b>Autonomy</b>	
<b>Justice</b>	
<b>Virtue</b>	
<b>Root Cause</b>	