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**Pharmacy 543 – Pharmacy Laws & Ethics
FINAL EXAMINATION
December 11, 2006**

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 41-53 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.**

.....
MULTIPLE CHOICE QUESTIONS

1. What does "at will" mean in the context of labor law?
 - a. Your work schedule is flexible
 - b. You are protected from being fired for frivolous reasons
 - c. You can be fired at any time *
 - d. You are not subject to time and one-half pay for overtime

2. Assuming Greg and Mike have valid advance directives and wills as above, under the Washington Natural Death Act, which additional individual must retain a copy of each brother's valid advance directive?
 - a. The attorney(s) who wrote each brother's will
 - b. Greg and Mike's father (mother is deceased).
 - c. Each brother's primary care physician (PCP) * RCW 70.122.030
 - d. Greg's girlfriend and Mike's fiancée.

3. Under federal and Washington law, what is a pharmacist's obligation if s/he suspects that a coworker is diverting controlled substances?
- I. Report the suspected diversion to the employer
 - II. Report the suspected diversion to the Drug Enforcement Administration
 - III. Report the suspected diversion to the Washington Board of Pharmacy
- a. I only * 21CFR1309-- Sec. 1301.91 Employee responsibility to report diversion
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II and III.
4. Under the Americans with Disabilities Act, which of the following questions would **NOT** be permitted during an 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 II only
 - d. II and III only
 - e. I, II and III
5. Greg and Mike Z. are fraternal twin brothers, born February 23, 1980. Both are in exceptional health. Both brothers live in the Seattle city limits in two different residences, both at least since February 2004. Both brothers filed valid wills disposing of their respective real and personal property with the King County auditor on October 1, 2006. Note that each brother's will was validly executed and neither brother was named as a beneficiary or served as a witness on the opposite brother's will.
- Now it is December 4, 2006, and each brother wants to file a copy of their individual health care advance directive (living will) with the most appropriate individual. If Greg signed as a witness on Mike's advance directive and Mike signed as a witness on Greg's advance directive, then how many additional witness signatures would each brother have to obtain before either advance directive would be considered valid under Washington Law?
- a. One
 - b. Two * RCW 70.122.030
 - c. Three
 - d. Four
6. Which of the following constitute workplace harassment?
- I. Frequent derogatory comments about women, even though not sexual in nature
 - II. Unwelcome conduct by a person of the same gender
 - III. Frequent derogatory comments about a supervisor
- a. I only
 - b. III only
 - c. I and II only *
 - d. II and III only
 - e. I, II and III.

Name: _____

Last

First

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

7. The federal Family and Medical Leave Act provides which of the following protections?
- 6 weeks paid leave for adoption
 - 12 weeks paid leave for birth
 - 18 weeks unpaid leave for child's serious health condition
 - 12 week unpaid leave for own illness *
8. Which of the following would NOT be considered "Life Sustaining Treatment" under Washington's Natural Death Act?
- Water and nutrition given via tube feeding (enterally)
 - Intubation and respiration via ventilator
 - Renal dialysis
 - Narcotics for end-stage cancer pain (regardless of route of administration) * RCW 70.122.020
9. Under Washington law, what can an individual acting as attorney-in-fact under a valid durable power of attorney do that an individual acting under a general power of attorney cannot? Assume documents enabling attorney-in-fact in either case are VALID.
- Write checks in principal's name from principal's bank account to pay bills for principal.
 - Oversee sale of principal's house after principal's death on behalf of principal's estate
 - Obtain principal's medical records from past medical treatments to aid principal's current MD in his treatment. * RCW 11.94.043, .046; RCW 71.05.217
 - Authorize psychiatric team who is consulting on principal's case at the teaching hospital to give electroconvulsive therapy ("ECT" or "shock therapy") to principal for treatment of depression
10. Your cousin has bipolar disorder. Now that Cousin Phil has reached his 40th birthday, his acute manic episodes are becoming more frequent and more pronounced. Your immediate family and Phil's immediate family meet to decide what to do the next time Phil "cycles", since the overall concern is he will have to be admitted to a psychiatric hospital, perhaps involuntarily. They look to you for advice. What would be the best solution, taking into account Phil's wishes and autonomy?
- Arrange to stage a family wide "intervention" with Phil ASAP and discuss his mental illness.
 - Draw up a durable power of attorney for Phil appointing you as attorney in fact, and get Phil to sign it.
 - Contact Phil's psychiatrist for an update, and go from there.
 - Tell the family that you plan to discuss a Mental Health Advance Directive with Phil, and that you would appreciate their participation once you and Phil have discussed the MH Advance Directive. * RCW 70.122.030, RCW 71.32.050, RCW 71.05.217 – isn't this obvious?
11. Which of the following does **NOT** terminate a general power of attorney?
- The death of the principal
 - The incapacity of the principal
 - Physical destruction of the general power of attorney document by principal.
 - A one-month absence for a business trip of the attorney-in-fact from the city where both s/he and the principle live * RCW 11.94 et seq

12. Under Washington law, which of the following functions may be performed by a pharmacy technician?
- a. Giving patient advice as to what OTC cough/cold preparation to use for their symptoms
 - b. Taking refill authorizations for an existing prescription off the doctor voice mail line * 246-901-020
 - c. Checking the patient medication record and medical history for drug-disease interactions after a regular customer asks if her new antibiotic will cause a flare up of her irritable bowel syndrome.
 - d. Calling up Dr. Jones to tell him that he cannot prescribe dicloxacillin to patient Wells because Ms. Wells has a penicillin allergy

13. Defenses to a negligence claim are:

- I. Contributory negligence
- II. Statute of limitations
- III. Comparative fault

Which of these choices, if argued successfully by the attorney representing the Defendant Pharmacist in Anystate, USA, would **COMPLETELY** bar the Patient Plaintiff from recovery of damages?

- a. I only
 - b. III only
 - c. I and II only *
 - d. II and III only
 - e. I, II and III
14. You have been practicing as a pharmacist for two years now, and are implicated in an error at the teaching hospital where you work. Even though the exact circumstances of the error have not been completely investigated by the Departments of Pharmacy and Risk Management at the hospital, an investigation against you personally has been initiated by the Board of Pharmacy. An older colleague has suggested that you hire an attorney. If you are penalized by the Board of Pharmacy only, what sanctions **CANNOT** be imposed?.
- a. Suspension of your pharmacist license
 - b. A monetary fine
 - c. Jail time * 18.130.160
 - d. Probation

15. Which of the following are features of the Medicare Program?

- I. Medicare is supported by only federal funds.
 - II. Medicare is administered by insurance companies.
 - III. Medicare is prohibited by law from negotiating prescription drug prices.
- a. I only
 - b. III only
 - c. I and II only
 - d. II and III only
 - e. I, II and III *

Name: _____

Last

First

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

16. Joe Smith is an 80 year old man with high blood pressure and a history of myocardial infarction (prior MI's at age 75 and 77). He is currently doing pretty well, mainly due to exercise, diet, and adherence to his medication regimen. Mr. Smith comes to get his monthly supply of medications supply and leaves your pharmacy at 1 PM on a Friday. At 1:45, you, the intern, realize that Mr. Smith did not receive his Imdur (a nitrate that improves circulation around the heart and prevents chest pain), which was separated from the rest of the medications because it required a refill authorization. Mr. Smith mentioned he was planning on going on a fairly strenuous bird watching hike early tomorrow morning. What would be the **BEST** (most expedient) thing for you to do to assure Mr. Smith gets his medication before his hike?
- Call Mr. Smith's phone number and leave him a message to call you or the evening pharmacist (leaving your names) ASAP
 - Flag the Imdur on the shelf so that the evening tech will see it when she cleans the shelves before closing and will likely point out the problem to the evening pharmacist.
 - Call Mr. Smith's daughter and request that she come pick up the Imdur to take to his house.
 - Take the Imdur yourself to his house, which is on the way home from work. Your shift ends at 6pm, which is about the time he takes his next dose. **Best answer**
17. Which of the following are features of the Medicaid Program?
- Medicaid is supported by a combination of federal and state funds.
 - Restricted formularies are allowed.
 - The federal government establishes dispensing fees for the program.
- I only *
 - III only
 - I & II only
 - II & III only
 - I, II & III
18. Which of the following are required in order to participate in the Medicare program?
- Home IV pharmacies must comply with the Conditions of Participation.
 - Pharmacists must review the drug regimen of each skilled nursing facility patient on a monthly basis. *
 - Pharmacies must agree to specific dispensing fees for prescriptions.
 - Community pharmacies must comply with the Conditions of Participation.
 - All patients must receive Medication Therapy Management (MTM.)
19. Which of the following State Agencies has a contract with the Federal Government to inspect hospitals for compliance with the Medicare Conditions of Participation?
- Department of Labor and Industries
 - Department of Revenue
 - Department of Social and Health Services
 - Department of Health *
 - State Auditor's Office

20. Which agency has taken a particular interest in banning the use of confusing abbreviations in hospitals?
- Department of Health
 - Department of Social and Health Services
 - State Board of Pharmacy
 - Department of Labor and Industries
 - Joint Commission on Accreditation of Healthcare Organizations *
21. In a Skilled Nursing Facility (SNF) what information must a pharmacist add to the manufacturer's label of an Over the Counter (OTC) drug that is intended for a specific patient?
- Prescription number
 - SNF name
 - SNF address
 - Patient's name *
 - Specific dosage instructions
22. In addition to the usual prescription labeling requirements, what additional information must a pharmacist add to the label of a controlled substance that is dispensed for a patient in a Skilled Nursing Facility?
- Controlled Substances Schedule *
 - Price charged for the drug
 - DEA number of the prescriber
 - DEA number of the pharmacy
 - Expiration date that does NOT exceed 6 months
23. A drug manufacturer distributes 15 different package sizes of a drug that is subject to the Child Resistant Container (CRC) rules. How many package sizes may this manufacturer distribute in container(s) that do **NOT** comply with these rules?
- 1 *
 - 2
 - 3
 - 4
 - 5
24. Which of the following may determine that **NONE** of a patient's prescriptions shall be dispensed in Child Resistant Containers?
- The prescriber
 - The dispensing pharmacist
 - The patient *
 - Agents of the Consumer Product Safety Commission
 - Board of Pharmacy Investigators
25. Which of the following drugs are **NOT** required to be dispensed in Child Resistant Containers?
- Nitroglycerin Sublingual tablets 0.4 mg, No. 100 *
 - Aspirin tablets 81 mg, No. 25
 - Aspirin tablets 325 mg, No. 12
 - Acetaminophen tablets 325 mg, No. 50
 - Birth control pills intended for emergency contraception, No. 4

Name: _____

Last

First

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

26. Which of the following are you **NOT** allowed to place on the label of a package, containing controlled substances, that you are mailing to a patient?
- Pharmacy address
 - Patient address
 - Patient name
 - Drug name *
 - Value of the contents
27. Which of the following is **NOT** a requirement of the Prescription Drug Marketing Act of 1987?
- States must license wholesale distributors of prescription drugs.
 - Only manufacturers are allowed to re-import drugs that they have sent outside of the U.S.
 - Prescription drug samples may not be sold, traded or purchased.
 - Record keeping requirements were placed on companies that distribute prescription drug samples.
 - Hospitals may resell no more than 10% of the prescription drugs that they purchase at discounted prices. *
28. Which of the following OTC products is **NOT** required to be packaged in a tamper resistant package (TRP)?
- Insulin 40 units/ml, 10 ml *
 - Aspirin tablets, 81 mg No. 25
 - Acetaminophen tablets 325 mg, No. 12
 - Hydrocortisone cream 0.1%, 30 gm
 - Metamucil powder, 400 gm
29. Which of the following statements are **FALSE** concerning the sale of sterile needles and hypodermic syringes in the State of Washington?
- Any person over the age of 18 may possess sterile needles and syringes for the purpose of reducing blood borne diseases.
 - Pharmacists may refuse to sell syringes to a person who is over 18 years old.
 - When selling sterile needles and syringes the retailer must satisfy himself or herself that the device will be used for the legal use intended.
 - The law allows the distribution of syringes through public health and community based HIV prevention programs and pharmacies.
 - When selling syringes to known drug addicts, pharmacists are required to provide materials related to drug prevention and treatment at the point of sale. *
30. A pharmacist could **NOT** be disciplined by the Board of Pharmacy for which of the following:
- Mis-filling a prescription.
 - Diverting controlled substances for personal use.
 - Insulting a patient using language that causes embarrassment to the profession of pharmacy. *
 - Allowing a pharmacy intern to practice pharmacy without supervision of a pharmacist.
 - Stealing money from a pharmacy

31. It is May 2008 and you discover that you are one credit short of the number required for graduation. However, staff in the Dean's office apparently missed this and included your name on the list of certified graduates that they sent to the Board of Pharmacy. You pass the licensing examinations and are issued a license. Which of the following violations could the Board charge you with if they discovered the facts in this case?
- a. Your license was procured through fraud, misrepresentation or deceit. *
 - b. You have knowingly violated a state law governing the possession, use, distribution or dispensing of drugs.
 - c. You have compounded or dispensed a drug that contains more or less than the ingredient specified by the prescriber.
 - d. You failed to cooperate with the Board of Pharmacy.
 - e. Aiding or abetting an unlicensed person to practice pharmacy.
32. A pharmacist may be fined up to \$ 5000.00 for each violation that the Board determines that he or she has committed. Under current Washington law, how much may a wholesale drug distributor be fined for each violation that the Board determines that the company has committed?
- a. \$ 0.00 *
 - b. \$ 500.00
 - c. \$ 1,000.00
 - d. \$ 5,000.00
 - e. \$ 10,000.00
33. If you needed to determine if a particular health professional was allowed to prescribe a certain drug, which of the following laws would **NOT** be helpful in making this determination?
- a. The health professional's Practice Act.
 - b. The Legend Drug Act.
 - c. The Uniform Disciplinary Act
 - d. The federal Food, Drug, and Cosmetic Act. *
34. Pursuant to the "legible prescription law" that was enacted in the 2006 Legislative Session, which of the following is **NOT** an option that is provided to prescribers in order to comply with this law?
- I. Hand printing the prescription.
 - II. Typewriting the prescription
 - III. Clearly handwriting the prescription
- a. I only
 - b. III only *
 - c. I & II only
 - d. II & III only
 - e. I, II & III
35. In Washington, which of the following methods are prescribers required to use to inform pharmacists that it is **ACCEPTABLE** to substitute a therapeutically equivalent generic drug pursuant to a written prescription?
- a. Sign the prescription on the line on the Right hand side where "Substitution Permitted" is printed.
 - b. Sign the prescription on the Left hand side where "Substitution Permitted" is printed. *
 - c. Sign the prescription on the Right hand side where "Substitution Acceptable" is printed.
 - d. Sign the prescription on the Left hand side where "Substitution Acceptable" is printed.
 - e. Handwrite "OK to Substitute" anywhere on the prescription.

Name: _____

Last

First

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

36. Pursuant to Washington's Preferred Drug List law, a pharmacist is **NOT** required to dispense a therapeutic alternative drug¹ if the prescribed drug is a refill of a drug that is classified in certain therapeutic classes. Which of the following drug classes are included in this exemption?
- a. Long-acting Opioids
 - b. Antipsychotic drugs *
 - c. Benzodiazepines
 - d. Antibiotics
 - e. ACE Inhibitors
37. The Washington State Board of Pharmacy allows internship credit for hours that students are involved in Initial and Advanced Pharmacy Practice Experience (formerly called "Clerkships".) How many of these hours can you expect to receive credit for by the time that you have graduated from UW?
- a. 300 hours
 - b. 500 hours
 - c. 1,000 hours
 - d. 1,200 hours *
 - e. 1,500 hours
38. Which of the following is **NOT** a requirement for a pharmacy to operate under differential hours?
- a. When the pharmacy is closed, written prescriptions may be left in a mail slot or drop box.
 - b. No prescriptions may be dispensed in the absence of a pharmacist.
 - c. The pharmacy must be enclosed by solid partitions at least 15 feet high. *
 - d. The times that the pharmacy is open for business must be displayed so that they are visible to any person depositing prescriptions.
 - e. The pharmacy must have a phone number that is separate from the remaining business establishment.
39. Which of the following drugs may **NOT** be distributed by a Medicare Approved Kidney Dialysis Center without a license to operate a licensed pharmacy?
- a. Epogen (Epoetin alfa 40,000 units per mL) *
 - b. Heparin injection 1,000 units per mL
 - c. Potassium Chloride, 2mEq/mL
 - d. Sodium Chloride 0.9% for injection
 - e. Commercially Available Dialysate
40. Which of the following is an example of "unwitting" fraud, in contrast to "purposeful" fraud?
- a. Charging for services provided to deceased (ghost) patients
 - b. Providing unnecessary services
 - c. Wrong billing code assigned to service *
 - d. Participating provider-patient payments
 - e. Charging for services provided by non-pharmacists

¹A "therapeutic alternative" is a drug that is different from the drug prescribed but is in the same therapeutic class

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

SHORT ANSWER QUESTIONS – 20 points total

Please confine your responses to the space provided – write inside the box – and write legibly.

41. Firms that purchase drugs that are short-dated, overstocked, or purchase in bulk and repackage, then resell to pharmacies are called: (1 point)

Secondary wholesalers

42. Order forms for schedule I and II controlled substances may be signed by which persons? (1 point)

DEA registered person who signed original application

Person with power of attorney

43. What **drug** details of a Schedule-II prescription may a pharmacist change after consulting with the prescriber? (2 points)

Drug strength

Dose frequency

Drug quantity

44. According to the federal Food, Drug and Cosmetics Act, as amended, and associated regulations, what is a drug component? (1 point)

Component means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product. 21CFR210.3(b)(3)

45. List three requirements that would enable a nurse to dispense emergency legend drugs to an outpatient? (2 points)

Valid prescription

Prepackaged medication by pharmacist

No more than 24-hour supply unless no pharmacy services are available for more than 24 hours

Nurse retains original prescription for verification by the pharmacist

Medications to be stored in secure place outside pharmacy

53. Contrast DEA and WA requirements for sales of OTC C-V anti-diarrheal products. (4 points)

Attribute	federal Drug Enforcement Administration, 21CFR1306 et seq.	Washington Uniform Controlled Substances Regulations, WAC 246-887-030
Example: Minimum age for sales	18	21
Maximum dosage units if not opium-containing	24	not specified
Maximum volume per purchase	240 ml	240 ml
Minimum time between initial and third purchase	48 hours	60 days
Verification of patient's identity by pharmacist required	if patient not known to pharmacist	purchaser must ... supply proof of identification

ETHICS CASE – 15 points

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

You are the pharmacy manager for a store in Remote WA that is part of an international big-box² chain. Remote is about 50 miles (as the crow flies) each from Moses Lake, the Tri-Cities and Pullman.³ You have recently received a memorandum from Big-Box corporate instructing all of its pharmacies to remove from inventory and order no further oral transmucosal fentanyl citrate products.⁴ The justification is a recent Wall Street Journal article⁵ noting significant “off-label” use; Big-Box wants to avoid the problems they encountered several years ago with DEA because of their alleged “outrageous” sales of sustained release oxycodone.

For reasons that you’ve not quite figured out, several Remote residents who are long-term patrons of your pharmacy have prostate cancer with bone metastasis. All are treated by a pain management team in Walla Walla and are receiving pain management regimens that include sustained release morphine and transmucosal fentanyl citrate for break-through pain.

Knowing Washington law, how should you respond to Big-Box corporate?

(2 points)

WAC 246-869-150
Physical standards for pharmacies — Adequate stock.
(1) The pharmacy must maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients.

Assume that Big-Box corporate prevails. Evaluate the bioethics of the case.

²Big-box store is a term of art in the retail trade that refers to a style of retail store, and by extension to the company behind the store. Generally, big-box stores can be broken down into two categories: general merchandisers, such as Wal-Mart and Target, and so-called category killers, such as Home Depot or Circuit City which specialize in goods within a specific range, such as hardware or electronics. [Abstracted from Wikipedia, accessed 05dec06].

³Note: so far as we can determine, there is no Remote WA, no pharmacy in Remote, let alone a big-box retail store of any sort. These aspects of the case are made up.

⁴ Label warning for fentanyl citrate lollipops: ACTIQ contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. ACTIQ can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing ACTIQ in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.... ACTIQ® is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.... ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Patients and their caregivers must be instructed that ACTIQ contains a medicine in an amount which can be fatal to a child. Patients and their caregivers must be instructed to keep all units out of the reach of children and to discard opened units properly. [Accessed from <http://www.actiq.com/> 05dec06]

⁵Narcotic 'lollipop' becomes a big seller; Actiq is for cancer, but it is prescribed for other conditions. Carreyrou J, Wall Street Journal (Europe), 06nov06, page 6.

Name: _____

Last

First

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

Perspective	(1)
Beneficence	(2)
Maleficence	(2)
Autonomy	(2)
Justice	(2)
Virtue	(2)
Root Cause	(2)