Name: _____ _____
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Pharmacy 543 – Pharmacy Laws & Ethics
FINAL EXAMINATION
December 12, 2003

Questions 1-50 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 you name and student number (both characters and bubbles). **Select the best answer from the available choices.** 50 points. Questions 51-75 are short answer. Please limit your responses to the space provided for each question. 25 points. Exam total: 75 points.

Legibility: please verify that your name and student number are legible and correct and that your answers are legible.

Turn in:

(1) the Standard Answer Form,
(2) your answers to the short answer questions, and
(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 midterm. 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. In McKee v. American Home Products,[1] the court found that a pharmacist who accurately filled a valid prescription has no duty to warn a patient of potential hazards associated with the prescribed drug. What is the current impact of this ruling?

   I. The ruling is still precedential[2]
   II. "Pharmacist's duty" codified in WAC 246-863-095 Pharmacist's professional responsibilities includes a duty to warn of drug regimen related potential hazards
   III. Washington counseling requirements in WAC 246-869-220 implies a duty to warn of drug regimen related potential hazards

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

[1] McKee v. American Home Products Corp., SUPREME COURT OF WASHINGTON, 113 Wn.2d 701; 782 P.2d 1045; 1989 Wash.

[2] prec·e·den·tial -- b. *Law*. A judicial decision that may be used as a standard in subsequent similar cases: a landmark decision that set a legal precedent. [from *American Heritage Dictionary*]

2. Which of the following is **NOT** an element of a tort claim?

a. Duty
b. Breach
c. Causation
d. Strict liability

3. A patient consumes a drug dispensed by a pharmacy filled pursuant to a valid prescription, follows the instructions provided with the prescription and sustains harm. In which of the following instances might the pharmacist be liable for the patient's harm?

I. Prescription required that the pharmacist compound a dermatologic preparation by grinding up tablets and suspending them in a cream
II. Prescription required that the pharmacist mix two ingredients (e.g., reconstitute an oral liquid antibiotic)
III. Prescription required labeling of a standard dose pack (e.g., birth control pills)

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

4. RCW 70.24.105[3] specifies to whom HIV or STD test results or information about treatments a patient has received may be disclosed. To which of the following may disclosure **NOT** be made?

a. The subject of the test
b. The subject's legal representative for health care decisions
c. A representative of a minor child over fourteen years of age who is otherwise competent
d. Court ordered access after good cause shown

5. Both the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Washington's Uniform Health Care Information Act (RCW 70.02) define the kind of information that generally may not be disclosed without a patient's permission. Which of the following is uniquely related to HIPAA?

I. [information] that is transmitted or maintained in any electronic format
II. Any information whether oral or recorded that identifies or can be readily associated with the identity of a patient and directly relates to the patient's health care
III. Information that is maintained by an agency that identifies or describes an individual, including ... medical or employment history.

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

[3]RCW 70.24.105 Disclosure of HIV antibody test or testing or treatment of sexually transmitted diseases -- Exchange of medical information.

6. 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. Orally, and made to those with a close personal relationship with the patient

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

7. An outraged patient complains to the Board of Pharmacy about the prices that were charged at a local pharmacy. Why would the Board take no action on the complaint?

I. The Board lacks jurisdiction over drug prices
II. Licensees are not required to cooperate with Board investigators on prescription price complaints
III. Licensees typically assert a 5th Amendment right

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

8. Which of the following pharmacies may mail controlled substances to their patients?

I. Veterans Affairs Pharmacies
II. Community Pharmacies
III. HMO Pharmacies

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

9. For which of the following types of drugs will Medicare reimburse?

I. Prescription drugs that must be administered by a health professional
II. Oral controlled substances
III. Prescription drugs that may be self administered

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

10. Which of the following are characteristics of the Medicare program?

I. The program is restricted to persons over age 65 and a few other types of patients
II. The program is funded using a combination of federal funds
III. The program will cover outpatient drugs in 2006

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

11. The rules that cover hospitals and nursing homes that accept Medicare Patients are called:

a. Medicare Regulations
b. Medicare Statutes
c. Conditions of Participation
d. Conditional Requirements

12. A hospital that meets which of the following requirements is considered to be in compliance with Medicare rules?

a. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
b. American Hospital Association
c. Food and Drug Administration
d. Drug Enforcement Administration

13. According to the Robinson-Patman Act, which of the following situations would **NOT** be considered to be a hospital's "own use" of drugs purchased at special hospital prices?

a. Dispensing the drugs to inpatients
b. Dispensing the drugs to hospital employees
c. Selling the drugs to another hospital in the same organization
d. Dispensing the drugs to a patient referred by a retail pharmacy

14. Which of the following may **NOT** dispense physician's samples?

a. A retail pharmacy
b. A hospital pharmacy
c. An HMO pharmacy
d. A physician assistant

15. Which of the following subjects were **NOT** covered in the Prescription Drug Marketing Act of 1987?

a. Licensing of prescription drug wholesalers
b. Prohibition of re-importation of prescription drugs
c. Controlling the dispensing of samples by physicians
d. Controlling the distribution of samples by manufacturers

16. Medicare requires a pharmacist to review the drug regimen of every patient in a skilled nursing facility every:

a. 15 days
b. 30 days
c. 45 days
d. 60 days

17. To which of the following laws would you refer if you wanted to know if a physician assistant could prescribe ampicillin?

a. Pharmacy Act
b. Legend Drug Act
c. Controlled Substances Act
d. Uniform Disciplinary Act

18. Which of the following would **NOT** be a violation of the Legend Drug Act?

a. Failing to notify a prescriber that you were seeing another prescriber to get the same drug
b. Forging a prescription
c. Calling in a prescription in your name
d. Obtaining two bottles of OTC codeine cough syrup on the same day

19. When a prescriber dispenses a prescription drug directly to a patient, which of the following pieces of information are **NOT** required on the label?

a. Prescriber's name
b. Patient's name
c. Drug name
d. Directions for use

20. The pharmacy board must classify a drug as a legend drug under which of the following conditions?

I. The drug requires practitioner's supervision for safe use
II. The drug is harmful to animals
III. The manufacturer requests it

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

21. When substitution is allowed, in order to substitute a therapeutically equivalent drug rather than a generically equivalent drug, the pharmacist must have which of the following:

a. Prior consent of the prescriber
b. Prior consent of the 3rd party payer
c. Prior consent of the patient
d. Prior consent of the manufacturer

22. In the context of Washington's drug product substitution law, how are the signature lines labeled?

a. Dispense as Written on the left and Substitution Permitted on the right
b. Dispense as Written on the right and Substitution Permitted on the left
c. Dispense as Written above and Substitution Permitted below
d. Dispense as Written below and Substitution Permitted above

23. When dispensing a substitute drug how much of the savings between the wholesale costs of the two drugs must be passed on to the patient?

a. 10%
b. 20%
c. 40%
d. 60%

24. Which of the following therapies may be prescribed in order to improve athletic performance?

I. Nutritional Supplements
II. Auto-transfusion
III. Anabolic steroids

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

25. Under current interpretations of Washington's Uniform Disciplinary Act (RCW 18.130), which of the following actions could **NOT** be taken by the Board of Pharmacy should it make a finding of "unprofessional conduct"?

a. Revocation of the license
b. Suspension of the license for a fixed or indefinite term
c. Require a license holder or applicant to submit to a mental examination
d. Restriction or limitation of the practice of a license holder

26. Which of the following constitute "unprofessional conduct" under Washington' s Uniform Disciplinary Act (RCW 18.130)?

I. Engaging in a profession involving contact with the public while suffering from a contagious or infectious disease involving serious risk to public health
II. The willful betrayal of a practitioner-patient privilege[4]
III. Acceptance of more than a nominal gratuity, hospitality, or subsidy offered by a representative or vendor of medical or health-related products or services intended for patients

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

[4] Privilege – Information exchanged between two people who (1) have a relationship in which private communications are protected by law, and (2) intend that the information be kept in confidence. The law recognizes certain parties whose communications will be considered confidential and protected, including spouses, doctor and patient, attorney and client, and priest and confessor. Communications between these individuals cannot be disclosed in court unless the protected party waives that protection. [http://www.nolopress.com/lawcenter/dictionary]

27. Which of the following is a "medical experiment" compared to "provision of therapy" in the context of informed consent?

I. Intention to maintain or improve the health of the subject
II. Withholding of medical treatment for any other purpose other than maintenance or improvement of the health of the subject
III. Systematic investigation designed to develop or contribute to generalizable knowledge

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

28. Which of the following is **NOT** a responsibility of an Institutional Review Board?

a. Assuring that risks to subjects is minimized
b. Assuring that "vulnerable" populations are excluded
c. Assuring that selection of subjects is equitable
d. Assuring that risks to subjects is reasonable in relation to anticipated benefits

29. FDA's *Compliance Policy Guide 460.200 Pharmacy Compounding* identifies circumstances in which it might initiate enforcement activities related to pharmacy compounding. These circumstances include:

I. Activities normally associated with a drug manufacturer that result in significant violations of the new drug, adulteration, or misbranding provisions of the Food, Drug & Cosmetic Act, as amended
II. Using commercial scale manufacturing or testing equipment for compounding drug products
III. Failure of state Boards of Pharmacy to cooperate in investigations, referrals, and follow-up actions

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

30. A prescription calls for the use of a component that is unavailable in drugs with approved New Drug Applications or effective Investigational New Drug applications, nor is it listed in an official compendium. If you prepare the prescription, the resulting product:

I. Would be violative[5] under FDA's CPG 460.200 Pharmacy Compounding
II. Would be violative under WAC 246-878 GOOD COMPOUNDING PRACTICES
III. Could be sold to another pharmacy for subsequent dispensing

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

[5]vio·lative adj. 1. To break or disregard (a law or promise, for example). [American Heritage Dictionary]

31. Under Washington's *WAC 246-878-020 Compounded drug products -- Pharmacist*, when compounding a drug product that is commercially available in the marketplace, who must authorize its preparation and sale?

I. The Prescriber
II. The Patient
III. The Board of Pharmacy

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

32. What may a pharmacist **NOT** do under the FDA Center for Veterinary Medicine's *Compliance Policy Guide 608.400 Compounding of Drugs for Use in Animals*?

I. Establish "withdrawal" times for the compounded drug
II. Compound from a human drug for use in food-producing animals if an approved animal drug can be used for the compounding
III. Compound from approved human drugs for which FDA has implemented a restricted distribution system

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

33. You are entering a prescription in your community pharmacy computer system and come the screen where you select the drug product. You find that the system only lists the brand name, and you know that you only have the generic in stock. If you select the listed drug, you might be guilty of fraud because of:

I. Upcoding
II. Unbundling
III. Price fixing

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

34. Which of the following quality assurance evaluations is **NOT** required for compounding of drugs under *WAC 246-878-100 Drug compounding controls*?

a. Capsule weight variation
b. Antimicrobial preservative effectiveness
c. Adequacy of mixing to assure uniformity and homogeneity
d. Clarity, completeness, or pH of solutions

35. Which of the following are **EXCLUDED** from the definition of drug or device in *RCW 18.64.011 Definitions*?

I. Oxygen
II. Surgical instruments
III. Medicated feeds for animals other than man

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

36. *RCW 18.64.245 Prescription records--Penalty* specifies that records must be kept for two years, but also requires compliance with Drug Enforcement Administration record-keeping requirements. How long must prescription records be kept to be in full compliance?

a. 2 years
b. 2 years 6 months
c. 3 years
d. 3 years 6 months

37. Which of the following is more restrictive regarding on-the-job discrimination?

a. Seattle Human Rights Ordinance
b. RCW 49.60.180 Unfair practices of employers
c. American with Disabilities Act
d. Civil Rights Act [Title VII]

38. The American with Disabilities Act prohibits discrimination against Americans with the following disabilities, **EXCEPT**:

a. Patients undergoing rehabilitation for alcohol abuse
b. Patients undergoing rehabilitation for illegal drug abuse
c. Patients with an impairment (e.g., vision or hearing) if qualified for the job
d. Patients with HIV infection or AIDS

39. The Drug Enforcement Administration specifies storage security requirements for Scheduled drugs in *21 CFR § 1301.75 Physical security controls for practitioners*. Generally, what is required for storage of a Schedule II drug in a community pharmacy?

I. Stored in a securely locked, substantially constructed cabinet
II. Disperses throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances
III. Stored in a locked tackle box

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

40. Which is the following is **FALSE** regarding registered nurse dispensing of emergency outpatient drugs in Washington?

a. No more than a 24-hour supply is provided to the patient except when the pharmacist has informed appropriate hospital personnel that normal services will not be available within 24 hours
b. The container is labeled by the designated registered nurse(s) before presenting to the patient and shows the following: Name of patient; directions for use by the patient; Date; Identifying number; Name of prescribing practitioner; Initials of the registered nurse
c. The procedures outlined in this rule may never be used for controlled substances
d. The original or a direct copy of the order by the prescriber is retained for verification by the pharmacist after completion by the designated registered nurse(s)

41. Which of the following may a pharmacist change on a prescription for a Schedule II drug?

I. Patient name
II. Drug strength, dose
III. Administration schedule

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

42. If a prescriber has signed a prescription on the "dispense as written" line and a patient asks for a generic equivalent, the pharmacist could:

I. Dispense the generic equivalent
II. Dispense the indicated drug
III. Contact the prescriber to modify the prescription

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

43. Under the Abbott v. Portland Retail Druggists Association[6] ruling, to whom may the pharmacy **NOT** provide drugs under the rulings "own use" provisions?

I. Refills for patients previously seen in the emergency room
II. Inpatients for use in the hospital
III. Emergency room patients

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

44. Which legislative committee selects bills that are permitted go to floor vote?

a. Ways and Means
b. Appropriations
c. Rules
d. Finance

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[6]ABBOTT LABORATORIES ET AL. v. PORTLAND RETAIL DRUGGISTS ASSN., INC. No. 74-1274 SUPREME COURT OF THE UNITED STATES 425 U.S. 1; 96 S. Ct. 1305; 47 L. Ed. 2d 537

45. What is the normal implementation date for a bill that has been passed by the Washington legislature and signed by the Governor?

a. Effective when signed by the Governor
b. An implementation date is usually provided in the bill
c. 90 days after the session
d. With the beginning of the next fiscal year

46. Which of the following federal and state agencies have regulatory authority over pharmacy?

I. Consumer Product Safety Commission
II. Center for Medicare & Medicaid Services (DHHS-CMS)
III. Washington State Department of Labor & Industries

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

47. Which of the following actions may the Governor take in processing a bill approved by the legislature?

I. Not sign
II. Sign
III. Veto

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

48. In which of the following states may you **NOT** obtain a licence to practice pharmacy by reciprocity?

a. Arizona
b. California
c. Idaho
d. Oregon

49. Which of the following does not require tamper resistant packaging?

a. Aspirin
b. Acetaminophen
c. Ibuprofen
d. Insulin

50. Which of the following is the correct relationship?

I. Federal congress produced regulations
II. State legislature produced statutes
III. FDA produced Guidelines

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

Name: _____ _____
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SHORT ANSWER QUESTIONS – Confine answers to space provided. 25 points total

SHORT ANSWER – Please confine your response to the space provided and write clearly.

Please complete the following grid. Indicate which profession may prescribe the indicated drugs in Washington, and any requirements beyond licensure and Drug Enforcement Administration registration, necessary for prescriptive authority. 10 points.

Question	Profession	May Prescribe	Yes|No	Additional Requirements for Prescriptive Authority
Example	CRNA	C-II pain med	Yes	Facility-specific Protocol
51.	Pharmacist			
52.		Legend antiinflammatory		
54.	MD | DO	Subutex 8 mg SL, buprenorphine HCl,C-III		

56. What are the prescription requirements for each of the following Drug Enforcement Administration drug Schedules? Fill in the blanks. 5 points

Schedule	Prescription Requirements (written, verbal, electronic, fax)	Number of Refills in Number of Months
IV		

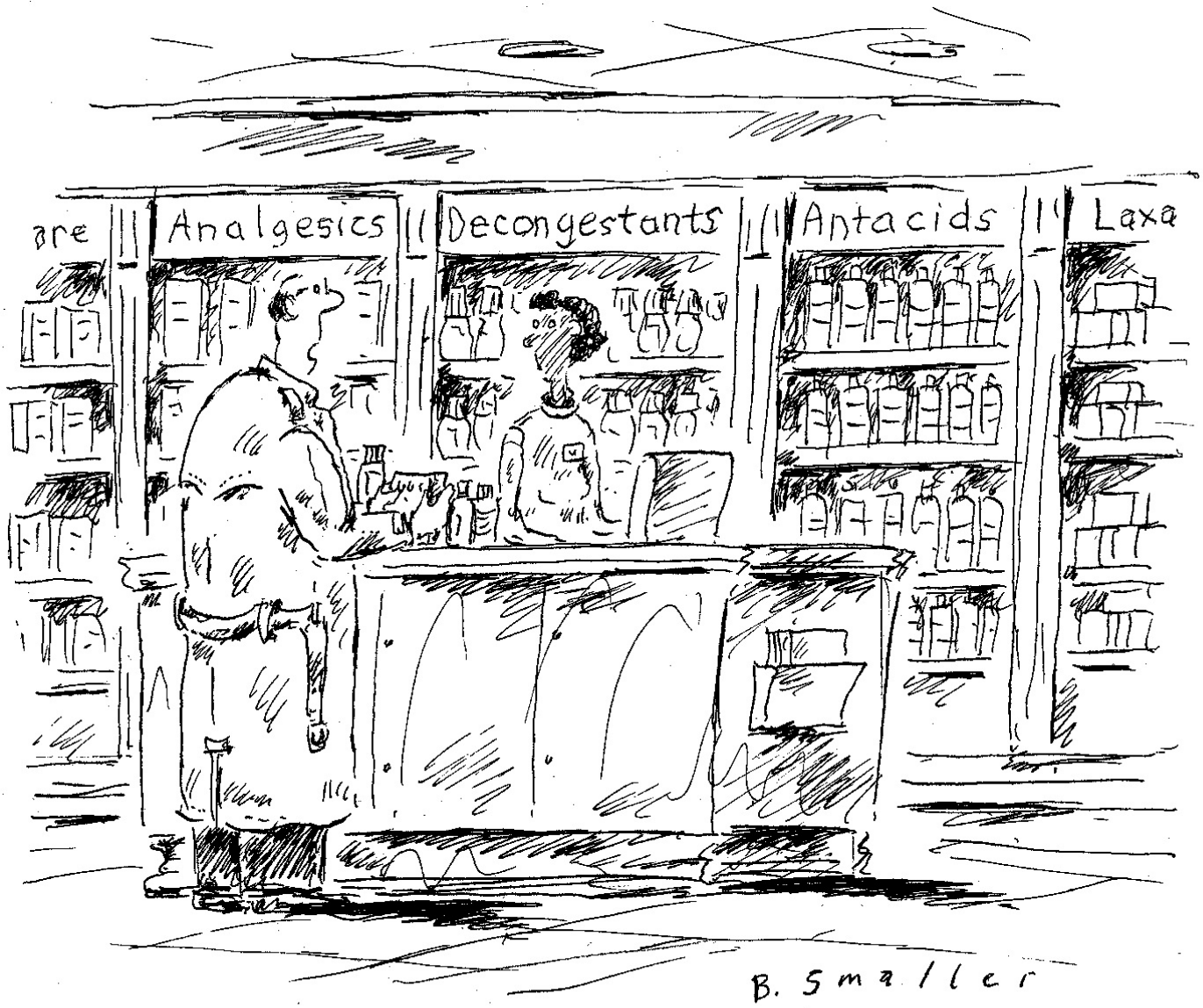
57. Which of the following activities are included in the *RCW 18.64 Definitions* for the practice of pharmacy? Check all that are correct. 5 points.

Check	Activity
✔	Interpreting prescription order
✔	Compounding, dispensing, label, administration, and distribution of drugs and devices
	Administration of medications, treatments, tests, and inoculations, whether or not the severing or penetrating of tissues is involved and whether or not a degree of independent judgment and skill is required
	Diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality
✔	Monitoring of drug therapy and use
	Initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs
0	Administration or prescribing drugs or medicinal preparations to be used by any other person
	Proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof
✔	Participation in drug utilization reviews and drug product selection
	Provision of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices

58. *RCW 18.64.246 Prescriptions -- Labels -- Cover or cap to meet safety standards -- Penalty* state, in part, "To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the ...."

Fill in missing information appropriate for outpatient dispensing. 5 points

name and address of the dispensing pharmacy
the prescriber's directions
the name and strength of the medication
the date
the identification of the licensed pharmacist responsible for each dispensing
for a combination medication product, the generic names of the medications combined or the trade name used by the manufacturer or distributor for the product shall be noted on the label



"I would go to the doctor, but I can't afford to take on any new conditions at this time."