

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.

There are 5 short answer questions and one ethics essay. Limit your answers to the space provided for each question.

Turn in (1) the Standard Answer Form, (2) your answers to the short answer and essay questions, and other pages as necessary (see below). **Complete your name and student number on any sheet you turn in if you want credit for that work.**

Grading: multiple choice questions are 1 point each (total 30 points); short answer questions are 2 points each (total 10 points) and the ethics question is 10 points. Exam total is 50 points.

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.

1. The structure of both the Federal and State legal system is:
 - a. Bipartite: includes House of Representatives and Senate
 - b. Bipartite: includes Democrats and Republicans
 - c. Tripartite: includes Congress, Administrative Branch, and Judicial Branch
 - d. Tripartite: Includes House of Representatives, Senate, and President or Governor
 - e. None of the above
2. In U.S. law, if the President signs a bill that has been passed by Congress, it is collected into:
 - a. The U.S. Code
 - b. The Federal Register
 - c. Code of Federal Regulations
 - d. W.A.C.
 - e. R.C.W.
3. Administrative agencies are responsible for :
 - a. Developing statutes to implement laws
 - b. Promulgating regulations pursuant to "notice & comment rulemaking"
 - c. Interpreting & defining statutes to be written into the States' constitutions
4. Case Law is decided by:
 - a. Juries
 - b. Judges
 - c. Juries and Judges
 - d. Administrative Agencies
 - e. The State or Federal Constitution

5. Alternatives to the 4 prima facie principles described in the Pellegrino Article include:
 - a. Virtue based theories
 - b. Ethics of Caring
 - c. Casuistry
 - d. a. and b.
 - e. All of the above

6. Administrative agencies in the state of Washington:
 - a. Are **NOT** subject to legislative review
 - b. Have authority granted by the legislature and case law
 - c. Have substantial discretion to set their own policies and procedures
 - d. Have authority granted only by the Enabling Act
 - e. May override or supercede the provisions of the Administrative Procedure Act

7. In considering the chronological sequence of making a regulation, which of the following does **NOT** occur:
 - a. An agency identifies a problem that may require adoption of a rule
 - b. Impact analysis and draft of proposed rule
 - c. Officially propose rule and file with Code Reviser
 - d. Vote on proposed rule in House and Senate
 - e. Rule adoption

8. Through the process of Judicial Review, a court may uphold a rule if it finds an agency's actions:
 - a. Arbitrary and capricious
 - b. Unconstitutional
 - c. Originated from an incorrect interpretation of the law
 - d. Was adopted without compliance with statutory rule-making procedures
 - e. Within the scope of statutory authority

9. The Title VII of the 1964 Civil Rights Act protects an employee from discrimination on the basis of race, color, sex, national origin, or perception as such.
 - a. True
 - b. False

10. A job requires heavy lifting and a college degree. William is a college-educated male with no physical limitations. Stephen is an ethnic male with armed services experience but without college education. While in the Armed Forces his right arm was amputated. Stephen applied for the same job as William, and William was hired. Could Stephen seek redress under the Americans with Disabilities Act?
 - a. Yes
 - b. No

11. Which of the following situations may **NOT** occur according to the Americans with Disabilities Act?
 - a. Refusing to hire a person with active tuberculosis
 - b. Forcing a job candidate to submit to a serum drug test before employment
 - c. Refusing to remodel a restroom for disabled workers and the employer is financially sound.
 - d. Firing a current employee addicted to a controlled substance
 - e. Refusing to hire a job candidate who is not visibly impaired and who can provide no documentation of disability

12. Jennifer has just graduated from pharmacy school and has gotten her first job as a pharmacist at Harborview Medical Center in Seattle. Within a month her infant daughter requires continuous care. Jennifer stays home for 16 weeks with her daughter believing that she is covered by the Family and Medical Leave Act (FMLA). In accordance with FMLA, must she be restored to her previous or equivalent position when she returns?
 - a. Yes
 - b. No

13. In the state of Washington, what agency is responsible for administering state law regarding the health and safety of workers?
 - a. Occupational Safety and Health Administration
 - b. Department of Labor
 - c. Washington Industrial Safety and Health Administration Sect 18
 - d. Department of Labor and Industries
 - e. Workers' Compensation Board

14. The Belmont Report, which is the basis for the Federal regulations governing the protection of human subjects in investigations, comments on the relative weights of the principles – that one principle **NEVER** overrides another.
 - a. True
 - b. False

15. Under the federal Food, Drug and Cosmetic Act, as amended, which of the following would **NOT** classify something as a "drug":
 - a. recognized in an "official compendium"
 - b. intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals
 - c. intended to be applied for the purpose of cleaning, beautifying, promoting attractiveness, altering appearance
 - d. intended to affect the structure or function of the body of man or other animals, but not food
 - e. it is a component used in preparing a drug

16. When billing Medicare for a lipid panel, the practice of billing for each test result separately would be best described as this act of billing fraud:
- a. Kickback
 - b. Unbundling
 - c. Upcoding
 - d. Anti-trust
17. Which one of the following terms does **NOT** refer to the person who informs the government about fraudulent billing in a Qui Tam action?
- a. Whistleblower
 - b. Relator
 - c. Perpetrator
 - d. None of the above
18. Which one of the following would be considered "unwitting" fraud as opposed to "purposeful" fraud?
- a. Billing for a brand drug while dispensing a generic
 - b. Billing for a prescription today that was not picked up by the patient for a week
 - c. Billing Medicare for services without medical necessity documentation
 - d. Billing for ghost patients
19. Which one of the following is **NOT** an Omnibus Budget Reconciliation Act-1990 (OBRA-90) requirement for participation by pharmacists providing Medicaid prescriptions?
- a. Counseling patients
 - b. Prospective DUR
 - c. Screening prescriptions for drug interactions
 - d. Documenting interventions
 - e. Billing for immunizations
20. How long from the date of issuance by a prescriber may a Schedule III prescription be filled?
- a. 72 hours
 - b. Five days
 - c. 30 days
 - d. 60 days
 - e. Six months
21. A controlled substance prescription issued by a doctor in one of the uniformed services must include which of the following?
- a. Patient's social security number
 - b. Practitioner's social security number
 - c. Patient's address
 - d. a. and b. only
 - e. b. and c. only

22. Which of the following methods of controlled substance storage may be utilized by a community pharmacy?
- a. Storage in a drawer near the computer
 - b. Dispersed throughout the legend drugs
 - c. In a locked metal cabinet.
 - d. a. and b. only
 - e. b. and c. only
23. How many legislator's affirmative votes does it take in the Washington Senate to pass a bill?
- a. 25
 - b. 35
 - c. 49
 - d. 98
 - e. 99
24. The Food, Drug and Cosmetic Act of 1938 (21 U.S.C. § 301 et seq. 52 Stat. 1040) mandated, for drugs,
- a. demonstration of safety under conditions of intended use
 - b. truthful labeling
 - c. good manufacturing practices
 - d. demonstration of efficacy under conditions of intended use
 - e. prescription status for certain drugs and the federal "legend"
25. Drug products sold in the United States must have an expiration date on the label or immediate container that is clearly visible to the consumer at the time of sale.
- a. True
 - b. False
26. Why would a controlled substance be listed in Schedule I versus Schedule II? For the C-I (but **NOT** a C-II) substance,
- a. there is a lack of accepted safety for use of the drug or other substance under medical supervision
 - b. the drug or other substance has no currently accepted medical use in treatment in the United States.
 - c. the drug or other substance has a high potential for abuse
 - d. a. and b.
 - e. a., b., and c.

Short Answer Questions

31. Which of the following takes precedence?¹ Explain. Limit your answer to the space provided.

WAC 246-869-100 Prescription record requirements. (d) Prescription refill limitations. No prescription may be refilled for a period longer than one year from the date of the original prescription. "PRN" prescriptions shall expire at the end of one year. Expired prescriptions require authorization before filling. If granted a new prescription shall be written and placed in the files.

21 CFR § 1306.22 Refilling of prescriptions. (a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times.

32. List two characteristics that would render a drug (as defined by US FDA) **misbranded**.

33. List two characteristics that would render a drug (as defined by US FDA) **adulterated**.

34. 21CFR207.35(b)(3) FDA requests but does not require that the NDC number appear on all drug labels and in other drug labeling, including the label of any prescription drug container furnished to a consumer. Why is NDC so important in pharmacy practice? Limit your answer to the space provided.

35. Describe how to avoid fraudulent billing by pharmacists when using the "incident to" billing procedure. Limit your answer to the space provided.

¹prec-e-dence (prs-dns, pr-sdns) also prec-e-den-cy (prs-dn-s, pr-sdn-s) n.

1. The fact, state, or right of preceding; priority: Applications arriving first will receive precedence.

2. Priority claimed or received because of preeminence or superiority: The company asserted its precedence as the leading manufacturer of microchips.

3. A ceremonial order of rank or preference, especially as observed on formal occasions: Recipients of military honors were called in order of precedence, highest ranking officers first.

American Heritage Dictionary, 2000

Perspective:
Principle 1:
Principle 2:
Principle 3:
Principle 4:
Principle 5: