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 2-part ethics question. 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 ethics questions (separate pages), and  
(3) 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.

Please do not turn in pages that do not need to be graded.

Grading: multiple choice questions are 1 point each (total 30 points); short answer question points are indicated (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, and FALSE are presented in BOLD, ALL-CAPS.

**Use the following prescription to answer questions 1 thru 5.**

1. The pharmacist has only 15 tablets of morphine sulfate 10 mg in stock, what is the longest time period that the pharmacist has to supply the remaining tablets?
   - A. Within 24 hours  
   - B. Within 48 hours  
   - **C. Within 72 hours**  
   - D. Within 96 hours  
   - E. Within 120 hours

   John D. Powers, M.D.  
   63 Plymouth Street  
   Anytown WA 98700  
   DEA ??123456?

   Patient: Mary Johnson  
   123 Franklin St, Anytown WA  
   Morphine Sulfate Tablets 10 mg No. 30  
   Sig: 1 q4h prn pain

   Substitution Permitted  
   Dispense As Written
2. If the pharmacist has no 10 mg morphine sulfate but has sufficient 5 mg tablets in stock, with the permission of the prescriber, the pharmacist may do which of the following?

I. Change the Rx to 5 mg and double the quantity and Sig
II. Prepare a new prescription for this dosage strength
III. The pharmacist is **NOT** allowed to change this prescription

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

3. If the prescription for Ms. Johnston was phoned in as an emergency, which of the following conditions **MUST** be met?

I. Immediate administration of this drug is necessary
II. No alternative treatment is available
III. It is **NOT** reasonably possible for the prescriber to provide a written prescription

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

4. If the prescription for Ms. Johnson was **NOT** an emergency and was transmitted to the pharmacy, on a Friday afternoon via FAX, the pharmacist could do which of the following?

I. Fill the prescription as written and dispense to patient
II. Dispense up to a 72-hour supply
III. Use the FAX copy for reference and dispense upon receipt of the original

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

5. Which of the following information is **NOT** required to be on the prescription label for Ms. Johnson’s prescription?

A. Pharmacy address
B. Doctor’s address
C. Patient name
D. Date of filling
E. Transfer caution

**End of questions related to this prescription. Continue with the examination.**

6. How long from the date of issuance by a prescriber may a Schedule III prescription be filled?

A. 72 hours
B. 5 days
C. 30 days
D. 60 days
E. 6 months
7. You receive a prescription for Vicodin (Hydrocodone 5 mg / Acetaminophen 325 mg) Tablets No. 100 but you have only 50 tablets in stock. How much time do you have to supply the remaining 50 tablets? Vicodin is Schedule III.

   A. 72 hours
   B. 96 hours
   C. 30 days
   D. 6 months
   E. 12 months

8. Which of the following DEA numbers would be valid for Albert Schweitzer, MD?

   A. AA 1234561
   B. AS 1234562
   C. MS 1234563
   D. AS 1234563
   E. AS 1234564

9. A controlled substance prescription issued by a doctor in one of the uniformed services **MUST** include which of the following?

   I. Patient’s social security number
   II. Practitioner’s social security number
   III. Patient’s address

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

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

    I. Storage in a drawer near the computer
    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

11. How many members are on the Washington State Board of Pharmacy?

    A. Three
    B. Four
    C. Five
    D. Seven
    E. Nine

12. Which of the following items may **NOT** be regulated by the Washington State Board of Pharmacy?

    I. Medicated Animal Feeds
II. Medical Gases
III. Pesticides

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

13. Which of the following are NOT grounds for disciplinary action against a Washington pharmacist’s license?

I. Being found to be mentally incompetent
II. Knowingly violating a State or Federal law
III. Allowing an intern to fill and dispense a prescription without checking it

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

14. Which of the following may enter a hospital pharmacy in the absence of a pharmacist in order to obtain an emergency supply of a medication for a patient?

I. A Registered Nurse, designated by the hospital
II. A Licensed Practical Nurse, designated by the hospital
III. A Licensed Physician, designated by the hospital

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

15. Which of the following medications may a Medicare approved Dialysis Program NOT dispense to its patients without being licensed as a pharmacy?

A. Heparin
B. Sodium Chloride for Injection
C. Potassium Chloride for Injection
D. Magnesium Sulfate for Injection
E. Dyalysate

16. In order to substitute a therapeutically equivalent drug that is NOT chemically equivalent to the drug prescribed, a pharmacist MUST have which of the following:

I. Prior consent of the prescriber
II. The prescriber’s signature on the “Substitution Permitted” line
III. The drug is included on the State’s Preferred Drug List.

A. I only
B. III only
C. I and II only
D. II and III only
E. I, II, and III
17. Authorization to prescribe, dispense or administer prescription drugs in Washington may be found in which of the following laws:

I. Legend Drug Act (Chapter 69.41 RCW)
II. Uniform Controlled Substances Act (Chapter 69.50 RCW)
III. Individual Health Professional Practice Acts (Chapter 18 RCW)

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

18. The ethical principle of autonomy includes

I. Competence  
II. Confidentiality  
III. Informed Consent

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

19. Application of the research principle of "respect for persons" includes:

I. informed consent  
II. voluntariness  
III. risk/benefit assessment

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

20. The U.S. Constitution:

I. Is the Declaration of Independence 
II. Requires a 2/3 vote by both houses of Congress to propose amendment, and 3/4 of legislatures of each state to ratify an amendment 
III. Is the supreme law of the land

A. I only  
B. III only  
C. I and II only  
D. II and III only  
E. I, II and III
21. Administrative Law is the body of law created by administrative agencies. The WAC is such an example.

A. True.
B. False.

22. *Stare Decisis:*

   I. Means that courts follow earlier court decisions, or "precedent"
   II. Allows courts to distinguish earlier precedent based on different facts
   III. Is codified in statute.

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

23. A Washington Board of Pharmacy investigation against a newly licensed pharmacist:

   I. Is NOT a legal action
   II. Could include sanctions such as warnings or license suspension or revocation.
   III. Is an example of an administrative action.

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

24. A Medical Device

   I. Is the same as "drug" except it does NOT achieve any of its principal intended purposes through chemical action ... and is NOT dependent upon being metabolized...
   II. Could be regulated by FDA’s CDRH BECAUSE it is similar to an existing (predicate) product
   III. Is NOT listed in a official compendium like drugs are.

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

25. A competent adult can create an advance directive under the Washington State Natural Death Act directing the withdrawal of "life-sustaining treatment". Pain therapy is excluded from this statutory definition of "life-sustaining treatment" most likely:

   I. to prevent providers from withdrawing drugs for pain control when patients become incompetent or "terminal".
   II. to prevent the extra costs of pain management at end of life.
   III. because pain treatment may hasten death

A. I only
B. III only
C. I and II only
D. II and III only
E. I, II and III
26. Violations of HIPAA and Washington’s RCW 70.02 Medical Records -- Health Care Information Access and Disclosure statute include:

I. Talking about a patient with another pharmacist **NOT** involved with that patient's care, over lunch in a public place.

II. Careless disposal or mishandling of patient records.

III. Forwarding of email with patient information to non-secure site.

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

27. Good Compounding practice presumes a prescriber-patient-pharmacy relationship because

I. This enhances the financial lucratively of compounding.

II. The regulations require it.

III. The pharmacist needs to take extra care to look out for possible compounding-related safety and effectiveness problems.

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

28. Purposeful fraud includes

I. misrepresentation on a pharmacy license application
II. charging for patients that don't exist
III. incorrect provider numbers

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

29. Unwitting fraud includes:

I. prescriptions billed for but **NOT** picked up by a patient
II. kickbacks
III. unbundling

A. I only
B. II only
C. I and II only
D. II and III only
E. I, II and III
30. The “Common Rule”, 45 CFR § 46.111 Criteria for IRB approval of research:

I. Tells pharmacists how to bill the government.
II. Provides detailed regulations on how researchers are to conduct research on patients.
III. Tells IRBs how to conduct research in their federally funded institutions, and certain ways they need to protect patients.

A. I only
B. II only
C. I and II only
D. II and III only
E. I, II and III
Short Answer Questions. (10 points) Confine your answers to the space provided.

31. The [intent] of the provider distinguishes research from innovative therapy. (1)

32. How might FDA’s “Orange Book” be appropriately used in Washington pharmacy practice? (2)

Selecting a therapeutically equivalent drug

33. Use the following four abbreviations in a sentence that explains their meaning and relationships: CFR, RCW, USC, and WAC. (2)

Federal statutes are codified in the USC and federal agencies promulgate regulations that are codified in the CFR; a similar process takes place for Washington state statutes codified in the RCW and promulgated regulations in WAC.

34. What is the name of the publication in which a federal agency’s promulgation of a “final rule” MUST be announced? What is described in the “preamble” of a final rule? (3)

<table>
<thead>
<tr>
<th>a. Final Rule</th>
<th>Federal Register</th>
</tr>
</thead>
<tbody>
<tr>
<td>b. Preamble</td>
<td>Shows the agency’s interpretation of specific sections of regulations through a discussion of comments received in a prior Notice of Proposed Rulemaking.</td>
</tr>
</tbody>
</table>

See reverse side for next question.
35. A fifteen-year-old patient is receiving prescription drug therapy. Under Washington law what would a pharmacy need to receive to release prescription information to: (2)

<table>
<thead>
<tr>
<th>Information Released to</th>
<th>Pharmacy <strong>MUST</strong> receive the following for legal disclosure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parent</td>
<td>nothing release from the patient [corrected 07-Nov-05]</td>
</tr>
<tr>
<td>Health Care Provider</td>
<td>reasonable assurance of the provider’s status</td>
</tr>
<tr>
<td>The Courts</td>
<td>compulsory process</td>
</tr>
<tr>
<td>Law Enforcement Officer</td>
<td>could be a release from the patient, compulsory process, emergency</td>
</tr>
</tbody>
</table>
Ethics Question. (10 points) Read the abstract by Hardin and Yusufaly.

Background: Advance directives are widely promoted as a means to plan for patients’ decisional incapacity, yet there is little evidence of their effectiveness. We devised a study to assess physicians’ compliance with hypothetical advance directives and further examine their clinical reasoning.

Methods: The study consisted of an analysis of a mailed written survey containing 6 hypothetical cases of seriously ill patients. Each case contained an explicit advance directive with potential conflict between the directive and (1) prognosis, (2) wishes of family or friends, or (3) quality of life. Data were collected on the clinical treatment decisions made by physicians and the reasons for those decisions. Study participants were all internal medicine faculty and resident physicians from a single academic institution.

Results: A total of 47% analyzable surveys (117/250) were returned. Decisions by faculty and residents were not consistent with the advance directive in 65% of cases. This inconsistency was similar for faculty and residents (68% and 61%, respectively; \( P > .05 \)). When physicians made decisions inconsistent with the advance directive, they were more likely to list reasons other than the directive for their decisions (89%; \( P < .001 \)).

Conclusions: Internists frequently made treatment decisions that were not consistent with an explicit advance directive. In difficult clinical situations, internists appear to consider other factors such as prognosis, perceived quality of life, and the wishes of family or friends as more determinative than the directive. Future work needs to explore the generalizability of these findings and examine how strictly patients desire their advance directives to be followed.

Arch Intern Med. 2004;164:1531-1533

Question: under Washington’s Natural Death Act (RCW 70.122 et seq.), would the circumstances described in the abstract be actionable? Explain. (3 points) Limit your answer to this page.

Yes. RCW 70.122.060(3) The directive shall be conclusively presumed, unless revoked, to be the directions of the patient regarding the withholding or withdrawal of life-sustaining treatment. No physician, health facility, or health personnel acting in good faith with the directive or in accordance with the written plan in subsection (2) of this section shall be criminally or civilly liable for failing to effectuate the directive of the qualified patient pursuant to this subsection.

Actions by the health care providers that are against the patient’s directions would be actionable.

\(^1\)actionable
giving cause for legal action: giving a basis for somebody to take legal action
[Encarta® World English Dictionary, accessed 28Oct05]
**Ethics Evaluation.** Given the findings in the Hardin & Yusufaly article, explain each of the principles and values below and evaluate a case where a patient has an advance directive in place that requests that nutrition and “heroic measures” be withheld. Assume that the advance directive meets all legal requirements, that the patient is in a permanent vegetative state and that the health care team continues to provide life-sustaining care.

Limit your answers to the space provided for each section. (7 points)

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