Please review the following questions prior to coming to the session, and be ready for discussion.

Most of the answers can be found in the "Salmon Book" [Pharmacy Lawbook 2003] or from various web resources:

- Pharm 543 Pharmacy Laws & Ethics class web site
  http://courses.washington.edu/pharm543

- Board of Pharmacy
  https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/laws.htm

- Drug Enforcement Administration (Controlled Substances Act & DEA Regulations, 21 CFR 1300 et seq.)

- DEA Pharmacist Manual

Note: several sections were omitted from or revised since publication of the 2003 (salmon) edition of the Pharmacy Law Book. They are available on the Board of Pharmacy site (above) or the Washington State Legislature’s web site:

http://search.leg.wa.gov/pub/textsearch/default.asp

70.115 RCW  Drug Injection Devices
WAC 246-877  Pharmaceutical - Sales Prohibited
WAC 246-899  Pharmaceutical - Drug Product Substitution

Abood & Brushwood’s Pharmacy Practice and the Law, 3rd Ed. may be helpful for some federal law questions.

Study Strategy

For each question, review applicable RCWs, WACs, CFRs and lecture notes. Think through the answer so that you understand both the "what" and the "why". Use old exams (beware: answers have NOT been updated) to check your understanding.

Be able to differentiate between federal (e.g., DEA, FDA, CPSC, CMS [aka HCFA]) and Washington-specific rules and regulations, and others, such as contractual obligations with pharmacy benefits managers. Make charts when helpful.

Come to the review session with questions about the questions. If you have not encountered an area covered in the review questions in your internship experience – have you ever seen the back side of a Form 222? – be sure that you hunt down the opportunity before you take the licensure exam.

1. List five violations for which a pharmacist could have the Board take action against his/her license.

2. What must be on the label of an outpatient prescription? In-patient? Home-IV? Skilled-nursing facility? Board & Care homes?

3. Are there special requirements for mail order pharmacies?
4. May a pharmacist compound an "OTC" drug?

5. How long must the pharmacy maintain the following records:
   - original prescriptions,
   - refill records,
   - drug purchase records,
   - patient profiles?

   Are there differences for legend drugs vs. controlled substances? If any of these can be maintained on the computer, how long do they need to be maintained "on-line"?

6. Do pharmacist licenses have to be on display? The original or official copy? Is a photocopy ok?

7. What day of the month does a drug expire when only the month and year are included on the label?

8. If an Army physician issues a prescription for one of his/her patients, may you fill this prescription?

9. What identifying number must an Army physician place on the prescription?

10. When receiving a shipment of a Schedule II controlled substance, what action must be taken to comply with record-keeping requirements?

11. Make a list of information required by the DEA when conducting an inventory.

12. Who may sign a request for additional Schedule II order forms (DEA-222)?

13. What is the maximum number of refills allowed for C-3s through C-5s under DEA and Washington regulations?

14. When may a pharmacist partially fill a Schedule II prescription?

15. When a pharmacist is only able to provide a partial quantity of a Schedule II prescription, how long does s/he have to provide the remaining quantity?

16. Is there any requirement for a daily printout of prescriptions for controlled substances that were entered into the computer?

17. When a controlled substance prescription is transferred between pharmacies, what must each pharmacist do to keep proper records of the transfer?

18. How long are prescriptions valid for each of the following under DEA vs. Washington regulations?
19. The Secretary of HHS has defined, by rule, the circumstances under which a pharmacist may accept an oral Schedule II EMERGENCY prescription. What are the requirements that must be met? How soon must the prescriber provide a signed prescription?

20. How does a pharmacy intern differ from a pharmacist regarding permitted activities?

21. What are the responsibilities of students when engaged in intern activities?

22. What are the responsibilities of preceptors of pharmacy interns?

23. What minimum sets of references, products, or equipment are required in all community pharmacies?

24. What are the current Washington requirements for patient counseling for new and refilled prescriptions?

25. Is there any provision for dispensing an emergency refill supply of legend drugs when there are no refills left and the prescriber cannot be contacted? What is allowed/required?

26. What information must be placed on the original copy of the transferred prescription by the receiving pharmacy?

27. How long are prescriptions for legend drugs valid from the date issued?

28. What is the maximum number of refills allowed for legend drugs in Washington?

29. What are the differences between the OBRA-90 and the Washington State counseling requirements?

30. Can printed materials satisfy the counseling requirement? Under what circumstances?

31. May a person be responsible manager / pharmacist-in-charge for more than one pharmacy?

32. Are there any special requirements to be responsible manager / pharmacist-in-charge?

33. Must every pharmacy have a responsible manager / pharmacist-in-charge?

34. Is it possible for pharmacies under common ownership to share a single patient/prescription database? If so, what are the rules for prescription transfers?
35. Does the offer to counsel need to be documented? Does the refusal of the offer need to be documented? How?

36. Under Washington law, what information must be recorded by the transferring and receiving pharmacies when transferring a prescription? Contrast with DEA requirements.

37. Must information regarding the transfer of legend drugs be recorded on the hard copy of the original prescription, or can it merely be recorded in the computer?

38. Can refills of legend drugs be transferred from one pharmacy to another? Can they be transferred back?

39. Do pharmacy hours have to be posted? Where?

40. Can the store be open but the pharmacy department closed? Under what requirements?

41. Is a CRC required if you remove oral contraceptive tablets from a memory pack to dispense as emergency contraceptive pills?

42. Who may authorize a prescription drug to be dispensed in a NON-CRC?

43. How is the counseling requirement satisfied for prescriptions that are delivered or mailed to the patient?

44. Is a patient counseling area that is separate from the dispensing area required?

45. How must the offer to counsel be made under Washington law? Under OBRA90?

46. Can legend drug prescriptions be transferred electronically (i.e., by computer)? Under what circumstances and requirements?

47. What is currently permitted for electronic exchange of prescription information?

48. What are the requirements for a FAXed prescription?

49. What is required on the label of a parenteral solution dispensed to a patient for home infusion therapy?

50. What must be on the label of a multiple-dose container dispensed for a patient in a hospital? In a nursing home?

51. What must be on the label of a unit-dose or single-dose package of a legend drug dispensed for a patient in a hospital or nursing home?

52. Are patient profiles (medication record systems) required for all patients? What information must be present?
53. What are the requirements for use of computers to process prescriptions? Distinguish between federal and Washington law.

54. What use of the patient profile is required? Review prior to dispensing new Rx's? Review prior to refills?

55. What references should a pharmacist check to verify that an ingredient may be used in compounding prescriptions?

56. To whom must a pharmacist disclose the pharmacy's prescription prices?

57. What Schedule II drug may be used by humane societies to euthanize injured or unwanted animals? What legend drugs may be used?

58. Under what circumstances may a pharmacist fill prescriptions written in another state?

59. Distinguish between the duties of pharmacy technicians and pharmacy assistants in Washington?

60. What are special requirements, if any, to be a nuclear pharmacist?

61. What is required on the label of a radiopharmaceutical agent?

62. List the diseases for which Schedule II stimulant drugs may be used in Washington.

63. Do patients have the option of demanding the brand name when substitution is permitted? How about patients whose prescriptions are paid for by public funds?

64. Can a patient refuse to give certain information for the profile? If so, must the refusal be documented, and how?

65. List the items that OBRA-90 requires to be covered when a patient is counseled about a new prescription.

66. When should a "preferred drug" be substituted for a therapeutically equivalent one in Washington?

67. What documentation is required of the pharmacist when product interchange ("generic substitution") is performed?

68. Under what conditions, if any, is therapeutic substitution (interchange) allowed?

69. Is generic substitution subject to positive formulary, negative formulary, or other requirements in Washington?
70. What does "therapeutically equivalent" mean in Washington law?

71. What wording is required under the signature lines of prescriptions in Washington?

72. Can a pharmacist legally repackage another pharmacy's prescription? Under what circumstances?

73. What are the medical conditions for which a physician may recommend the use of marijuana in Washington?

74. Under what conditions may a pharmacy sell needles or syringes?

75. How does the Robinson-Patman Act restrict a hospital's use of prescription drugs that it purchases at special prices or on contract? (e.g., to whom may a hospital sell these drugs?)

76. Which is the most serious level of an FDA drug recall?

77. When must the Board of Pharmacy be notified of any of the following?
   - change of responsible manager/pharmacist-in-charge,
   - change of pharmacy address,
   - closing or sale of a pharmacy,
   - change of pharmacy telephone number,
   - change of an individual pharmacist's address,
   - change of an intern's address,
   - change of a technician's address,
   - change of a person's name?
   - change in hours
   - change in utilization plans for technicians/assistants
   - change in prescriptive authority protocols
   - change in facility (e.g., remodel)

78. Which health professionals can prescribe legend drugs and controlled substances (which classes) in Washington?

79. Are there any required notices that must be displayed to the public in a community pharmacy?