PHAR 6778: LAW IN PHARMACY PRACTICE

Syllabus
Spring 2017
1 Credit
03/27/17 – 5/13/17

Location & Time
Online

Instructor Information
Course Director: Jennell C. Bilek, J.D., Pharm.D., Ph.D.
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PLEASE USE THE EMAIL ADDRESS ABOVE.

Co-Director: Shelly Jonas, Pharm.D., J.D. Candidate (2016)
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Required Textbook
Abood, RA et al., Pharmacy Practice and the Law, Eighth Edition (Jones & Bartlett Learning, 2016)
Print: ISBN #978-1284089110

COURSE DESCRIPTION
The course covers both federal and state laws that impact and regulate the practice of pharmacy.

OBJECTIVES OF THE COURSE
Upon completion of the course, the student will have an understanding of the primary federal and state laws that impact and regulate the practice of pharmacy. Students will be exposed to:

- Brief overview of the legal system including nature and sources of U.S. law, and distinguishing administrative, federal, and state law.
- The Federal Food, Drug, and Cosmetic Act, related Amendments, and other important federal laws governing the regulation of medications.
- Brief overview of federal regulation of medications covering development, production, dispensing, controlled substances, and marketing issues.
- Overview of the federal regulation of pharmacy practice.
- Overview of pharmacist negligence and other liability concerns facing pharmacists.
- State regulation of pharmacy practice and pharmacy professionals including, but not limited to, Minnesota Rules dealing with licensing, continuing education, pharmacy operations, controlled substances, and operations in institutions.
- Minnesota Pharmacy Practice Act.

**EXPECTATIONS**

**General:** All students are expected to view lectures and read the assigned readings. Please refer to the syllabus as a guide in preparing for each lecture and throughout the course.

Due to time constraints, portions of Minnesota Rules, Statutes, and Abood (2016) will not be covered in this course. This course will cover many topics you will be responsible for on the Multistate Pharmacy Jurisprudence Examination (MPJE). But there will be materials we do not have time to cover, and it is your responsibility to fill in the blanks while preparing for the MPJE.

**Grading Policy:** Weekly quizzes and one final examination form the basis of the final grade. The final examination constitutes 70% of your final grade. Weekly multiple-choice quizzes each count for 6% of your final grade except for the first week, which will serve as a practice to familiarize you with the format.

**Final exam:**
Students may submit correction requests via email regarding the final examination. The request must include an explanation of why and where a change is required. Any such requests must occur within five days of the examination.

**Grade Scale:**
- A  90-100%
- A- 87-89%
- B+ 83-86%
- B  80-82%
- B- 77-79%
- C+ 73-76%
- C  70-72%
- C- 60-69%
- F <60%

**Minimum Passing Level:** According to Academic Standing Committee Policy, students who receive a grade below C- in this course must successfully repeat the course before graduation.

**Honor Code:** Each student is bound by the following specific provisions of the Honor Code: *Academic misconduct is any unauthorized act which may give a student an unfair advantage over other students, including but not limited to: falsification, plagiarism, misuse of test materials, receiving unauthorized assistance and giving unauthorized assistance.*
Recording Lectures Is Prohibited: The lectures will be made available to you online. Recording, downloading, or reposting of the lectures and quizzes is a violation of the Honor Code and will result in an automatic “F” in PHAR 6778. All Powerpoint slides will be available to you as PDFs on Moodle to the extent you want to take notes, print, and/or save the slides to your computer.

Violations of the Honor Code will at the very least result in the student failing this course.

Other General Rules: Students are encouraged to use their textbook or other materials for the weekly quizzes. But all materials are prohibited during the final examination.

Course Evaluations: Students will have an opportunity to complete online course evaluations for instructors and the course itself (including instructional strategies, etc) at the end of the semester. You are encouraged to contact the course director any time you have concerns about the course or your progress in the course.

Disability Accommodations: It is University policy to provide, on a flexible and individualized basis, reasonable accommodations to students who have documented disability conditions (e.g., physical, learning, psychiatric, vision, hearing, or systemic) that may affect their ability to participate in course activities or to meet course requirements. Students with disabilities are encouraged to contact Disability Services and their instructors for a confidential discussion of their needs.

On the Duluth campus Disability Services is located in Kirby Student Center (KSC), Rooms 256-258, telephone: 218.726.8217 or 218.726.7380 TTY/TDD. On the Twin Cities campus Disability Services is in Suite 180 McNamara Alumni Center, 200 Oak Street, telephone: 612.626.1333 voice or TTY.

Additional Information: Instructors reserve the right to modify the contents or sequence of the syllabus, including reading assignments at any time during the semester. It is the student’s responsibility to be aware of these changes in the event of class absence.

Required Text and Readings:
Richard Abood, Pharmacy Practice and the Law, 8th Edition (Jones and Bartlett, 2016)

Minnesota Board of Pharmacy Statutes and Rules via internet at:
Rules: http://mn.gov/boards/pharmacy/statutes/rules.jsp
Statutes: http://mn.gov/boards/pharmacy/statutes/statutes.jsp

Students may purchase books through the Minnesota Board of Pharmacy or access the Rules and Statutes through the Minnesota Board of Pharmacy website. Contact the Minnesota Board of Pharmacy with any questions about purchasing the books.
ASSIGNMENTS

Module 1 (Week of 3/27)
Prior to the first class:
Read Abood Chapter 1, pages 2-40
Read Abood Chapter 2, pages 41-104

Module 2 (Week of 4/3)
Prior to class:
Read Abood Chapter 8, pages 425-466
Read Abood Chapter 6, pages 305-313, 346-350, 324-340 (skim)
Read Minnesota Statute 151.21 to 151.22, 151.40, 151.415

Module 3 (Week of 4/10)
Prior to class:
Read Minnesota Rules 6800.0200 – 1050 (Licensing Pharmacies)
Read Minnesota Rules 6800.1500 – 1600 (Continuing Education)
Read Minnesota Rules 6800.2150 – 4075 (Operation of Pharmacies)
Read Minnesota Rules 6800.6100 – 6800 (Operation in Long-Term Care Facilities)
Read Minnesota Rules 6800.7100 – 7950 (Operations in Hospitals; Hospital Service Policies)
Read Minnesota Rules 6800.9950 – 9954 (Dispensing by Practitioners)
Read Minnesota Statute 151.58 (Automated Drug Distribution)

Module 4 (Week of 4/17)
Prior to class:
Read Abood Chapter 3, pages 158-165 (Pharmacy Compounding Versus Manufacturing)
Read Minnesota Statute 151.01 – 151.302 (Board of Pharmacy)
Read Minnesota Statute 151.43 to 151.50 (Wholesale Drug Distribution Licensing Act)

Module 5 (Week of 4/24)
Prior to class:
Read Abood Chapter 4
Read Abood Chapter 5
Minnesota Statute 152.10-152.135 (Sales and Records; Prescriptions)

Module 6 (Week of 5/1)
Prior to class:
Read Minnesota Rules 6800.9100-.6800.9700 (Disciplinary Proceedings)
Read Minnesota Statute 151.60 to 151.70 (Pharmacy Audit Integrity Program)

FINAL EXAM DURING WEEK OF MAY 8
**Helpful Resources:**
Minnesota Rules online, Chapter 6800:
http://www.revisor.leg.state.mn.us/arule/6800/

Minnesota Statutes online, Chapter 151:
http://www.revisor.leg.state.mn.us/revisor/pages/statute/statute_chapter_toc.php?chapter=151

Minnesota Statutes online, Chapter 152:
http://www.revisor.leg.state.mn.us/revisor/pages/statute/statute_chapter_toc.php?chapter=152

Minnesota Statutes online, Chapter 214:
http://www.revisor.leg.state.mn.us/revisor/pages/statute/statute_chapter_toc.php?chapter=214

Minnesota Statutes online, Chapter 148:
http://www.revisor.leg.state.mn.us/revisor/pages/statute/statute_chapter_toc.php?chapter=148

Drug Enforcement Administration Pharmacist’s Manual:

**Know the following for the MPJE:**
Abood, chapters 1-6
Chapter 6800 – Know everything except 6800.4210
Minnesota Statutes
151 (all)
152.10 – 152.135
214.02
214.03 sub. 1
214.09
214.31 – 214.36
Review Chapter 148 (prescribing by nurses and optometrists)

**MPJE details:**
- Computer adaptive
- Combines federal and state specific law questions
- Questions tailored to the specific laws in each state
- Consists of 90 multiple-choice questions: 60 questions are used to calculate the test score while 30 randomly dispersed questions serve as pretest questions

Among other things, the MPJE tests candidates on:
• Legal aspects of pharmacy practice, including responsibilities with regard to the
distribution and dispensing of pharmaceuticals and for the care of patient
• Licensure, registration, certification, and operational requirements
• Regulatory structure and terms of the laws and rules that regulate or affect
pharmacists, pharmacies, manufacturers, and distributors

Please refer to http://www.nabp.net/programs/examination/mpje for more information on
the MPJE.