PHAR 6778: LAW IN PHARMACY PRACTICE

Syllabus
Spring 2018
1 Credit
January 29 – April 30, 2018

Location & Time
Online

Instructor Information
Course Director:  Cody Wiberg, Pharm.D., M.S., R.Ph.
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    Co-Director:  Jennell C. Bilek, J.D., Pharm.D., Ph.D.
    Office: Off-campus
    Office Hours: By appointment
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Required Textbook (available on Moodle)

COURSE DESCRIPTION

The course covers both federal and state laws and regulations that impact the practice of pharmacy.

COURSE OBJECTIVES

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.
- Those portions of the Federal and State Controlled Substances Acts that are most pertinent to the practice of pharmacy.
• 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, 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.

**Grading Policy:** Weekly quizzes and one final examination form the basis of the final grade. The final examination constitutes 75% of your final grade. Weekly multiple-choice quizzes in modules 1-5 each count for 5% of your final grade.

**Final Exam:**
The final exam will be scheduled during finals week. It will be available on Moodle for a minimum of eight hours, and it must be completed during this window. The final exam will consist entirely of multiple choice questions. The final exam is **CLOSED BOOK**—the use of any printed or electronic materials or consulting with anyone during or after the exam is strictly prohibited and will result in an Honor Code violation. 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:**

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<tr>
<td>A</td>
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<td>A-</td>
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<td>B+</td>
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<td>B-</td>
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**Grading Curve:**
The final grades in this course will be adjusted on a curve.

**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.
Proper Use of Course Materials: The lectures will be made available to you online. Recording, downloading, distributing or reposting the lectures and quizzes is a violation of the Honor Code and will result in an automatic “F” in PHAR 6778. Lecture handouts will also be available on Moodle. These handouts, and any other course materials, may not be distributed to any person not enrolled in PHAR 6778 during the Spring 2017 semester.

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

Use of Materials During Quizzes and the Final Exam: Students are encouraged to use their textbook or other materials for the weekly quizzes. Students may not work together on quizzes—consulting other individuals during a quiz or discussing a quiz after it has been completed will result in an Honor Code violation. While course materials may be consulted during the quiz, the use of course materials is strictly 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. The primary form of communication is email. Students must check their University of Minnesota email regularly.

For information that applies to all courses, please review the following document:

- University of Minnesota and College of Pharmacy Central Syllabus
Minnesota Board of Pharmacy Statutes and Rules via internet at:

**Board of Pharmacy Rules**: [https://www.revisor.mn.gov/rules/?id=6800](https://www.revisor.mn.gov/rules/?id=6800)


**Minn. Stats. Chapter 152** (Controlled Substances Act): [https://www.revisor.mn.gov/statutes/?id=152](https://www.revisor.mn.gov/statutes/?id=152).

Students may purchase books through [Minnesota’s Bookstore](https://www.revisor.mn.gov) or access the Rules and Statutes through the links above. Note that for the purposes of this course, students will only be responsible for reading the specific statutes and rules noted below under assignments. However, refer to the MPJE Information section for recommendations on what to study for that examination.

**ASSIGNMENTS**

**Module 1 (Two weeks starting 1/29) (Bilek)** – Introduction to Law and the Legal System; Malpractice

**Prior to class:**
Read Abood Chapter 1, pages 2-40
Read Abood Chapter 8, pages 425-466
Quiz 1 due 2/11/2018

**Module 2 (Two weeks starting 2/12) (Bilek)** – Federal Regulation of Medications: Development, Production and Marketing & Federal Regulations of Medications: Dispensing

**Prior to class:**
Read Abood Chapter 2, pages 41-104
Read Abood Chapter 3, pages 158-165 (Pharmacy Compounding Versus Manufacturing)
Quiz 2 due 2/25/2018

**Module 3 (Two weeks starting 2/26) (Wiberg)** – Federal Regulation of Pharmacy Practice & State Regulation of Pharmacy Practice

**Prior to class:**
Read Abood Chapter 6, pages 305-313, 346-350, skim 324-340
Read Abood Chapter 7

Quiz 3 due 3/11/2018

**Spring Break**: March 12 – 18, 2018
Module 4 (Two weeks starting 3/19) (Wiberg) – Minnesota Board of Pharmacy Statutes

Prior to class:
Read Minnesota Statutes 151.01 – 151.58 (Board of Pharmacy)
Read Minnesota Statutes 151.43 to 151.50 (Wholesale Drug Distribution Licensing Act)
Read Minnesota Statutes Chapter 214, sections:
• 214.075 (Criminal Background Checks)
• 214.077 (Temporary License Suspension)
• 214.10 (Complaint, Investigation & Hearing)
• 214.101 (Child Support; Suspension of License)
• 214.103 (Health-related Licensing Boards; Complaint, Investigation and Hearing)
• 214.104 (Health-related Licensing Boards; Substantiated Maltreatment)
• 214.105 (Health-related Licensing Boards; Default on Federal Loans or Service Obligations)
• 214.106 (Health-related Licensing Boards; Response to Insurance Fraud)
• 214.31 – 214.37 (Health Professionals Services Program)

Quiz 4 due 4/1/2018

Module 5 (Two weeks starting 4/2) (Wiberg) – Minnesota Board of Pharmacy Rules

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)

Quiz 5 due 4/15/2018

Module 6 (Two weeks starting 4/16) (Wiberg) – Federal and State Regulation of Controlled Substances

Prior to class:
Read Abood Chapter 4
Read Abood Chapter 5
Read DEA Pharmacists Manual
Read Minn. Stats. §152.02, subd. 6 (portions related to restriction of methamphetamine precursor sales)
Read Minnesota Statute 152.10-152.135 (Sales and Records; Prescriptions)
Note there is no quiz due this period. Consider using this time to prepare for the final exam.

FINAL EXAM DURING WEEK OF MAY 7TH
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:

MPJE INFORMATION

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.

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 (portions related to 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 120 multiple-choice questions: 100 questions are used to calculate the test score while 20 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 https://nabp.pharmacy/programs/mpje/ for more information on the MPJE.