

## PHAR 6778: LAW IN PHARMACY PRACTICE

### Syllabus

Spring 2020

0.7 Credit

January 27 – May 8, 2020

### **Location & Time**

Online

### **Instructor Information**

Course Director: Cody Wiberg, Pharm.D., M.S., R.Ph.  
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Office Hours: By appointment  
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Co-Director: Jennell C. Bilek, J.D., Pharm.D., Ph.D.  
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### **Required Reading Materials**

There is no required textbook to purchase. Links to reading materials for each module (two-week period) are supplied in the Assignments section below. **However, students also have free access to *Pharmacy Practice and the Law* (Abood and Burns). For the purposes of passing the MPJE, it would be advantageous for students to read the optional portions of this textbook, as described in each module.**

### **COURSE DESCRIPTION**

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

### **COURSE OBJECTIVES**

Upon completion of the course, the student will understand the primary federal and state laws and regulations that govern 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 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 (Chapter 6800) dealing with licensing, continuing education, pharmacy operations, and operations in institutions.
- Minnesota Pharmacy Practice and Wholesale Distribution Act. (Chapter 151)

### **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.

**Grading Policy:** Weekly quizzes and one final examination form the basis of the final grade. The final examination constitutes 50% of your final grade. Weekly multiple-choice quizzes in modules 1-5 each count for 10% of your final grade.

**Final Exam:**

The final exam will be scheduled during finals week. It will be available on Canvas 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:**

Final grades will be rounded to the nearest whole number using common rounding rules (as per Microsoft Excel® where values  $\geq 0.5$  are rounded up). Letter grade assignments appearing on transcripts will reflect the table below.

A	93-100%	A-	90-92%
B+	87-89%	B	83-86%
B-	80-82%	C+	77-79%
C	73-76%	C-	70-72%
D	60-69%		
F	< 60%		

**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 Canvas. These handouts, and any other course materials, may not be distributed to any person not enrolled in PHAR 6778 during the Spring 2020 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>

**Minn. Stats. Chapter 151** (Pharmacy Practice and Wholesale Drug Distribution Acts):  
<https://www.revisor.mn.gov/statutes/?id=151>.

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

Students may purchase paperback books of the Minnesota Statutes and Rules through [Minnesota's Bookstore](#) 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 1/27) (Bilek) – Introduction to Law and the Legal System; Negligence**

**Prior to class:**

- Read [Outline of the U.S. Legal System](#). (Bureau of International Information Programs United States Department of State – 2004); pages 6 – 17. (The rest of the document is optional).
- Read [Negligence](#) (Legal Information Institute - Cornell Law School)
- Read [Minn. Stats. §151.01](#)
- Read [OBRA at Sweet Sixteen: A Retrospective Review](#)

**Optional:**

- Read Abood Chapter 1, pages 2-40
- Read Abood Chapter 8, pages 425-466

Quiz 1 due 2/7/2020

**Module 2 (Two weeks starting 2/10) (Bilek) – Federal Regulation of Medications: Development, Production and Marketing & Federal Regulations of Medications: Dispensing and Compounding**

**Prior to class:**

- Read [Food, Drug & Cosmetic Act Summary](#). *Pharmacy Law—Examination and Board Review*; Feinberg, William. Available on Access Pharmacy.
- Read [Poison Prevention Packaging Act](#). *Pharmacy Law—Examination and Board Review*; Feinberg, William. Available on Access Pharmacy.
- Read [Minn. Stat. § 151.253](#) (compounding)
- Read [Minn. Stat. § 151.01](#) (compounding and dispensing definitions)
- Read *Official General USP Chapter 795 and Chapter 797* (last revised 2014). Please download a free copy of these Chapters from USP at the links above.
- Read the documents under [“Human Drug Compounding”](#) accessible on the left hand side of the Web page.
- Read: [Warning Letter Resurrects Issue of Makena and FDA’s Use of Enforcement Discretion](#)
- Skim: <https://www.fda.gov/media/132003/download>
- Read the following article: <https://www.fda.gov/news-events/press-announcements/fdawarns-15-companies-illegally-selling-various-products-containing-cannabidiol-agencydetails>

**Optional:**

- Read Abood Chapter 2, pages 41-104
- Read Abood Chapter 3, pages 158-165 (Pharmacy Compounding Versus Manufacturing)

Quiz 2 due 2/21/2020

**Module 3 (Two weeks starting 2/24) (Wiberg) – Federal Regulation of Pharmacy Practice & State Regulation of Pharmacy Practice**

**Prior to class:**

- Read [Minn. Rules 6800.0910 Patient Access to Pharmacist](#).
- Read [Minn. Rules 6800.3110 Patient Medication Profiles](#).
- Read [Minn. Stats. § 214.001 Policy and Regulation](#).
- Read [Minn. Stats. § 151.02 State Board of Pharmacy](#).
- Read [Minn. Stats. § 151.03 Membership](#).
- Read [Minn. Stats. § 214.02 Public Member, Defined](#).
- Read [Minn. Stats. § 151.06 Powers and Duties](#).

**Optional:**

- Read Abood Chapter 6, pages 305-313, 346-350, skim 324-340
- Read Abood Chapter 7

Quiz 3 due 3/6/2020

**Spring Break:** March 9 – 13, 2020

**Module 4 (Two weeks starting 3/23) (Wiberg) – Minnesota Board of Pharmacy Statutes**

**Prior to class:**

Read [Minnesota Statutes Chapter 151](#) (except for sections already read)

Read Minnesota Statutes Chapter 214, sections:

- [214.075](#) (Criminal Background Checks)
- [214.077](#) (Temporary License Suspension)
- [214.10](#) (Complaint, Investigation & Hearing)
- [214.103](#) (Health-related Licensing Boards; Complaint, Investigation and Hearing)
- [214.31](#) – 214.37 (Health Professionals Services Program)

Quiz 4 due 4/3/2020

**Module 5 (Two weeks starting 4/6) (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 4/17/2020

**Module 6 (Two weeks starting 4/20) (Wiberg) – Federal and State Regulation of Controlled Substances**

**Prior to class:**

- Read [Controlled Substances Act \(CSA\) Summary](#). Pharmacy Law— Examination and Board Review; Feinberg, William. Available on Access Pharmacy.

- Read [Minn. Stats. §152.02, subd. 6](#) (portions related to restriction of methamphetamine precursor sales)
- Read [Minnesota Statutes Sections 152.10-152.135](#) (Sales and Records; Prescriptions)

**Optional:**

- Read Abood Chapter 4
- Read Abood Chapter 5

**May 4<sup>th</sup>: Instructors will be on campus for a Law Review.** 1:25 – 3:20PM Weaver-Densford Hall.

Note there is no quiz due this period. Consider using this time to prepare for the final exam.

**FINAL EXAM DURING WEEK OF MAY 11<sup>TH</sup>**

**HELPFUL RESOURCES**

Minnesota Rules online, Chapter 6800: <http://www.revisor.leg.state.mn.us/arule/6800/>

Minnesota Statutes online, Chapter 151: <https://www.revisor.mn.gov/statutes/cite/151>

Minnesota Statutes online, Chapter 152: <https://www.revisor.mn.gov/statutes/cite/152>

Minnesota Statutes online, Chapter 214: <https://www.revisor.mn.gov/statutes/cite/214>

Minnesota Statutes online, Chapter 148: <https://www.revisor.mn.gov/statutes/cite/148>

**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:**

- Minnesota Rules 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)
- Compounding requirements of USP Chapter 795 and Chapter 797. (Which you may need to know for the NAPLEX as well). You can download a [free copy of these Chapters from USP](#)

**College of Pharmacy, Washington State University Review Questions about State Laws & Regulations William E. Fassett, Ph.D., R.Ph.**

This Web site has a list of 77 questions about pharmacy law but has no answers –it is intended to be used as a study guide. If you can answer these questions for any state in which you are seeking licensure, you will have a better chance of passing the law exam. <https://pharmacy.wsu.edu/documents/2017/12/questions-state-pharmacy-law-exams.pdf/>

**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.