PHAR 6778 Pharmacy Law

*** DRAFT SYLLABUS- THIS COURSE HAS NOT YET BEEN APPROVED BY COLLEGE ASSEMBLY

Meeting Time, Place, Credits

This will be an online course that runs for six weeks.

0.7 credits (Credit adjustment: note if this number is different that what is listed in the proposed curriculum.)
Course Web Site:  https://moodle.umn.edu/
Term: Spring 2016
Dates: March 28-May 13, 2016
Location: Online; In-person final exam during finals week
Target audience: PD3

Course Instructional Team

Course Team

Course Director
Name: Jennell Bilek, PharmD, PhD, JD
Office location: Off-campus
Phone: 612-436-9648
Email: jbilek@carlsoncaspers.com
Preferred method of contact: email
Office Hours: By appointment

Instructor
Name: Shelly Jonas, PharmD, JD Candidate (2016)
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Phone: 612-229-7440
Email: nipp0012@umn.edu
Preferred method of contact: email
Office Hours: By appointment

Overview of the course

Course content:
The course covers both federal and state laws that impact and regulate the practice of pharmacy including federal regulation of medications, regulation of controlled substances, and the Minnesota Pharmacy Practice Act.

Course format:
The course will be offered entirely online. Each week, students are expected to complete the assigned reading and watch the corresponding lectures. After completing each module, students will complete a multiple choice quiz. The multiple choice quizzes will incorporate hypothetical scenarios to assess how students interpret and apply the laws and regulations to these scenarios. After quizzes have been submitted, students will be given a detailed answer key with explanations. Instructors will also post recorded lectures that explain the answers in more detail. Students will take a
cumulative final examination at the end of the semester. Students will be allowed to access lectures and other course materials during their fourth year to assist them on rotations and in preparing for the MPJE.

Prerequisites

- Third-year pharmacy student

Computer/Technology Requirements

- Moodle: This course will use Moodle to distribute resources and host course activities (quizzes, resources). See Moodle setup requirements at http://www1.umn.edu/moodle/start/technical.html.
- Access to College of Pharmacy provided eTextbooks
- E-Mail: Course instructors will communicate through email about course administrative issues. We suggest that you check your U of M email daily.

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 able to:

- Summarize the distinctions between administrative, federal, and state law as applied to pharmacy practice
- Interpret federal regulations and laws governing medications
- Interpret federal regulations and laws governing pharmacy practice and apply those regulations and laws to practice scenarios
- Interpret state regulations and laws governing pharmacy practice and apply those regulations and laws to practice scenarios
- Describe pharmacist malpractice and other liability concerns facing pharmacists
- Interpret state and federal laws and regulations concerning controlled substances and apply those laws and regulations to practice scenarios
- Interpret state and federal laws and regulations concerning pharmacy compounding and apply those laws and regulations to practice scenarios

| Objective |
|-----------------|-----------------|-----------------|
| 1. Summarize the distinctions between administrative, federal, and state law as applied to pharmacy practice | Competency Domain | 3.8 |
| | Scientific Foundation | 5.5.1, 5.5.2 |
| 2. Interpret federal regulations and laws governing medications | Competency Domain | 3.8 |
| | Scientific Foundation | 5.5.1, 5.5.2 |
| 3. Interpret federal regulations and laws governing pharmacy practice and apply those regulations and laws to practice scenarios | Competency Domain | 3.8 , 6.0 |
| | Scientific Foundation | 5.5.1, 5.5.2 |
4. Interpret state regulations and laws governing pharmacy practice and apply those regulations and laws to practice scenarios  
   3.8, 6.0  
   5.5.1, 5.5.2

5. Describe pharmacist malpractice and other liability concerns facing pharmacists  
   3.8, 6.0  
   5.5.1, 5.5.2, 5.5.3, 5.5.4

6. Interpret state and federal laws and regulations concerning controlled substances and apply those laws and regulations to practice scenarios  
   3.8, 6.0  
   5.5.1, 5.5.2, 5.5.3, 5.5.4

7. Interpret state and federal laws and regulations concerning pharmacy compounding and apply those laws and regulations to practice scenarios  
   3.8, 6.0  
   5.5.1, 5.5.2

If time allows: Describe the basic aspects of health care fraud and how health care fraud may arise in a pharmacy practice setting  
   3.8, 6.0  
   5.5.2, 5.5.3, 5.5.4

Domains below provided for reference.  
Link to full competency domain document.  
Scientific Foundations document

**Competency Domains**

**Domain 1: Patient-Centered Care**
As a provider of care, the pharmacist is ethical, benevolent, empathetic, competent, open-minded, prudent in making judgments, and devoted to serving others. The pharmacist applies knowledge, experience, and skills to protect the welfare of humanity. The pharmacist willingly and respectfully cares for patients to assure optimal therapeutic outcomes.

**Domain 2: Population Health & Vulnerable Communities**
As a promoter of public health, the pharmacist uses his/her expertise to partner with others to improve care for vulnerable communities or at risk populations. The pharmacist recognizes the differences between populations of individuals and seeks to alleviate disparities that exist.

**Domain 3: Health Systems Management**
As a manager of health system resources, the pharmacist examines critical issues, assumptions, and limitations to produce and validate ways to deliver medications safely, effectively, and in a timely manner. The pharmacist demonstrates imagination, inventiveness, and courage by undertaking new endeavors to produce improved quality, productivity, efficiency, effectiveness, and innovation.

**Domain 4: Leadership & Engagement**
In leading, the pharmacist demonstrates integrity and is habitually resolute, focused on excellence, knowledgeable about the "big picture," strategic, focused, persuasive, open to feedback, decisive, visionary, empowering, and service-oriented.

**Domain 5: Professional & Interprofessional Development**
When collaborating, the pharmacist demonstrates critical thinking, excellent communication and leadership, and is goal-oriented, cooperative, assertive, respectful, enthusiastic, and reliable. The pharmacist consistently and consciously demonstrates high ethical and moral standards by considering how and when to act, acting in a manner that is clearly consistent with those standards and exercising accountability for those actions.

**Domain 6: Knowledge, Scientific Inquiry, and Scholarly Thinking**
In making use of scientific knowledge, the pharmacist explains with thoroughly researched, evidence based accounts of facts and data, and provides interpretations based on analysis of the importance, meaning, and significance. The pharmacist applies knowledge fluently, flexibly, and efficiently in diverse contexts.

* refer to College of Pharmacy Competency Domains for Section descriptions.  
Link to full competency domain document.
Attendance Policy

This is a completely online course that does not require students to login at any specific time. However, there are due dates throughout the course, so it is expected that students will be in the course site regularly to complete course work.

Course Materials

**Required (or Optional) Text, eReserve, or Materials**


Minnesota Rules are available at [http://mn.gov/health-licensing-boards/pharmacy/statutes/rules.jsp](http://mn.gov/health-licensing-boards/pharmacy/statutes/rules.jsp)

Minnesota Statutes are available at [http://mn.gov/health-licensing-boards/pharmacy/statutes/statutes.jsp](http://mn.gov/health-licensing-boards/pharmacy/statutes/statutes.jsp)

Students who wish to purchase a bound copy of the Minnesota Rules or Statutes may do so, but this is not required. The links to purchase these books are found on the Board of Pharmacy’s website [http://mn.gov/health-licensing-boards/pharmacy/statutes/](http://mn.gov/health-licensing-boards/pharmacy/statutes/)

Assessments and Grading

Quizzes will incorporate hypothetical scenarios to assess how students interpret and apply the laws and regulations to these scenarios. They will be non-cumulative, open-book, multiple-choice and administered online. Students will have one hour to complete each quiz, and quizzes will be available throughout the week, so students can complete them when ready. Students will receive scores and feedback after quizzes close at the end of each week. The first quiz will not count towards final grades as it is used for students to experience the format of the quizzes, but it is still a requirement in order to pass the course.

The final exam will be cumulative, closed-book, multiple-choice, and administered in-person through Moodle (proctored) in the same format as the quizzes.

**Graded Assessments**

[Include quizzes and exams in this table. Indicate delivery method, etc.]

The following graded assessments will count toward your final grade for this course in the following amounts:

<table>
<thead>
<tr>
<th>#</th>
<th>Date</th>
<th>Title Brief description</th>
<th>Assessment Goal</th>
<th>% of final grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Week 1</td>
<td>Module 1 multiple choice quiz</td>
<td>Objective 1 &amp; 2</td>
<td>0%</td>
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<tr>
<td>2</td>
<td>Week 2</td>
<td>Module 2 multiple choice quiz</td>
<td>Objective 5</td>
<td>6%</td>
</tr>
<tr>
<td>3</td>
<td>Week 3</td>
<td>Module 3 multiple choice quiz</td>
<td>Objective 3 &amp; 4</td>
<td>6%</td>
</tr>
<tr>
<td>4</td>
<td>Week 4</td>
<td>Module 4 multiple choice quiz</td>
<td>Objective 4</td>
<td>6%</td>
</tr>
<tr>
<td>5</td>
<td>Week 5</td>
<td>Module 5 multiple choice quiz</td>
<td>Objective 6 &amp; 7</td>
<td>6%</td>
</tr>
<tr>
<td>Week 6</td>
<td>Module 6 multiple choice quiz</td>
<td>Objective 6 &amp; 7</td>
<td>6%</td>
<td></td>
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<tr>
<td>--------</td>
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<td>-----------------</td>
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<td></td>
</tr>
<tr>
<td>7</td>
<td>Finals week</td>
<td>Final Exam, in-person on Moodle, cumulative</td>
<td>Objectives 1-7</td>
<td>70%</td>
</tr>
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</table>

**Statement on Penalties for Late Work**
Late work will not be accepted without accompanying documentation. The student will receive 0% for late work.

**Exam Policy**

- Quizzes: online, non-cumulative, multiple-choice, open-book
- Exam: cumulative, closed-book, multiple-choice, taken in-person on Moodle during final exams week

**Absence from Exam**

Make-up exams will be given to those students who have an excused absence AND who have permission from the course director BEFORE the scheduled start of the examination. Students are responsible for scheduling the make-up exam as soon as reasonably possible. Students must arrange a make-up time directly with the course director. An unexcused absence will result in the student failing this course. The course director will determine what constitutes an excused absence. Students may submit to the TA correction requests via email regarding the final examination. The request must include an explanation about why and where a change is required. Any such requests must occur within five days of the examination.

**Grading Information**

Grades will be determined by six quizzes and one final exam. The first quiz is worth 0%, so that students can get used to the format, but it is still a requirement in order to pass the course. The remaining five quizzes will account for 30% of final grades, and the final exam will be 70% of final grades. Final grades will be curved.

**Course Letter Grades**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>A</td>
<td>90.0 - 100</td>
</tr>
<tr>
<td>A-</td>
<td>87.0 - 89.9</td>
</tr>
<tr>
<td>B+</td>
<td>83.0 - 86.9</td>
</tr>
<tr>
<td>B</td>
<td>80.0 - 82.9</td>
</tr>
<tr>
<td>B-</td>
<td>77.0 - 79.9</td>
</tr>
<tr>
<td>C+</td>
<td>73.0 - 76.9</td>
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</table>
**Statement on Extra Credit**

Extra credit will not be offered.

**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.

**Detailed Course Outline & Schedule**

<table>
<thead>
<tr>
<th>Class</th>
<th>Agenda/Topics</th>
<th>Competency/ Learning Objective</th>
<th>Activities / Assignments / Assessments</th>
<th>Total EST HRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MODULE 1</td>
<td>Bilek</td>
<td>Legal System Overview Federal Regulation of Medications: Development, Production, and Dispensing</td>
<td>Summarize the distinctions between administrative, federal, and state law as applied to pharmacy practice; Interpret federal regulations and laws governing medications</td>
<td>Abood Chapter 1, pages 2-23 Abood Chapter 2, pages 39-56, 63-74 Abood Chapter 3, pages 123-134, 147-160</td>
</tr>
<tr>
<td>MODULE 4</td>
<td>Bilek</td>
<td>New Legislation Affecting Pharmacy Practice Pharmacy Practice Act with emphasis on Compounding, Manufacturing, and Wholesaling</td>
<td>Interpret federal and state regulations and laws governing pharmacy practice and apply those regulations and laws to practice scenarios; Interpret state and federal laws and regulations concerning pharmacy compounding</td>
<td>Abood Chapter 3, pages 161-164 Minnesota Statute 151.01-151.302 Minnesota Statute 151.43-151.5</td>
</tr>
<tr>
<td>MODULE 5</td>
<td>Bilek</td>
<td>Controlled Substances Act DEA Enforcement Dispensing Controlled Substances</td>
<td>Interpret state and federal laws and regulations concerning controlled substances and apply those laws and regulations to practice scenarios</td>
<td>Abood Chapter 4, pages 183-201, 210-215 Abood Chapter 5 Minnesota Statute 152.1-152.135</td>
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<td>MODULE 6</td>
<td>Bilek</td>
<td>Controlled Substances Act Healthcare Fraud Laws Practice Problems Federal Regulation of Pharmacy Practice and Medications Revisited Final Exam Review</td>
<td>Interpret federal and state regulations and laws governing pharmacy practice and controlled substances and apply those regulations and laws to practice scenarios</td>
<td>Minnesota Rules 6800.9100-6800.9700 Minnesota Statute 151.60-151.70</td>
</tr>
</tbody>
</table>

* Subject to change at course instructor’s discretion.

**University of Minnesota and College of Pharmacy Policy Reference** *(Centralized Syllabus)*
[This page includes all required UMN and CoP policies, e.g., Academic Freedom; Copyright; Course Evaluations; Disability Accommodations; FERPA, etc.]