
PHA 6278: State Regulation of Drugs & Pharmacy (2020)

Three Semester Credit Hours

Course Purpose:

This course is designed to provide an understanding of state licensure and standards setting for health care professions and practice sites. Students study how, why and under what circumstances administrative boards determine and enforce items such as: Initial and continuing competence of practitioners; professional misconduct; role of professional self-regulation. The course also explores federal initiatives to regulate healthcare professionals and practice sites and the role of non-governmental organizations and influences on practice regulation

Course Faculty and Office Hours

Course Coordinator and Instructor:

Cody Wiberg, Pharm.D., M.S., R.Ph.

Office Hours

Students may send e-mails to the course coordinator at any time. E-mails will usually be answered within 24 hours. Students may also set up a telephone conversation with the course coordinator. Students may contact the course coordinator by telephone for urgent matters.

Place and Time of Class Sessions

All classes are held online, using Canvas, on Sundays from 6:00PM – 8:00PM Eastern Time.

Course Objectives

Upon successful completion of this course, the student will be able to:

- Compare and contrast the responsibilities of federal health regulators and the responsibilities of state health regulators. Also, describe how those responsibilities sometimes overlap – particularly regarding drug compounding.
- Understand the origin of state regulation of pharmacy and other health professions in the United States.
- Discuss economic arguments made for and against the licensing of professions and occupations.
- Describe how state health regulators receive their authority to regulate the practice of pharmacy and the manufacturing and distribution of drugs.
- Describe the processes that a licensing board must follow when taking disciplinary action against the licenses and registrations that it issues.
- List the steps that are taken through notice-and-comment rulemaking to develop and implement standards of practice for pharmacists, pharmacies, and other facilities licensed by boards of pharmacy.

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- Assess changes in practice and technology that will have an impact on the future of regulatory activity in the areas of pharmacy practice and drug manufacturing and distribution.

Pre-Requisite Knowledge and Skills

None.

Course Structure & Outline

Course Structure. Learning activities include weekly on-line (real-time) classes, two-hours each; assigned readings; four weekly *short* (one – two page) papers; and five weekly quizzes. There is no textbook and there are no mid-term or final examinations.

This course has five modules, to be completed over a period of five weeks. The five modules are:

- **History of State Regulation of Pharmacy & Drugs; Comparison with Federal Regulation**
- **Operations of State Boards: Creation, Powers and Duties, Licensing, Rulemaking, Inspections**
- **Operations of State Boards: Complaints and Discipline**
- **Case Law Concerning State Regulation of Health Professionals**
- **Emerging Issues for Regulation of Pharmacy and Drugs**

Course Schedule:

Week 1: **History of State Regulation of Pharmacy & Drugs; Comparison with Federal Regulation**

- Live class meets on May 10th.
- Question for Paper 1 released May 10th at 7:00am. One- or two-page paper is due at 11:59 PM on May 20th.
- Exam 1 opens on Thursday, May 14th at 7 AM, closes on Sunday, May 17th at 11:59 PM.

Week 2: **Operations of State Boards: Creation, Powers and Duties, Licensing, Rulemaking, Inspections**

- Live class meets on May 17th.
- Question for Paper 2 released May 17th at 7:00am. One- or two-page paper is due at 11:59 PM on May 27th.
- Exam 2 opens on **Wednesday**, May 20th at 7 AM, closes on Sunday, May 24th at 11:59 PM.

Week 3: **Operations of State Boards: Complaints and Discipline**

- No live class due to Memorial Day. Students will have to watch a recorded class.
- Question for Paper 3 released May 24th at 7:00am. One- or two-page paper is due at 11:59 PM on June 3rd.
- Exam 3 opens on Thursday, May 28th at 7 AM, closes on Sunday, May 31st at 11:59 PM.

Week 4: Case Law Concerning State Regulation of Health Professionals

- Live class meets on May 31st.
- Question for Paper 4 released May 31st at 7:00am. One- or two-page paper is due at 11:59 PM on June 10th.
- Exam 4 opens on Thursday June 4th at 7 AM, closes on Sunday June 7th at 11:59 PM.

Week 5: Emerging Issues for Regulation of Pharmacy and Drugs

- Live class meets on June 7th.
- Exam 5 opens on **Wednesday**, June 10th at 7 AM, closes on **Saturday** June 13th at 11:59 PM.

Required Readings

- Book Chapter
 - Fox, William F. *Chapter 1: Understanding Administrative Law*, 4th Edition. Copyright 2000.
- Journal Articles
 - Casey et. al. Current Practices and State Regulations Regarding Telepharmacy in Rural Hospitals
 - Chaudhry et. al. Medical Board Expectations for Physicians Recommending Marijuana
 - Ford et al An Assessment of State Board of Pharmacy Legal Documents for Public Health Emergency Preparedness
 - Kleiner, Morris M. *A License for Protection*. Regulation (a journal of the Cato Institute). Fall, 2006.
- Legal Case Studies
 - U.S. v. Sullivan (SCOTUS 1948)
 - Dent v. West Virginia (SCOTUS 1889)
 - Thompson v. Western States Medical Center, 122 S.Ct. 1497 (SCOTUS 2002)
 - Medical Center Pharmacy v. Mukasey, No. 06-51583 (5th Circuit)
 - VIRGINIA STATE BOARD OF PHARMACY ET AL. v. VIRGINIA CITIZENS CONSUMER COUNCIL, INC., ET AL.
 - Whalen, Commissioner of Health of New York v. Roe et. al.
 - Storman's, Inc., DBA Ralph's Thriftway, et. al. v. John Wiesman, Secretary, Washington State Department of Health et. al.
 - WILLIAM H. SORRELL, ATTORNEY GENERAL OF VERMONT, et al., Petitioners v. IMS HEALTH INC. et al. (SCOTUS 2011)
- Other Documents
 - Apex Drugstore Mock Disciplinary Letter
 - Apex Drugstore Mock Notice of Conference
 - Wiberg, Cody C. *Minnesota Board of Pharmacy Sunset Report 2011*
 - Law, Marc T., and Kim, Sukkoo. *Specialization and Regulation: The Rise of Professionals and the Emergence of Occupational Licensing Regulation*. National Bureau of Economic Research Working Papers Series. May 2004.

Student Evaluation & Grading

Evaluation Methods

Class participation	10%
Weekly Quizzes	50%
Papers	40%

The weekly quizzes consist of multiple choice, true-false and fill-in-the-blank questions. Students will write short (one or two pages) weekly papers for the first four weeks – there is no paper assigned for week five. All quizzes and exams are opened on Thursday mornings at 7:00AM Eastern time and closed on Sunday evenings at 11:55PM Eastern time. Students have four hours to complete quizzes. The questions for the papers are released on Sunday mornings and students have ten days to submit the paper. (For example, the first week question for the paper will be released on Sunday, May 10th at 7:00AM, the paper will be due on Wednesday, May 20th at 11:59PM).

Grading Scale

95-100 = A
90-94 = A-
86-89 = B+
83-85 = B
80-82 = B-
76-79 = C+
73-75 = C
70-72 = C-
66-69 = D+
63-65 = D
60-62 = D-
<60 = E

Class Attendance Policy

Students are expected to attend and participate in the weekly on-line class sessions. However, students can miss some classes for reasons such as personal or family illnesses, unavoidable conflicts with work, etc. Students should notify the Course Director in advance of missing a class if possible. Students who miss a class session must watch the video for that session.

Quiz/Paper Policy

Students are expected to complete all quizzes and papers. Due to the nature of the course, quizzes and papers are open book. Students are expected to do their own work – they are not to share answers with one another. Students may use and cite references when completing the papers questions but are expected to answer such questions in their own words.

Make-up Quiz/Paper Policy

Students should make every attempt to complete quizzes and papers within the periods during which they are open. However, students may contact the course coordinator to make alternative arrangements if they have an urgent situation that will prevent them from completing a quiz or paper during the scheduled open period.

Policy on Old Quizzes and Assignments

Students are not provided with old quizzes and assignments.

Assignment Deadlines

Students who do not complete all quizzes and papers will most likely receive a lower grade. Students who do not complete more than one of the quizzes or papers will probably fail the course. However, as explained in the Make-up Quiz/Paper Policy section, students can make alternative arrangements if they have an urgent situation that will prevent them from completing a quiz or exam during the scheduled open period.

General College of Pharmacy Course Policies

The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

Complaints

Should you have any complaints with your experience in this course please visit:

<http://www.distancelearning.ufl.edu/student-complaints> to submit a complaint.