

Online POP Course Syllabus

PHA 6278: State Regulation of Drugs & Pharmacy (2022)

3 Credit Hours

Note: The final syllabus posted in the Course Canvas site is the most current and supersedes this syllabus.

Class Meeting Times

Sundays from 6:00PM – 8:00PM Eastern Time.

Class Meeting Location

Class meetings are held in Zoom, which can be accessed via the course Canvas site. If you are having trouble accessing the course Canvas site, please contact Distance Education Support Services at DESS@ahc.ufl.edu.

Instructor

Cody Wiberg, PharmD, MS, RPh

Email: ccwj7@outlook.com OR use Canvas Inbox for fastest response

Office Hours: By appointment. Please email me to set up a conference meeting.

Office Location: via Zoom or phone

Course Description

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 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.

Online POP Course Syllabus

- 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.

Relationship to Program Outcomes

This 3-credit course pertains to the following POP program Student Learning Outcomes (SLO):

Pharmaceutical Regulation

- Identify, interpret, and utilize core knowledge across the spectrum of Pharmaceutical Regulation
- Evaluate a problem that is related to pharmaceutical regulation

Required Textbooks and/or Software

There are no required texts.

Additional reading assignments from current websites, journal articles, and news articles are assigned for each module. These reading assignments are provided in Canvas.

Recommended Materials

None

Course Pre-Requisites

None

Structure and Organization

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 six modules, to be completed over a period of six weeks.

Course Schedule

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

- Live class meets on May 8th.

Online POP Course Syllabus

- Question for Paper 1 released May 8th at 7:00am. One- or two-page paper is due at 11:59 PM on May 22nd.
- Week One Exam opens on Thursday, May 12th at 7 AM, closes on Sunday, May 15th at 11:59 PM.

Week 2: **Operations of State Boards: Creation, Powers and Duties, Administrative Procedures Act, Rulemaking, Guidance**

- Live class meets on May 15th.
- Question for Paper 2 released May 15th at 7:00am. One- or two-page paper is due at 11:59 PM on May 29th.
- Week Two Exam opens on Thursday, May 19th at 7 AM, closes on Sunday, May 22nd at 11:59 PM.

Week 3: **Operations of State Boards: Licensing, Inspections, Continuing Education, Other Programs**

- Live class meets of May 22nd.
- No paper assigned due to Memorial Day.
- No exam assigned due to Memorial Day.

Week 4: **Operations of State Boards: Complaints and Discipline**

- No live class on May 29th, but students will need to watch a recorded lecture.
- Question for Paper 3 released May 29th at 7:00am. One- or two-page paper is due at 11:59 PM on June 8th.
- Week Four Exam opens on June 2nd at 7:00am, closes on June 5th at 11:59 PM.

Week 5: **Case Law Concerning State Regulation of Health Professionals**

- Live class meets on June 5th.
- Question for Paper 4 released June 5th at 7:00am. One- or two-page paper is due at 11:59 PM on June 15th.
- Week Five Exam opens on Thursday June 9th at 7 AM, closes on Sunday June 12th at 11:59 PM.

Week 6: **Emerging Issues for Regulation of Pharmacy and Drugs**

- Live class meets on June 12th.
- No paper assigned.
- Week Six Exam opens on **Wednesday**, June 15th at 7 AM, closes on **Saturday** June 18th at 11:59 PM.

Required Readings

Book Chapter

- Fox, William F. Chapter 1: Understanding Administrative Law, 4th Edition. Copyright 2000.

Online POP Course Syllabus

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.

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.

Online POP Course Syllabus

Attendance Policy for this Course

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.

Attendance Policy for UF Graduate Students

Students may not attend classes unless they are registered officially or approved to audit with evidence of having paid audit fees. After the end of drop/add, the Office of the University Registrar provides official class rolls/addenda to instructors. Students who do not attend at least one of the first 2 class meetings of a course or laboratory in which they are registered and who have not contacted the academic unit to indicate their intent may be dropped from the course. Students must not assume that they will automatically be dropped if they fail to attend the first few days of class. The academic unit will notify students dropped from courses or laboratories by posting a notice in the academic unit office. Students may request reinstatement on a space-available basis if documented evidence is presented. The University recognizes the right of the individual professor to make attendance mandatory. After due warning, professors may prohibit further attendance and then assign a failing grade for excessive absences. Students who have registration changes, at any time during the semester, should verify their registrations before the last day of class of the term. Retroactive drop/add or other registration changes will not be permitted. See the [UF graduate academic regulations](#) for more information.

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.

Due Dates and Make-up Policy:

Students should make every attempt to complete quizzes and papers within the periods during which they are open. Students who do not complete all quizzes and papers will most likely receive a lower grade. Those who do not complete more than one of the quizzes or papers will probably fail the course. 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.

Grading Policy

The only passing grades for graduate students are A, A-, B+, B, B-, C+, C, and S. Grades of B-, C+ or C count toward a graduate degree if an equal number of credits in courses numbered 5000 or higher have been

Online POP Course Syllabus

earned with grades of B+, A- and A, respectively. Grade points are not given for S and U grades; S and U grades are not used to calculate grade point averages. All letter-graded courses eligible to count toward the graduate degree, except 1000- and 2000-level courses, are used to calculate the cumulative grade-point average. Letter grades of C-, D+, D, D- or E are not considered passing at the graduate level, although the grade points associated with these letter grades are included in grade point average calculations. See the [UF graduate academic regulations](#) for more information.

A	>92.500%
A-	89.500–92.499%
B+	86.500–89.499%
B	82.500–86.499%
B-	79.500–82.499%
C+	76.500–79.499%
C	72.500–76.499%
C-	69.500–72.499%
D+	66.500–69.499%
D	62.500–66.499%
D-	59.500–62.499%
E	<59.499%

Course Technology Support

Your instructor is not able to handle technological issues or answer questions related to computer issues.

- **Assistance accessing course Canvas page:** Contact Distance Education Support Services at DESS@ahc.ufl.edu
- **IT Support:** Contact UF Computing Help Desk at 352-392-HELP (4357) or helpdesk@ufl.edu or submit an [online request form](#). If a technical problem causes you to miss an assignment, you must report the problem to the Help Desk and then email your instructor your Help Desk ticket number to the instructor in order to receive an extension.

Online POP Course Syllabus

Students Requiring Academic Accommodations

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the [Disability Resource Center](#). It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.

Course technologies meet online learning accessibility standards for sight and hearing-impaired learners. Likewise, course materials are developed in accordance with accessibility standards. Course documents and webpages are formatted for screen-reader accessibility with the use of headings, styles, or alternative text tagging for images. Accessibility design tools in Microsoft Office products and in Canvas are used to evaluate and update accessibility issues detected in the instructional materials. Synchronous class sessions in Zoom are recorded. These recordings are posted to the course site to accommodate students unable to attend.

- [Canvas Accessibility](#)
- [Zoom Accessibility](#)

Course Evaluations

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. [Click here for guidance on how to give feedback in a professional and respectful manner](#). Students will be notified when the evaluation period opens and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via ufl.bluera.com/ufl/.

University Honesty Policy and Academic Integrity

UF students are bound by The Honor Pledge which states, “We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: “On my honor, I have neither given nor received unauthorized aid in doing this assignment.” [The Honor Code](#) specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Regarding academic integrity, students in the program are strongly encouraged to be mindful of what constitutes plagiarism. Written assignments that contain the research or other original published work of someone else must be properly quoted, cited, paraphrased, or referenced appropriately. A software (TurnItIn) that is integrated with Canvas Assignments may be utilized to help students determine if a written submission meets the criteria for a properly referenced research paper. Please ask for help, utilize resource materials and

Online POP Course Syllabus

take advantage of opportunities like creating a draft of your paper to test, ensuring you have addressed any errors prior to the final submission.

Please watch these short videos about this topic:

- [Understanding and Avoiding Plagiarism: Types of Plagiarism](#)
- [Avoiding Plagiarism](#)

Software Use and Course Technology

All faculty, staff, and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

Educational technology in the program is primarily the Canvas Learning Management System (LMS) and Zoom web conferencing software. These tools firmly support learning objectives and course goals. Writing with communication tools, reading articles from digital collections, and viewing video presentations in high-quality, accessible formats are essential to facilitate meaningful learning experiences. These experiences expand knowledge and influence professional work habits and skills such as information-gathering techniques and evidence-based practice. Synchronous class sessions in Zoom provide learners with opportunities to gain confidence and practice how they interact and collaborate in online meetings.

- [Canvas Student Guide](#)
- [Zoom Resources](#)

A minimum number of other technical skills are required for success in the online courses. These include accessing course webpages to read text and listen to recorded videos, using word processing tools (MS Word, PowerPoint), downloading/uploading content, submitting online assignments and using a variety of communication tools (Canvas Inbox, Discussions, Zoom Conferences).

Course Communication

Canvas (Inbox tool) will be used as the primary communication tool between the instructor and students. Check daily for new announcements or notifications about course updates. UF email will also be used occasionally for mass communication to the class, so please check your email at least once a day as well. All emails sent out to the entire class will also be posted as an Announcement on Canvas.

General questions about course content (e.g., assignments or lectures) or policies should be posted to the course discussion board. We expect students to help each other track down answers as best as possible. Read through all the other posts in the discussion board first before posting to make sure your question has not

Online POP Course Syllabus

been addressed/answered already. Please include a clear subject title for your topics to make it clear what your post pertains to.

Emotions can easily be misinterpreted on a discussion board/emails, so make sure your message is clear before sending it since there are no physical gestures or voice inflections that accompany posts/emails. Any posts/emails deemed inappropriate by the faculty will be dealt with on a case-by-case basis with either the faculty directly or they will be sent on to the Associate Dean for Professional Affairs.

For personal issues/questions, please email your instructor. Be sure to include in your subject line the course listing and then a quick subject (e.g., PHAXXXX – Your Name -). This will allow instructors to quickly identify emails related to the course amongst the many emails that are received each day. Emails not correctly addressed may get lost in the shuffle and unintentionally deleted or ignored so be sure to follow the guidelines exactly.

Student Privacy

There are federal laws protecting your privacy in terms of grades earned in courses and on individual assignments. For more information, please see the [Notification to Students of FERPA Rights](#).

Recordings of weekly class sessions in Zoom are created for the purpose of course teaching and learning, as well as for use as a resource for students who miss a class session.

The use of video (or web camera) feature in Zoom is not a requirement, but rather is voluntary for meeting participants. For both the audio and video features in Zoom, you will have the option to Start or Stop these functions.

Students who participate with their camera engaged or who utilize a profile image are agreeing to have their video or image recorded. If you are unwilling to consent to have your profile or video image recorded, be sure to keep your camera off and do not use a profile image. Likewise, students who un-mute during class and participate orally are agreeing to have their voices recorded. If you are not willing to consent to have your voice recorded during class, you will need to keep your mute button activated and communicate exclusively using the "chat" feature, which allows students to type questions and comments live. As in all courses, unauthorized recording and unauthorized sharing of recorded materials is prohibited.

- [Zoom Software Privacy Statement](#)
- [Canvas \(by Instructure\) Privacy Policies](#)

Security

Online activity in Canvas requires an active UF GatorLink account to log in, as well as enrollment in courses. The Zoom Conference meetings for weekly classes are accessed within Canvas. These meetings have a pass code applied as an additional security setting. Students in the class do not need to enter the passcode, however anyone not enrolled in the course cannot join the meeting without it.

Online POP Course Syllabus

Library Resources

For remote access to UF library resources such as e-journals or other digital collections, use the [UF VPN or proxy server to connect](#).

Additional University Resources

- **U Matter, We Care:** If you or a friend is in distress, please contact umatter@ufl.edu or 352 392-1575 so that a team member can reach out to the student.
- [Counseling and Wellness Center](#)
- **Sexual Assault Recovery Services (SARS):** Student Health Care Center, 392-1161.
- **University Police Department** at 392-1111 (or 9-1-1 for emergencies), or police.ufl.edu
- [E-learning technical support](#): 352-392-4357 (select option 2) or e-mail to Learning-support@ufl.edu.
- [Teaching Center](#): Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.
- [Writing Studio](#): 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers.
- [On-Line Students Complaints](#)