

# PHA 6278: State Regulation of Drugs & Pharmacy 3 credit hours

**Note:** The final syllabus posted in the course Canvas site is the most current and supersedes the syllabus posted on the internet.

Class Meeting Times Sundays, 6:00-8:00 PM Eastern

#### **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 <u>DESS@ahc.ufl.edu</u>.

#### Instructor

Cody Wiberg, Pharm.D., M.S., R.Ph. Email: <u>ccwj7@outlook.com</u> Phone: (651)888-9197 Office: via Zoom or phone Office Hours: By appointment, or before and after class meetings

## **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. State regulation of pharmaceuticals is also covered.

## **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.

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- 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.
- 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.

## **Relationship to Program-level Student Learning Outcomes**

This course pertains to the following program-level student learning outcomes:

1. Interpret and apply laws, regulations, guidance, and policies related to drug development and/or use.

## **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**

This course is organized into weekly modules in UF's e-learning system, Canvas. The assigned work (eg, readings, videos, and assignments) for each module is clearly detailed in Canvas. In addition, the faculty and students meet synchronously once per week using Zoom. This course is self-paced to accommodate the time constraints of individual students. However, students are expected to complete the assigned work for each module before each weekly synchronous class meetings and by the posted deadline.



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# **Course Schedule**

Week	Date	Торіс	Assignments
1	Sunday, May 14	History of State Regulation of Pharmacy & Drugs; Comparison with Federal Regulation	<ul> <li>Live class meets on May 14th.</li> <li>Question for Paper 1 released May 14th at 7:00am. One- or two-page paper is due at 11:59 PM on May 25th.</li> <li>Week One Exam opens on Thursday, May 18th at 7 AM, closes on Sunday, May 21st at 11:59 PM.</li> </ul>
2	Sunday, May 21	Operations of State Boards: Creation, Powers and Duties, Administrative Procedures Act, Rulemaking, Guidance	<ul> <li>Live class meets on May 21st.</li> <li>Question for Paper 2 released May 21st at 7:00am. One- or two-page paper is due at 11:59 PM on June 1st.</li> <li>Week Two Exam opens on Thursday, May 25th at 7 AM, closes on Sunday, May 28th at 11:59 PM.</li> </ul>
3	Sunday, May 28th	Operations of State Boards: Licensing, Inspections, Continuing Education, Other Programs	<ul> <li>No live class, but students need to view a recorded lecture.</li> <li>No paper assigned to Memorial Day.</li> <li>No exam assigned due to Memorial Day</li> </ul>
4	Sunday, June 4th	Operations of State Boards: Complaints and Discipline	<ul> <li>Live class meets on June 4<sup>th.</sup></li> <li>Question for Paper 3 released June 4th at 7:00am. One- or two-page paper is due at 11:59 PM on June 15th.</li> <li>Week Four Exam opens on June 8th at 7:00am, closes on June 11th at 11:59 PM</li> </ul>

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5	Sunday, June 11th	Case Law Concerning State Regulation of Health Professionals	<ul> <li>Live class meets on June 11th.</li> <li>Question for Paper 4 released June 11th at 7:00am. One- or two-page paper is due at 11:59 PM on June 22<sup>nd</sup>.</li> <li>Week Five Exam opens on Thursday June 15th at 7 AM, closes on Sunday June 18th at 11:59 PM.</li> </ul>
6	Sunday, June 18th	Emerging Issues for Regulation of Pharmacy and Drugs	<ul> <li>Live class meets on June 18th.</li> <li>No paper assigned.</li> <li>Week Six Exam opens on Sunday, June 18th at 7 AM, closes on Saturday June 25<sup>th</sup> at 11:59 PM.</li> </ul>

#### **Evaluation Methods**

#### **Class Participation (10%):**

Students are expected to actively contribute to discussions in the synchronous class meetings. The instructor will call on individual students during synchronous class meetings. This strategy is intended elevate and advance the conversation, not to challenge the student with a question that is difficult to answer. Students are encouraged to be prepared for the discussion, but they should be comfortable responding to the question with another question or expressing points of ambiguity about the topic.

#### Weekly Quizzes (50%)

The weekly quizzes consist of ten multiple choice, true-false and fill-in-the-blank questions. Students have four hours to complete quizzes. Each quiz counts for 10% of the course grade.

#### Weekly Papers (40%):

Students will submit a final paper in this course. Students will write four short (one or two page) papers, assigned for Weeks 1, 2, 4 and 5. The questions for the papers are released on Sunday mornings and students have ten days to submit the paper.

#### Timeline for instructor feedback:

Grades and feedback from the instructor will be posted within 7 calendar days.



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## **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 must 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 Online POP**

Students are expected to formally <u>drop or withdraw</u> from the course if they no longer wish to participate. See the program's <u>Academic Calendar</u> for applicable deadlines. In some cases, the University may automatically drop students for inactivity and/or for failure to pay tuition. It is crucial for students to communicate with the DESS (DESS@ahc.ufl.edu) about their status in the course, and about any tuition deferments or other special conditions related to their tuition payment. Any student who remains enrolled in the course after the drop/add deadline is considered tuition-liable, unless exempted by University petition. The official UF Attendance Policy can be found <u>here</u>.

#### Make-up Policy:

Each assignment is posted with a clear due date. **Assignments that are not submitted by the due date will be given a zero.** The instructor will consider extenuating circumstances on a case-by-case basis – if he is contacted by the student in advance of the due date. No other makeup assignments are offered. Contact the instructor for any concerns.

# **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 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 <u>UF graduate academic regulations</u> for more information.

- A >92.500%
- A- 89.500-92.499%
- B+ 86.500-89.499%



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- 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 <u>DESS@ahc.ufl.edu</u>
- IT Support: Contact UF Computing Help Desk at 352-392-HELP (4357) or <u>helpdesk@ufl.edu</u> or submit an <u>online request form</u>. 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.

#### **Students Requiring Academic Accommodations**

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the <u>Disability Resource Center</u>. 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



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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.

- <u>Canvas Accessibility</u>
- 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. <u>Click here for guidance on how to give feedback in a professional and respectful manner</u>. 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 <u>ufl.bluera.com/ufl/</u>.

## **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." <u>The Honor Code</u> 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 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:

- <u>Understanding and Avoiding Plagiarism: Types of Plagiarism</u>
- 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

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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.

- <u>Canvas Student Guide</u>
- 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. The instructor will generally respond to student messages within 48 hours.

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 been addressed/answered already. Please include a clear subject title for your topics to make it clear what your post pertains to. The instructor will generally respond to questions posted on the course discussion board within 48 hours.

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



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#### **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 <u>Notification to Students of FERPA Rights</u>.

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
- <u>Canvas (by Instructure) Privacy Policies</u>

#### **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.

## **Library Resources**

For remote access to UF library resources such as e-journals or other digital collections, use the <u>UF VPN or proxy</u> server to connect.



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# **Additional University Resources**

- **U Matter, We Care:** If you or a friend is in distress, please contact <u>umatter@ufl.edu</u> 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
- <u>E-learning technical support</u>: 352-392-4357 (select option 2) or e-mail to Learningsupport@ufl.edu.
- Teaching Center: Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.
- <u>Writing Studio</u>: 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers.
- <u>Student Complaints</u>



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