

Online POP Course Syllabus

PHA6273: Structure, Process, & Outcomes of Regulation

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, 7:00-9:00 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 Ahc-dess@ufl.edu.

Instructor

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Office Hours: By appointment, before, or after class meetings

Office Location: via Zoom or phone

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Office Hours: By appointment, before, or after class meetings

Office Location: via Zoom or phone

Course Description

This course emphasizes the role of the legislative, executive and judicial branches of state and federal government in the establishment of standards for pharmacy practice and drug distribution. It also places special emphasis on the administrative rule making process. Additionally, the course focuses on the purpose of government agencies, the approach to standards setting by each type of agency, and the effects of regulation on public health.

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Course Objectives

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

1. Describe the structure and function of American Law and the American Legal System.
2. Facilitate discussion of the underlying purpose of regulation generally and health care regulation specifically.
3. Debate methods for regulating the assessment and improvement of quality in health care.
4. Describe the central principle of balance in health care regulation.
5. Deduce the strengths and limits of health care regulation.
6. Defend the regulation of hospitals, nursing homes, and other health care institutions.
7. Link the legal process for implementing changes in existing laws with expected outcomes.
8. Assess the attributes of a high quality health care institution.

Relationship to Program-level Student Learning Outcomes

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

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

Required Textbooks and/or Software

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

There are no required textbooks.

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, discussion boards, 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

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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.

Course Schedule

Week	Date	Topic	Assignments
1	Sunday, May 12	Module I Part A: Reasons to Regulate	<ul style="list-style-type: none"> Read: Why is Health Care Regulation So Complex? Read: Legislative History of APA Watch: Posted Videos
2	Sunday, May 19	Module I, Part B: Reasons to Regulate	<ul style="list-style-type: none"> Read: Ancheff v. Hartford Case Watch: Posted Videos Quiz 1
3	Sunday, May 26	Module II, Part A: Ways to Regulate	<ul style="list-style-type: none"> Read: Contract Manufacturing & Quality Agreements Watch: Posted Videos Quiz 2
4	Sunday, June 2	Module II, Part B: Ways to Regulate	<ul style="list-style-type: none"> Read: pages 8 – 15 & 17 of Advancing Regulatory Science at FDA (2022) Read: Smith v. Heckler Case Watch: Posted Videos Quiz 3
5	Sunday, June 9	Module III, Part A: Regulating Healthcare Institutions	<ul style="list-style-type: none"> Read: Regulating Health Care, Self-Regulation Watch: Posted Videos Quiz 4
6	Sunday, June 16	Module III, Part B: Regulating Healthcare Institutions	<ul style="list-style-type: none"> Read: Digital Health and Regulatory Experimentation Read: Thompson v. Nason Watch: Posted Videos
7	Sunday, June 23	Final Exam Due	<ul style="list-style-type: none"> Final Exam

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Evaluation Methods

Online Quizzes (25%):

Quizzes (4 total) will open at 10:00 pm Eastern on Wednesdays, and will close at 12 noon Eastern on Saturdays. Quizzes consist of 10 multiple-choice/true-false questions over the material assigned for the given week. Students will have 30 minutes to complete the quiz. Quiz scores are revealed upon submission. Quiz keys will be made available once all students have completed the quiz.

Assignments (25%):

Assignments (2 total) will be posted at 8:00 pm Eastern on Sunday, and are due by 6:00 pm Eastern on the following Sunday on assigned days. Assignments are found under the 'Assignments' tab on Canvas. Responses to these assignments must be in essay format. Formatting instructions are provided in the 'Directions' section atop each assignment. Assignments are designed to provide students the opportunity to critically analyze an issue(s). These assignments foreshadow what students will see on exams. Please submit by uploading your response as a Word attachment. If you have any difficulty uploading your paper to Canvas. Students who feel their writing skills are in need of improvement should contact Dr. Phillips very early on in order to discuss an improvement plan.

Exam (25%):

There is one cumulative final exam in this course. The Final exam will be posted at 8:00 pm Eastern Sunday, June 12th, and is due on Sunday, June 19th at 8:00 pm Eastern. Please be sure to set aside at least 6-8 hours during to work on your exam. Please download the exam as close to 8:00 pm on Sunday, June 12th as possible, and save it to your computer. Accessing the exam on Sunday evening allows for an opportunity to address unforeseen technical glitches in a timely manner. Final exams format will be announced prior to exam release. Please submit by uploading your responses as a single Word attachment (with your name included).

Class Participation/Discussion Board (25%):

Students are expected to be participatory in both the live interactive classes as well as on the discussion board. Each week, a new and responsive thread of intellectual value shall be posted on the discussion board to achieve full credit for that's week's discussion board and active participation during weekly class discussions will be evaluated as well.

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 the synchronous class meetings. Students who miss 30 minutes or more of the synchronous class meeting are considered absent.

Unexcused absences from a class carry a 5-point (1/2 letter grade) penalty taken off the final grade.

Excused absences require a make-up reflection paper on the module topic to be submitted within 2 weeks of the missed class (unless the class is near the end of the semester and a shorter timeline will be required). Absences are considered excused when the student (not a peer) has emailed the instructor before the synchronous class meeting begins and conveys why the student will miss class, such as illness, job conflict, and other emergencies. Two or more excused absences will be addressed by the instructor and may result in an incomplete final grade for the course.

Attendance Policy for Online POP

Students are expected to formally [drop or withdraw](#) from the course if they no longer wish to participate. See the program's [Academic Calendar](#) 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 (Ahc-dess@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 [here](#).

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 she 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

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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 Ahdess@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.

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

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

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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.

The University policy on use of ChatGPT is available [here](#).

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. 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

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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 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

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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 [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.
- [Student Complaints](#)