

Online POP Course Syllabus

PHA6275: Federal Regulation of Controlled Substances

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, 8:00-10:30 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

Course Description

The Controlled Substances Act (CSA) and its implementing regulations establish federal requirements regarding both illicit and licit controlled substances. With respect to pharmaceutical controlled substances, DEA's responsibility is twofold: to prevent diversion and misuse of these substances while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. In carrying out this mission, DEA works closely with state and local authorities and other federal agencies. Under the framework of the CSA, all controlled substance transactions take place within a "closed system" of distribution established by Congress. Within this "closed system," all legitimate handlers of controlled substances—manufacturers, distributors, physicians, pharmacies, and others—must be registered with DEA (unless exempt) and maintain strict accounting for all controlled substance transactions.

This course will examine the Federal Controlled Substances Act (CSA), regulations promulgated by the Drug Enforcement Administration (DEA), and emerging issues related to this area. Topics covered will include the federal policy towards drug abuse at the time the CSA was passed; the closed system of distribution and how the DEA regulates legal controlled substances to work towards the goal of allowing patient access to legitimate controlled substances while preventing diversion (course focus will be on the pharmacy profession); trends, responses, and

Online POP Course Syllabus

strategies to the opioid epidemic; recent civil, criminal and administrative actions surrounding controlled substances; criticisms of the DEA; and upcoming and/or expected regulatory changes surrounding controlled substances. Federal versus state legal conflicts related to controlled substances will also be discussed, including marijuana (as well as other Schedule I controlled substances) and/or other state efforts (e.g. safe injection facilities). In addition to class lectures and discussions, students will participate in active learning exercises allowing them to become more familiar with policy development involving controlled substances.

Course Objectives

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

1. Recognize the original reasons the federal Controlled Substances Act (CSA) was passed.
2. Recognize the role of the Drug Enforcement Administration (DEA) regarding controlled substances under the Federal Controlled Substances Act (CSA).
3. Describe the closed system of controlled substance distribution.
4. Explain the regulatory classification system for controlled substances.
5. Explain how DEA regulations attempt to balance patient access to legitimate controlled substances while prevention diversion.
6. Discuss the concepts of “legitimate medical purpose” and “usual course of professional practice.”
7. Explain how controlled substances are diverted from legitimate medical use to illicit use.
8. Review various strategies to address the opioid epidemic.
9. Identify appropriate resources in the development of policies for the use of controlled substances.
10. Review recent civil, criminal, and/or administrative legal actions involving controlled substances.
11. Describe the “chilling effect” of aggressive regulation on legitimate patient care.
12. Identify recent and/or expected DEA regulatory changes involving controlled substances
13. Discuss state versus federal authority in the regulation of controlled substances.

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.

Online POP Course Syllabus

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 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, June 30	History/Purpose of CSA; Closed System of Distribution; Balancing Access vs. Diversion (Regulation of Pharmacy Profession as Example)	<ul style="list-style-type: none"> • TBA • See Canvas for additional details
2	Sunday, July 7	Background information on "opioid epidemic"; challenges; trends; responses; strategies over last 10-15 years	<ul style="list-style-type: none"> • TBA • See Canvas for additional details
3	Sunday, July 14	DEA Regulation through cases / DEA trends; Criticisms of DEA	<ul style="list-style-type: none"> • TBA • See Canvas for additional details
4	Sunday, July 21	Overall legal landscape – various viewpoints	<ul style="list-style-type: none"> • TBA • See Canvas for additional details
5	Sunday, July 28	Recent / Upcoming Changes	<ul style="list-style-type: none"> • TBA • See Canvas for additional details
6	Sunday, Aug 4	Fed vs. State conflicts; Other approaches; what's next?	<ul style="list-style-type: none"> • TBA • See Canvas for additional details

Online POP Course Syllabus

Evaluation Methods

Assignments (30%):

Each student will have 2 assignments to complete over the course of the term. Each assignment is weighted equally. Additional information regarding each assignment will be provided in Canvas.

Discussion Board and Class Participation (30%):

Students are expected to actively contribute to discussions both in the synchronous class meetings and through online discussion boards in Canvas. Class Participation points will be awarded for each of the modules (when synchronous). **For Discussion Boards, students are expected to post at least one substantive original comment and one substantive reply to the Canvas discussion board each week (regardless if the week is synchronous or asynchronous).** Your original comment is to be posted between Wednesday and Friday of the current week on the topic(s) being covered, and your reply is to be completed prior to the start of the next class (Wednesday).

Substantive posts are characterized by the following: demonstrates understanding significant ideas relevant to the issue, elaborates with accurate explanations or evidence, provides accurate information, distinguishes fact from opinion, stimulates inquiry through thoughtful posts, asks clarifying questions, synthesizes points of agreement or disagreement, attempts to motivate the group discussion, presents creative approaches to the topic. Posts should include citations when appropriate. All citations should be in AMA, or another nationally recognized, format.

Students are expected to contribute to the class discussion. 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.

Final Paper (40%):

Students will submit a final paper in this course. Details about the paper will be provided in Canvas.

Timeline for instructor feedback:

For assignments, the goal will be to have grades and feedback from the instructor posted within 7 calendar days. Faculty will communicate any adjustments to this timeframe if needed as soon as possible.

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.

Online POP Course Syllabus

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 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%

Online POP Course Syllabus

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 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.

Online POP Course Syllabus

- [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.

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

Online POP Course Syllabus

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 – 72 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 -72 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

Online POP Course Syllabus

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.
- [Student Complaints](#)