PHA6269: PHARMACEUTICAL PRODUCTS & PUBLIC POLICY
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
> *There is no class meeting on Sunday, March 31; instead students will watch a recorded lecture of that week's materials, available on Canvas that week and complete the quiz and discussion post

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
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Office Hours: By appointment, before, or after class meetings
Office Location: via Zoom or phone

Course Description
This course challenges students to think about the development of public policy positions and the articulation of organizational policy positions. Students will have the opportunity to develop and debate public policy positions related to the supplying of pharmaceutical products and services and to decide whether specific policies stimulate or stifle the process. Channels of distribution for pharmaceutical products are examined, contrasting the flow of goods and the flow of payments. Product pricing is deliberated along with levers that the government has to address pricing issues.

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

1. Understand the fundamentals of the prescription drug supply chain and prescription drug pricing in the United States, as well as the structure of different types of pharmacy benefits (e.g., commercial, Medicare, Medicaid);
2. Articulate and defend a proposed solution to a public policy issue, including the tradeoffs of policy solutions;

3. Develop an advocacy communication (e.g., a letter or email) supporting a position on a public policy issue and submit it to a policymaker;

4. Discuss current public policy issues related to prescription drug products and their use, including, but not limited to:
   a. Explore recent government actions at the federal and state level to address prescription drug pricing;
   b. Identify and discuss the history of and policy consequences associated with the 340B prescription drug discount program and the federal government's response to the prescription opioid crisis;
   c. Discuss efforts by the U.S. Food and Drug Administration and Congress to address the safety of the pharmaceutical supply chain and the review and approval of biosimilar biologic medicines;
   d. Describe the differences between fraud, waste, and abuse in the Medicare program, and steps that the government has taken to address each issue.

Relationship to Program-level Student Learning Outcomes
This course pertains to the following program-level student learning outcomes:
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. Students should complete the assigned reading for each week prior to that week's class (i.e., reading for Week 1 should be completed prior to Week 1 meeting on Sunday, March 10).

Recommended Materials
Many news organizations cover health policy issues. Students are expected to stay informed on health policy generally throughout the semester. The University of Florida provides a complimentary subscription to *STAT News*, one of my favorite health policy news sites. Students are expected to take advantage of this access throughout the course.

The following sites are provided as examples and suggestions (several also offer regular newsletters). If sites have a paywall, I have made a note for convenience; subscriptions are not required for this course. I have also not listed well-known national news sources such as the New York Times, Wall Street Journal, Washington Post, National Public Radio, Vox, etc., all of which also cover health policy issues:

- Health Affairs Blog: https://www.healthaffairs.org/blog
- Kaiser Health News (not related to Kaiser Permanente): https://khn.org/
- Politico PULSE Newsletter (publishes M-F at 10:00 am ET): https://www.politico.com/politicopulse/

Other Health Policy Resources:
- Congressional Budget Office (CBO): The CBO is a non-partisan office that conducts objective, impartial analysis of budgetary and economic issues on behalf of Congress. This is the office responsible for estimating how much money legislation may save or cost the federal government. They routinely publish cost analyses/estimates and policy options for reducing federal spending: https://www.cbo.gov/topics/health-care
- Government Accountability Office (GAO): The GAO is an independent, non-partisan agency that works for Congress and examines how taxpayer dollars are spent, providing Congress and federal agencies with objective, non-partisan, fact-based information to help the government save money and work more efficiently. Their health care reports are available here: https://www.gao.gov/topics/health-care
- Kaiser Family Foundation (KFF): KFF (not related to Kaiser Permanente) is a non-profit, independent source for health policy research, polling and news (under the Kaiser Health News name, noted above). Their mission is to serve as a non-partisan source of information for policymakers, the media, the health policy community, and the public: https://www.kff.org/
- Medicare Payment Advisory Commission (MedPAC): MedPAC, a non-partisan Congressional advisory commission, maintains brief, accessible overviews of all the different payment systems used by Medicare. If you are interested in how Medicare pays for any service (from ambulance services to skilled nursing facilities), this is a great place to start: https://www.medpac.gov/document-type/payment-basic/
- Medicaid Payment Advisory Commission (MACPAC): MedPAC's companion, MACPAC, does not maintain a payment basics series, but if you have questions about Medicaid, they are an excellent resource: https://www.macpac.gov/topics/prescription-drugs/

Course Pre-Requisites
None

Online POP Course Syllabus

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
0	No later than Sunday, March 10 at 12:00 pm ET	Course Introduction	• Post an introduction on the class message board on Canvas no later than March 10 at 12 pm ET
1	Sunday, March 10	Foundation: • Class Overview • Drug Pricing 101 • Structures of Different Types of Benefits: Commercial, Medicare, Medicaid	• Weekly reading assignments posted in Canvas • Discussion board post (week 0 assignment noted above): March 10, 12:00 pm ET
2	Sunday, March 17	The Inflation Reduction Act: How Does it Impact Drug Prices and Innovation?	• Weekly reading assignments posted in Canvas • Quiz due by 12 pm ET March 17 • Discussion board post due by 12 pm ET March 17
3	Sunday, March 24	Pharmacy Benefit Manager Reform: Current Status and a Closer Look at the Role of Rebates in Drug Prices and Spending	• Weekly reading assignments posted in Canvas • Quiz due by 12 pm ET March 24 • Discussion board post due by 12 pm ET March 24
4	Sunday, March 31: Asynchronous Class **Recorded lecture will be available via Canvas no later than Wednesday, March 27**	Public Policy Considerations in Managing Access to High-Cost Treatments in Commercial, Medicare, and Medicaid Programs: • Regulating the use of copayment accumulators and maximizers	• Weekly reading assignments posted in Canvas • Quiz due by 9 pm ET April 1 • Discussion board post due by 9 pm ET April 1

		• Medicare coverage of antiobesity medications • Budgeting for high-cost products under Medicaid	
5	Sunday, April 7	When Public Policies Have Unintended Consequences: • The 340B Drug Discount Program • Public Policy Failures and the Opioid Crisis	• Weekly reading assignments posted in Canvas • Quiz due by 12 pm ET April 7 • Discussion board post due by 12 pm ET April 7
6	Sunday, April 14	Public Policy and the FDA: • Prescription drug shortages • Supply chain security and compounding	• Weekly reading assignments posted in Canvas • Quiz due by 12 pm ET April 14 • Discussion board post due by 12 pm ET April 14
7	Sunday, April 21	Fraud, Waste, and Abuse in Federal Health Care Programs: • Fraud in Medicare Part D • Medicare Payment for Discarded Drugs • Medicare Part D Policies to Combat Opioid and Benzodiazepine Misuse and Abuse	• Weekly reading assignments posted in Canvas • Quiz due by 12 pm ET April 21 • Discussion board post due by 12 pm ET April 21
8	Sunday, April 28	Final Class Meeting: • Catch up on topics we have discussed through the term • Opportunity to dive deeper into other topics of interest not otherwise covered	• No reading or quiz this week: focus on completing final projects! • Discussion board post due by 12 pm ET April 28

Evaluation Methods

Advocacy Proposal (35%)

Each student will provide an overview of a public policy problem and identify a potential solution to that problem. Papers should be approximately 3-5 pages in length. Students will be evaluated based on their demonstrated grasp of the topic and the quality of their defense of their selected solution. The problem does not have to be related to a policy we discuss in class, but it should be health care related. A grading rubric is available on the class website. The project must be submitted via Canvas no later than 11:59 pm on Sunday, April 28.

Example
Problem: While Medicare Part D has broadened access to outpatient prescription drugs to America's senior citizens, some still struggle to afford the high out-of-pocket costs associated with certain medications
Solution: Allow Medicare Part D beneficiaries to use copayment coupons provided by pharmaceutical manufacturers when filling prescriptions

- In defending this solution, the student would be expected to research previous studies on the impact of the use of copayment assistance provided by manufacturers: does it impact patient and prescriber behavior? In what ways? How might this policy solution impact federal spending?

Advocacy Communication (25%)

Students will identify a public policy issue of interest and draft a communication to a policymaker (Congress/state legislature or federal/state agency or Board of Pharmacy) explaining their opinion. The issue selected does not have to be an issue we discuss in class but should be health care related. It does not have to be related to the issue selected for the Advocacy Proposal. Communications should be no longer than 2 pages in length. Students will be evaluated based on the appropriateness of the issue, the effectiveness of the communication, and demonstrated understanding of the topic. A grading rubric is available on the class website. Students must submit, via Canvas a copy of the communication, plus confirmation of submission (e.g., a screenshot of the submitted communication or confirmation email). The project may be completed at any point during the course but must be turned in no later than 11:59 pm Sunday, April 28.

Example A: A student prepares a letter detailing their opinion on pharmacy benefit manager (PBM) reform under consideration in Congress. The student submits the letter to either their Representative or one of their Senators. In this example, the student would be expected to demonstrate knowledge of the difference between legislation under consideration in either the House or the Senate (as appropriate for the recipient).

Example B: A student identifies a proposed regulation of interest, subject to public comment, via the *Federal Register*. The student prepares a public comment in response to the proposed regulation and submits it prior to the comment deadline online via the *Federal Register*. In this example, the student would be expected to demonstrate knowledge of what the agency is specifically requesting comment on.

Discussion Board and Class Participation (20%):

Students are expected to actively contribute to discussions both in the synchronous class meetings and through online discussion boards in Canvas. Participation points will be awarded for each of the modules. **Students are expected to post at least one substantive comment to the Canvas discussion board each week.** The post can be an original/new post or a comment on another post.

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 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.

Weekly Quizzes (20%):

There will be a total of five weekly quizzes (no quiz Week 1 or Week 8), based primarily on the reading assignment for that week, but will also include questions based on the materials for class the previous week (e.g., for Week 2, the quiz will cover the Week 2 reading assignments and 1-2 questions based on the lecture for Week 1). The purpose of this assignment is to assess your comprehension of reading, as well as your focus during class. Students will have 30 minutes to complete each quiz once started and may only attempt each quiz once.

Quizzes will be available on Canvas by 10:00 am ET the Monday following class and must be completed by 12:00 pm ET the day of class. Canvas will automatically close the quiz at this time; students will be unable to complete the quiz after the deadline.

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

Diversity, Equity, and Inclusion

"An inclusive classroom climate refers to an environment where all students feel supported intellectually and academically and are extended a sense of belonging in the classroom regardless of identity, learning preferences, or education." -*Yale Center for Teaching and Learning*

The online Pharmaceutical Outcomes and Policy (POP) graduate program embraces the idea that we all benefit from our individual differences and that our collected diversity is a source of strength. Additionally, as members of the health care community, improving health equity for our patients or others whom we serve, begins with us.

Our instructors are committed to creating course environments that celebrate diversity, honor inclusivity, and ensure equity for all students. It is important that all class-related interactions feel like a safe space for students of all backgrounds and learning styles to feel welcome, heard, and supported.

And, as this is your learning experience, your suggestions to ensure this commitment is fulfilled are encouraged and appreciated. Interactions that do not honor the spirit of this commitment will be addressed as they arise on an as needed basis.

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 (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 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

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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.

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

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.

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 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 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**