

The course will examine in depth the federal and Florida state laws that impact the practice of pharmacy and the ethics of pharmacy practice. Students will also apply this knowledge by solving case studies related to pharmacy practice in all practice settings.

Course Prerequisites: Completion of all Year 2 Pharm.D. program coursework including milestones.

Course Corequisites: PHA5165L Professional Practice Skills Lab V

Course Faculty and Staff	
Course Director	Instructional Designer
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Academic Coordinators	
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Teaching Faculty	
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[Faculty and Staff: Who to Contact and Questions to Ask](#)

Office Hours: Please see the Canvas course site for posted office hours.

Faculty Locations:

Gainesville	PEP: HPNP 2336
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Course Objectives and Educational Outcomes	
Course Objectives	Linked Educational Outcome
1. Recommend requirements for the acquisition and distribution of pharmaceutical products, including samples.	Learner
2. Apply the legal requirements that must be observed in the issuance of a prescription/drug order.	Learner
3. Recommend procedures necessary to dispense properly a pharmaceutical product, including controlled substances, pursuant to a prescription/drug order.	Learner
4. Assess the conditions for making an offer to counsel or counseling appropriate patients and the need for documenting the counseling offer/session.	Learner
5. Recommend what is required to distribute and/or dispense each of the following products: non-prescription products and devices, poisons, and restricted products, materials (e.g., pseudoephedrine, dextromethorphan, emergency contraception, behind the counter products).	Learner

6. Recommend procedures for keeping records of information related to pharmacy practice, pharmaceutical products, and patients, including requirements for protecting patient confidentiality.	Learner Professional
7. Outline how to handle hazardous materials such as what is described in the USP.	Steward
8. Recommend the qualifications, application procedure, necessary examinations, and internship for licensure, registration, or certification of individuals engaged in the storage, distribution, and/or dispensing pharmaceutical products (prescription and non-prescription).	Learner
9. Describe the requirements and application procedure for the registration, licensure, certification, or permitting of a practice setting or business entity.	Learner
10. Outline the operational requirements for a registered, licensed, certified, or permitted pharmacy practice setting.	Learner
11. Apply the federal and Florida state laws and rules that regulate or affect the manufacture, storage, distribution, and dispensing of pharmaceutical products, preparations, bulk drug substances/excipients, and devices (prescription and non-prescription), including controlled substances.	Learner
12. Recognize the requirements for finding of pharmacy malpractice, risk management strategies, as well as drug product liability.	Learner Professional

Course Resources and Fees

Course Outline

See Appendix A. Please routinely check your Google campus calendar and the Canvas course site for any messages about changes in the schedule including meeting dates/times, deadlines, and room changes.

Required Textbooks/Readings

1. Aboud RS, Burns KA. Pharmacy Practice and the Law, 10th edition. Jones & Bartlett Learning, LLC. Burlington, MA 2020. ISBN – 13:978-128428013-5
 - Previously purchased during 1PD year
 - Not available via HSC library
2. Florida Statutes
 - Available online at <http://www.leg.state.fl.us/statutes/>
3. Florida Administrative Code
 - Available online at <https://www.flrules.org/>
4. Florida Department of Business and Professional Regulation
 - Available online at <http://www.myfloridalicense.com/dbpr/ddc/statutes.html>

Use [UF VPN to access UF Libraries Resources](#) when off-campus. The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the [HSC Library Website](http://www.library.health.ufl.edu/) at this URL:<http://www.library.health.ufl.edu/>

Suggested Textbooks/Readings

Will be posted on Canvas

Other Required Learning Resources

None

Materials & Supplies Fees

None

Evaluation and Grading	
Student Evaluation & Grading	
The Canvas© gradebook will be set-up using the percentages below to compute the grade.	
Assessment Item	Grade Percentage
iRATs (8*)	10%
tRATs (8)	10%
Pre-Class Assignments (8**)	5%
In Class Assignments (8***)	5%
Exam 1	30%
Exam 2	40%
Total	100%

*Lowest iRAT score will be dropped.

**Pre-class assignments are based on completed MS form submitted prior to each ALS session.

***In class assignments consist of completion of MS forms during class for all ALS sessions. MS forms submission will be graded based on answers being relevant to the case.

Grading Scale					
Percentage	Letter Grade	Percentage	Letter Grade	Percentage	Letter Grade
92.50-100%	A	79.50-82.49%	B-	66.50-69.49%	D+
89.50-92.49%	A-	76.50-79.49%	C+	62.50-66.49%	D
86.50-89.49%	B+	72.50-76.49%	C	59.50-62.49%	D-
82.50-86.49%	B	69.50-72.49%	C-	< 59.50%	E

Rounding of grades:

Final grades in Canvas will be rounded to the 2nd decimal place. If the decimal is X.495 or higher, Canvas will round the grade to X.50. The above scale depicts this policy and grades are determined accordingly. Grade assignment is made using this policy and NO EXCEPTIONS will be made in situations where a student's grade is "close."

University of Florida Honor Pledge and Academic Dishonesty

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 Conduct Code specifies a number of behaviors that are in violation of this code and the possible sanctions. Expectations for Artificial Intelligence and when use constitutes academic dishonesty is outlined below.

Tendering information (giving your work to another to be copied, giving someone answers to assessment questions, informing another person in a later section about the questions that appear on an assessment that you have taken, or giving or selling a paper to another student), is considered academic dishonesty.

Students are required to report any condition that facilitates academic misconduct to appropriate personnel. Failure to report is also considered academic dishonesty. If you have any questions or concerns, please consult the course's Teaching Partnership Leader/Course Director or Assistant Dean for Curricular Affairs.

See the [UF Conduct Code website](#) for more information. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Assignment Descriptions

All pre-class and in class assignments submitted via MS forms are to be completed by the group. One submission per group is expected.

Course-Related Policies

UF Resources and Policies

University of Florida resources and policies can be found at this URL: <https://go.ufl.edu/syllabuspolicies>

PharmD Course Policies

The Policies in the following link apply to this course. Review the General [Pharm.D. Course Policies](http://curriculum.pharmacy.ufl.edu/current-students/course-policies/) carefully, at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/course-policies/>

Attendance Policy

Attendance is mandatory for active learning sessions such as team-based learning sessions, case discussions, laboratory sessions, and other activities that the instructor designates as required. This course has 8 required sessions (ALS sessions). A student who misses greater than 2 session(s) for this course will receive an incomplete in the course and will retake the course during the next offering, resulting in delayed graduation.

Makeup Assignments

More than one absence (excused or unexcused) will result in a makeup assignment. It will not be easier than being in class. This will be assigned post 2nd absence and will be due in two weeks from notification. Failure to complete the assignment will result in an incomplete grade for the course until such time as the assignment is completed or the incomplete grade automatically turns into a failing grade.

Late Assignments

Pre-class late assignments will not be accepted and will receive a zero grade, as they are intended to be completed in preparation for the ALS session.

Educational Technology Use

The following technology below will be used during the course and the student must have the appropriate technology and software.

1. ExamSoft™ Testing Platform
2. Canvas™ Learning Management System

For technical support, navigate to [Educational Technology and IT Support Contact Information](http://curriculum.pharmacy.ufl.edu/current-students/technical-help/) at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/technical-help/>

Artificial Intelligence (AI) Use for Assessments

The use of generative AI in assessments is prohibited, unless explicitly allowed by the course instructor. Assessments include any submitted work, graded or ungraded, that will be evaluated. These include, but are not limited to, quizzes, exams, assignments, writing projects, etc. If a student is uncertain about the use of AI technology, it is the student's responsibility to ask the instructor prior to beginning the assignment or assessment.

When authorized by the course director/course instructors, students may use AI technologies in the completion of an assessment if they acknowledge all use by naming the technology, describing how it was employed, and adhering to any other requirement stipulated in the assessment's instructions. Failure to acknowledge the use of AI technology or disregarding instructions related to the use of AI for assessments is considered academic misconduct. Students must disclose the use of AI and AI-assisted technologies by following the instructions below.

Application of AI technology must be done with human oversight and control, and students should carefully review and edit the result, as AI can generate outputs that can be incorrect, incomplete, or biased. **Students assume full responsibility for all content, including errors and omissions, if AI is employed.** Additionally, privacy is a concern with AI-generated content. Most commercially available AI systems are not compliant with [HIPAA](#) or FERPA protections, inputting patient or student information is prohibited by federal law.

Instructions to acknowledge the use of AI:

Statement: During the preparation of this assignment I/we, [INSERT NAME/S], used [INSERT TOOL / SERVICE] in order to [INSERT REASON OR PURPOSE]. After using this tool/service, I/we reviewed and edited the content as needed and take full responsibility for the content of the submission.

Penalties for unauthorized use:

Unauthorized use of AI text generators for assessments is considered evidence of academic dishonesty (see [policy on academic dishonesty](#)).

Disability Resource Center

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the Disability Resource Center. See the [Get Started with the DRC webpage](#) on the Disability Resource Center site. 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 Evaluation Process

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online. Students can complete evaluations in three ways:

1. The email they receive from GatorEvals,
2. Their Canvas course menu under GatorEvals, or
3. The central portal at <https://my-ufl.bluera.com>

Guidance on how to provide constructive feedback is available at <https://gatorevals.aa.ufl.edu/students/>. Students will be notified when the evaluation period opens. Summaries of course evaluation results are available to students at <https://gatorevals.aa.ufl.edu/public-results/>

Appendix A: Course Outline

Date / Time	Mod #	Activity	Activity Title	Contact Time (min)	Responsible
	0	Lecture Video	Course introduction	18	Randell E Doty
	1	Module	Module 1: New drug approval, marketing unapproved drugs, human subjects research ethics, and advertising by manufacturers and pharmacies		Bill Allen, Randell E Doty
08/18/25		Reading	Textbook: New Drug Approval, Marketed Unapproved Drugs, Drugs Intended to Treat Serious and Life-Threatening Diseases, Biologics, Med Watch Voluntary Reporting Program, Medical Devices, Cosmetics, Approved Drugs for Off-Label (Unlabeled) Indications	46	Bill Allen
08/18/25	1.1	Lecture Video	Ethics of Clinical Research	34	Bill Allen
08/18/25	1.2	Lecture Video	Drug Advertising by Manufacturers and Pharmacies	31	Bill Allen
08/19/2025 at 2:00pm		Assignment (Graded)	Pre Class ALS 1 Case 1		
08/19/2025 at 3-4:50pm		Active Learning Session	Active Learning Session 1: New drug approval, marketing unapproved drugs, human subjects research ethics, and advertising by manufacturers and pharmacies	100	Bill Allen, Randell E Doty
08/19/25		Quiz (iRAT/tRAT)	iRAT & tRAT 1		Randell E Doty
08/19/25		In-class Activity	ALS 1 In Class Cases		Randell Doty
	2	Module	Module 2: Prescription drug labelling, compounding, & Prescription Drug Modernization Act of 1987		Bill Allen, Randell E Doty
08/22/25		Reading	Textbook: Pharmacy Compounding vs Manufacturing and all subsections through Take Away points	15	Randell E Doty
08/22/25		Reading	Textbook: Drug Supply Chain Security and all subsections through Take Away Points	18	Randell E Doty
08/22/25	2.1	Lecture Video	Florida Rules on Labeling, Compounding, and Drug Samples	42	Bill Allen
08/22/25	2.2	Lecture Video	Florida Rules on Storage, Distribution, and Record Keeping	43	Randell E Doty
08/25/2025 at 12pm		Assignment (Graded)	Pre Class ALS 2 Case 1		
08/25/2025 at 1-2:50pm	2	Active Learning Session	Active Learning Session 2: Prescription drug labelling, compounding, & Prescription Drug Modernization Act of 1987	100	Bill Allen, Randell E Doty
08/25/25		Quiz (iRAT/tRAT)	iRAT& tRAT 2		
		In-class Activity	ALS 2 In Class Cases		
	3	Module	Module 3: Closed System of Controlled Substances		Bill Allen, Randell E Doty
08/28/25	3.1	Lecture Video	The Closed System of Controlled Substance Distribution	34	Randell E Doty

Date / Time	Mod #	Activity	Activity Title	Contact Time (min)	Responsible
08/28/25	3.2	Lecture Video	Pharmacy Inspections, Opioid Treatment Programs, & Other Laws Related to the CSA	33	Bill Allen
08/28/25		Reading	Modification, Transfer and Termination of Registration; Denial Revocation or Suspension of Registration	5	
09/02/2025 at 9am		Assignment (Graded)	Pre Class ALS 3 Case 1		
09/02/2025 at 10-11:50am	3	Active Learning Session	Active Learning Session 3: Closed System of Controlled Substances	100	Bill Allen, Randell E Doty
09/02/25		Quiz (iRAT/tRAT)	iRAT & tRAT 3		
		In-class Activity	ALS 3 In Class Cases		
	4	Module	Module 4: State Regulation of Pharmacy Practice: Examination, licensing, and continuing education also Automated, Institutional Pharmacies, and Technicians and Interns		Bill Allen
09/09/25	4.1	Lecture Video	Pharmacy Licensing, Regulation, and Discipline	15	Bill Allen
09/09/25	4.2	Lecture Video	Standards of Practice, Repository Programs, State Hospital Pharmacy licensure issues, and State regulation of long term care	12	Bill Allen
09/09/25		Reading	Florida Statutes and Florida Administrative Codes: Licensing and Continuing Education	34	Bill Allen
09/09/25		Reading	Florida Statutes and Florida Administrative Codes: Dispensing, Techs, and Interns	34	Bill Allen
09/12/2025 at 12pm		Assignment (Graded)	Pre Class ALS 4 Case 1		
09/12/2025 at 1-2:50pm		Active Learning Session	Active Learning Session 4: State Regulation of Pharmacy Practice, Examination, licensing, and continuing education also Automated, Institutional Pharmacies, and Technicians and Interns	100	Bill Allen, Randell E Doty
09/12/25		Quiz (iRAT/tRAT)	iRAT & tRAT 4		
		In-class Activity	ALS 4 In Class Cases		
09/15/2025 at 1-3pm		Exam	Exam 1: Modules 1-4	2	Randell E Doty
	5	Module	Module 5: Federal and State Laws regarding Counseling, Medicare, Medicaid and the expansion and regulation of pharmacy services		Randell E Doty
09/15/25		Reading	Textbook: Medicare, Medicaid	34	Randell E Doty
09/15/25		Reading	Florida Statutes and Florida Administrative Codes	17	Randell E Doty
09/15/25	5.1	Lecture Video	Florida Rules on Patient Counseling, Records, Drug Therapy Management, Ordering Lab Tests, & Drugs that May Be Ordered by Pharmacists	53	Randell E Doty
09/15/25	5.2	Lecture Video	Florida HB389 Collaborative practice for chronic illnesses test and treat	35	Randell E Doty
09/15/25	5.3	Lecture Video	New Law Updates 21-24	29	Randell E Doty

Date / Time	Mod #	Activity	Activity Title	Contact Time (min)	Responsible
09/17/2025 at 9am		Assignment (Graded)	Pre Class ALS 5 Case 1		
09/17/2025 at 10-11:50am		Active Learning Session	Active Learning Session 5: Federal and State Laws regarding Counseling, Medicare, Medicaid and the expansion and regulation of pharmacy services	100	Bill Allen, Randell E Doty
09/17/25		Quiz (iRAT/tRAT)	iRAT& tRAT 5		Randell E Doty
		In-class Activity	ALS 5 In Class Cases		
		Exam Review	Exam Review - Law Exam 1		
	6	Module	Module 6: Federal Regulation of Pharmacy Practice: HIPAA, Antitrust and Fraud		Bill Allen, Randell E Doty
09/18/25		Reading	Textbook: Health Insurance Portability and Accountability Act of 1996 and Take Away Points	21	
09/18/25		Reading	Textbook: Federal Antitrust Laws and Take Away Points	20	
09/18/25	6.1	Lecture Video	Medicare/Medicaid Fraud and Abuse Laws, Federal Regulation of Long Term Care, Federal Anti-trust Laws, and Miscellaneous federal laws on pharmacy practice	61	Bill Allen
09/23/2025 at 9am		Assignment (Graded)	Pre Class ALS 6 Case 1		
09/23/2025 at 10-11:50am		Active Learning Session	Active Learning Session 6: Federal Regulation of Pharmacy Practice: HIPAA, Antitrust and Fraud	100	Bill Allen, Randell E Doty
09/23/25		Quiz (iRAT/tRAT)	iRAT& tRAT 6		Randell E Doty
		In-class Activity	ALS 6 In Class Cases		
	7	Module	Module 7: State Regulation of Pharmacy Practice: Pharmacy Permits, Closure/Transfer Ownership, Special Pharmacies		Bill Allen, Randell E Doty
09/24/25	7.1	Lecture Video	Self-Regulation in Pharmacy, Approaches to Regulation, and State Boards of Pharmacy	18	Bill Allen
09/25/25	7.2	Lecture Video	Florida Pharmacy Permits - Part 1	43	Randell E Doty
		Optional/Supplemental	Textbook: State Regulation of Pharmacy Practice		Randell E Doty
09/30/2025 at 9am		Assignment (Graded)	Pre Class ALS 7 Case 1		
09/30/2025 at 10-11:50am		Active Learning Session	Active Learning Session 7: State Regulation of Pharmacy Practice – Pharmacy Permits, Closure/Transfer Ownership, Special Pharmacies	100	Bill Allen, Randell E Doty
09/30/25		Quiz (iRAT/tRAT)	iRAT& tRAT 7		Randell E Doty
		In-class Activity	ALS 7 In Class Cases		
09/30/2025 at 2:50pm		Course Evaluation	Course Evaluations		

Date / Time	Mod #	Activity	Activity Title	Contact Time (min)	Responsible
	8	Module	Module 8: Professional Pharmacist Liability, Risk Management, & Product Liability		Bill Allen, Randell E Doty
10/01/25		Reading	Textbook: Pharmacist Malpractice Liability and Risk Management Strategies	50	Bill Allen
10/01/25	8.1	Lecture Video	Pharmacist as Risk Manager, Malpractice Insurance, and Drug Product Liability	28	Bill Allen
10/03/2025 at 8am		Assignment (Graded)	Pre Class ALS 8 Case 1		
10/03/2025 at 9-10:50am		Active Learning Session	Active Learning Session 8: Professional Pharmacist Liability, Risk Management, & Product Liability	100	Bill Allen, Randell E Doty
10/03/25		Quiz (iRAT/tRAT)	iRAT& tRAT 8		Randell E Doty
		In-class Activity	ALS 8 In Class Cases		
10/09/2025 at 2-4pm		Exam	Exam 2: Modules 5-9		Randell E Doty
			Total Course Contact Hours	32.5	