

PHA5239 Applications of Pharmacy Law and Ethics

Fall 2023

2 Credit Hours – [A-E Grading]

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.

Teaching Partnership Leaders

Randell Doty, PharmD.

- Email: doty@cop.ufl.edu
- Office: HPNP 2333
- Phone: 352-294-4984

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

See Appendix A. for Course Directory of Faculty and Staff Contact Information.

Entrustable Professional Activities

This course will prepare you to perform the following activities which the public entrusts a Pharmacist to perform:

1. Analyze EPA4. Safely and accurately dispense medications within a medication use system including supervision of pharmacy technicians.

Course-Level Objectives

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

1. Recommend requirements for the acquisition and distribution of pharmaceutical products, including samples.
2. Apply the legal requirements that must be observed in the issuance of a prescription/drug order.
3. Recommend procedures necessary to dispense properly a pharmaceutical product, including controlled substances, pursuant to a prescription/drug order.
4. Assess the conditions for making an offer to counsel or counseling appropriate patients and the need for documenting the counseling offer/session.
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).
6. Recommend procedures for keeping records of information related to pharmacy practice, pharmaceutical products, and patients, including requirements for protecting patient confidentiality.
7. Outline how to handle hazardous materials such as what is described in the USP.
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).
- Describe the requirements and application procedure for the registration, licensure, certification, or permitting of a practice setting or business entity.
 - Outline the operational requirements for a registered, licensed, certified, or permitted pharmacy practice setting.
 - 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.
 - Recognize the requirements for finding of pharmacy malpractice, risk management strategies, as well as drug product liability.

Course Pre-requisites

- Completion of all Year 2 Pharm.D. program coursework including milestones.

Course Co-requisites

- PHA5165L Professional Practice Skills Lab V

Course Outline

See Appendix. Please routinely check your 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

- Abood RS, Burns KA. Pharmacy Practice and the Law, 9th edition. Jones & Bartlett Learning, LLC. Burlington, MA 2020. ISBN – 13:978-1284154979
 - Previously purchased during 1PD year
 - Not available via HSC library
- Florida Statutes
 - Available online at <http://www.leg.state.fl.us/statutes/>
- Florida Administrative Code
 - Available online at <https://www.flrules.org/>
- Florida Department of Business and Professional Regulation
 - Available online at <http://www.myfloridalicense.com/dbpr/ddc/statutes.html>

**Student assigned statutes and regulations readings will be identified and provided online on the Canvas course website.

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](#) at this URL: <http://www.library.health.ufl.edu/>

Suggested Textbooks/Readings

Suggested readings will be posted on Canvas.

Other Required Learning Resources

None

Materials & Supplies Fees

None

Student Evaluation & Grading

Evaluation Methods and How Grades are calculated.

[The Canvas© gradebook will be set-up using the percentages below to compute the grade.]

Table 1.1 Evaluation and Grading

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.

Table 1.2 Grading Scale

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

Educational Technology Use

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

- ExamSoft™ Testing Platform
- Canvas™ Learning Management System

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

Artificial Intelligence Use

The use of artificial intelligence (AI) text generators such as ChatGPT on assignments, projects, quizzes, and exams is prohibited in this course. Use of AI text generators is considered evidence of academic dishonesty. 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.

Pharm.D. Course Policies

The Policies in the following link apply to this course. Review the General [Pharm.D. 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 ALS sessions. A student who misses greater than 2 sessions (25% of the required active learning sessions/activities) or laboratory sessions 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 not) will result in a makeup assignment. *It will not be easier than being in class.*

Late Assignments

Pre-class late assignments are not accepted as they are intended to be completed in preparation for the ALS session.

Accessibility and Belonging Statement

The University of Florida College of Pharmacy strives to stimulate a culture that promotes diversity and inclusion within an exceptional community of students, faculty, and staff. It is our intent that students from all diverse backgrounds and perspectives be well served by this course, that students' learning needs be addressed both in and out of class, and that the diversity that students bring to this class be viewed as a resource, strength, and benefit.

We intend to present materials and activities that are respectful of diversity: gender, sexuality, disability,

age, socioeconomic status, ethnicity, race, and culture. Your suggestions are encouraged and appreciated. Please let us know ways to improve the course's effectiveness for you personally or for other students or student groups.

If any of our class meetings conflict with any of your religious events, an excused absence will be provided when requested using the standard UF COP process as detailed in the [UF COP Course policies](#).

If you feel that you have experienced or witnessed any bias/treatment that falls short of these expectations, you may submit a report through the UF [COP Student Mistreatment Report](#).

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 via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at <https://gatorevals.aa.ufl.edu/students/>. 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 <https://ufl.bluera.com/ufl/>. Summaries of course evaluation results are available to students at <https://gatorevals.aa.ufl.edu/public-results/>.

Appendix A. Course Directory

Teaching Partnership Leader/Course Director(s):

Randell Doty, PharmD.

- Email: doty@cop.ufl.edu
- Office: HPNP 2333
- Phone: 352-294-4984

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

Questions to Ask:

- Concerns about performance
- Guidance when there are performance problems (failing grades)
- General questions about content

Other Teaching Partnership Faculty Members:

William Allen, J.D., M.Div.

- Email: wallen@cop.ufl.edu
- Office: G1-20 (Stetson – Medical Wing)
- Phone: 352-273-5155

Paul Ackerman, B.S. Pharmacy

- Email: paackerm@cop.ufl.edu
- Office: ---
- Phone: ---

Instructional Designer:

Chris Egan, M.Ed., NRP, CHSE

- Email: cegan@ufl.edu
- Phone: 352-294-5636

Academic Coordinator Gainesville Campus:

Ashleigh Langford

- Email: lynn8597@cop.ufl.edu
- Office: HPNP 4309
- Phone: 352-273-6284

Educational Coordinators:

Katie Orben

- Email: korben06@ufl.edu

- Office: Jacksonville Campus
- Phone: 904-244-9590

Jessica Linares

- Email: jnoriegalinares@ufl.edu
- Office: Orlando Campus
- Phone: 407-313-4087

Questions to Ask:

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence/tardy requests (Only the Academic Coordinator handles absence requests)
- Questions about dates, deadlines, meeting place
- Availability of handouts and other course materials
- Assignment directions
- Questions about grade entries in gradebook (missing grades, incorrect grade)
- Assistance with ExamSoft® (Distance campus students may contact the Educational Coordinator for use of Exemplify and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.)

Appendix B: Course Outline: See Link Below

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
08/21/23	0	Lecture Video	Course introduction		Randell E Doty
08/21/23	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
08/21/23		Reading	Textbook pp. 62-83, 119-120	0.92	Bill Allen
08/21/23	1.1	Lecture Video	Ethics of Clinical Research	0.68	Bill Allen
08/21/23	1.2	Lecture Video	Drug Advertising by Manufacturers and Pharmacies	0.45	Bill Allen
DUE 08/22/23 at 12pm		Assignment (Graded)	Pre Class ALS 1 Case 1		
08/22/23 at 1 - 2:50pm		Active Learning Session	Active Learning Session 1: New drug approval, marketing unapproved drugs, human subjects research ethics, and advertising by manufacturers and pharmacies	2	Bill Allen, Randell E Doty
08/22/23		Quiz (iRAT/tRAT)	RAT 1 iRAT& tRAT		Randell E Doty
08/22/23		In-class Activity	ALS 1 In Class Cases		
08/23/23	2	Module	Module 2: Prescription drug labelling, compounding, & Prescription Drug Modernization Act of 1987		Bill Allen, Randell E Doty
08/23/23		Reading	Textbook pp. 121-130	0.3	Randell E Doty
08/23/23		Reading	Textbook pp. 136-141	0.35	Randell E Doty
08/24/23	2.1	Lecture Video	Florida Rules on Labeling, Compounding, and Drug Samples	0.5	Bill Allen
08/24/23	2.2	Lecture Video	Florida Rules on Storage, Distribution, and Record Keeping	0.5	Randell E Doty
DUE 08/28/23 at 12pm		Assignment (Graded)	Pre Class ALS 2 Case 1		
08/28/23 at 1 - 2:50pm	2	Active Learning Session	Active Learning Session 2: Prescription drug labelling, compounding, & Prescription Drug Modernization Act of 1987	2	Bill Allen, Randell E Doty
08/28/23		Quiz (iRAT/tRAT)	iRAT& tRAT		
08/28/23		In-class Activity	ALS 2 In Class Cases		
08/29/23	3	Module	Module 3: Closed System of Controlled Substances		Bill Allen, Randell E Doty
08/29/23	3.1	Lecture Video	The Closed System of Controlled Substance Distribution	0.67	Randell E Doty
08/30/23		Reading	Textbook pp. 173, 177-188	0.83	Bill Allen
DUE 09/05/23 at 12pm		Assignment (Graded)	Pre Class ALS 3 Case 1		

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
09/05/23 at 1 - 2:50pm	3	Active Learning Session	Active Learning Session 3: Closed System of Controlled Substances	2	Bill Allen, Randell E Doty
09/05/23		Quiz (iRAT/tRAT)	iRAT& tRAT 3		
09/05/23		In-class Activity	ALS 3 In Class Cases		
09/06/23	4	Module	Module 4: State Regulation of Pharmacy Practice: Examination, licensing, and continuing education also Automated, Institutional Pharmacies, and Technicians and Interns		Bill Allen, Randell E Doty
09/06/23	4.1	Lecture Video	Pharmacy Licensing, Regulation, and Discipline	0.5	Bill Allen
09/06/23	4.2	Lecture Video	Standards of Practice, Repository Programs, State Hospital Pharmacy licensure issues, and State regulation of long-term care	0.83	Bill Allen
09/07/23		Reading	See Canvas	1	Bill Allen
09/07/23		Reading	Florida Statutes and Florida Administrative Codes: Licensing and Continuing Education	0.67	Bill Allen
09/07/23		Reading	Florida Statutes and Florida Administrative Codes: Dispensing, Techs, and interns for fall 2022	0.67	Bill Allen
DUE 09/11/23 at 2pm		Assignment (Graded)	Pre Class ALS 4 Case 1		
09/11/23 at 3 - 4:50pm		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	2	Bill Allen, Randell E Doty
09/11/23		Quiz (iRAT/tRAT)	iRAT& tRAT 4		
09/11/23		In-class Activity	ALS 4 In Class Cases		
09/13/23 at 1 3pm		Exam	Exam 1: Modules 1 4	2	Randell E Doty
09/14/23	5	Module	Module 5: Federal and State Laws regarding Counseling, Medicare, Medicaid and the expansion and regulation of pharmacy services		Bill Allen, Randell E Doty
09/14/23		Reading	Textbook pp. 241-246	0.33	Randell E Doty
09/14/23		Reading	Textbook pp. 256-269	0.67	Randell E Doty
09/15/23	5.1	Lecture Video	Florida Rules on Patient Counseling, Records, Drug Therapy Management, Ordering Lab Tests, & Drugs that May Be Ordered by Pharmacists	0.5	Randell E Doty
09/15/23	5.2	Lecture Video	Florida HB389 Collaborative practice for chronic illnesses test and treat	0.5	Randell E Doty
09/15/23	5.3	Lecture Video	Legal Changes in Recent Years	0.15	Randell E Doty
DUE 09/18/23 at 12pm		Assignment (Graded)	Pre Class ALS 5 Case 1		

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
09/18/23 at 1 - 2:50pm		Active Learning Session	Active Learning Session 5: Federal and State Laws regarding Counseling, Medicare, Medicaid and the expansion and regulation of pharmacy services	2	Bill Allen, Randell E Doty
09/18/23		Quiz (iRAT/tRAT)	iRAT& tRAT 5		Randell E Doty
09/18/23		In-class Activity	ALS 5 In Class Cases		
09/18/23 at 3 - 3:30 pm		Exam Review	Exam Review - Law Exam 1		
09/19/23	6	Module	Module 6: Federal Regulation of Pharmacy Practice: HIPAA, Antitrust and Fraud		Bill Allen, Randell E Doty
09/19/23		Reading	Textbook pp. 247-255	0.42	Bill Allen
09/19/23		Reading	Textbook pp. 278-286	0.4	
09/20/23	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	0.5	Bill Allen
DUE 09/25/23 at 2pm		Assignment (Graded)	Pre Class ALS 6 Case 1		
09/25/23 at 3 - 4:50pm		Active Learning Session	Active Learning Session 6: Federal Regulation of Pharmacy Practice: HIPAA, Antitrust and Fraud	2	Bill Allen, Randell E Doty
09/25/23		Quiz (iRAT/tRAT)	iRAT& tRAT 6		Randell E Doty
09/25/23		In-class Activity	ALS 6 In Class Cases		
09/26/23	7	Module	Module 7: State Regulation of Pharmacy Practice: Pharmacy Permits, Closure/Transfer Ownership, Special Pharmacies		Bill Allen, Randell E Doty
09/26/23	7.1	Lecture Video	Self-Regulation in Pharmacy, Approaches to Regulation, and State Boards of Pharmacy	0.33	Bill Allen
09/27/23	7.2	Lecture Video	Florida Pharmacy Permits	0.33	Randell E Doty
09/27/23		Reading	Florida Administrative Codes on Permitting on Canvas under Module 7	1.17	Randell E Doty
09/27/23		Optional/Supplemental	Text pp. 301-312 – Chapter 7 optional reference, not required reading		Randell E Doty
DUE 10/02/23 at 2pm		Assignment (Graded)	Pre Class ALS 7 Case 1		
10/02/23 at 3 - 4:50pm		Active Learning Session	Active Learning Session 7: State Regulation of Pharmacy Practice – Pharmacy Permits, Closure/Transfer Ownership, Special Pharmacies	2	Bill Allen, Randell E Doty
10/02/23		Quiz (iRAT/tRAT)	iRAT& tRAT 7		Randell E Doty
10/02/23		In-class Activity	ALS 7 In Class Cases		

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
10/03/23	8	Module	Module 8: Professional Pharmacist Liability, Risk Management, & Product Liability		Bill Allen, Randell E Doty
10/03/23		Reading	Textbook pp. 335-350	1	Bill Allen
10/04/23	8.1	Lecture Video	Pharmacist as Risk Manager, Malpractice Insurance, and Drug Product Liability	0.5	Bill Allen
DUE 10/09/23 at 2pm		Assignment (Graded)	Pre Class ALS 8 Case 1		
10/09/23 at 3 - 4:45pm		Active Learning Session	Active Learning Session 8: Professional Pharmacist Liability, Risk Management, & Product Liability	2	Bill Allen, Randell E Doty
10/09/23		Quiz (iRAT/tRAT)	iRAT& tRAT 8		Randell E Doty
10/09/23		In-class Activity	ALS 8 In Class Cases		
10/09/23 at 4:45 - 5:00pm		Course Evaluation	Course Evaluations		
10/16/23 at 10am 12pm		Exam	Exam 2: Modules 5 9		Randell E Doty
10/25/23 at 3 - 3:30pm		Exam Review	Exam 2 Review		
			Total Contact Time in Course:	33.67	