

PHA5703 Principles of Pharmacy Law and Ethics

Spring, 2023

1 Credit Hour – [A-E Grading]

The purpose of this course is to introduce principles of law and ethics in pharmacy with a focus on those laws and ethical situations that are most commonly encountered in a community pharmacy practice setting. The course will examine the federal and Florida state laws that impact the practice of pharmacy, while emphasizing the legal and ethical principles applied by pharmacists in their daily decision-making. Students will learn the governmental framework within which pharmacy is practiced, as well as acquire an understanding of the laws, regulations, and the ethical responsibilities applicable to pharmacists so that they will be able to protect the public, ensure patients' well-being, and protect patients' rights.

Teaching Partnership Leaders

Randell E. Doty, Pharm.D.

- Email: doty@cop.ufl.edu
- Office: HPNP 2333
- Phone: 352-294-4984
- Office Hours: Thursdays from 10:00 to 11:00. Zoom link listed on Canvas.

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:

Practice Manager Domain

13. Oversee the pharmacy operations for an assigned work shift.

ST13.1. Implement pharmacy policies and procedures.

ST13.9. Assist in the preparation for regulatory visits and inspections.

Course-Level Objectives

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

1. Explain the dispensing requirements for prescriptions, including those involving generic substitution.
2. a. Understand pharmacists' responsibilities with regard to prescriptions presented to pharmacies in each of the following formats: electronic prescriptions (i.e. e-prescribing) faxed prescriptions, hand-written prescriptions, computer-generated prescriptions, and phoned-in prescriptions.
3. Discuss how laws and the legal system function in the United States.
4. Explain the activities that must be completed by a licensed pharmacist, those activities that may be performed by a pharmacy intern, and the activities that may be performed by a pharmacy technician (NOTE: interns & technicians are under the direct supervision of a pharmacist).
5. Describe, generally, the importance of the federal Food Drug and Cosmetic Act and related Laws, including: Pure Food and Drug Act of 1906; Food Drug and Cosmetic Act of 1938; Durham-Humphrey Amendment of 1951; Kefauver-Harris Amendment 1962; FDA Modernization Act of

1997; FDA Amendment Act of 2007; OBRA-90; Orphan Drug Act of 1983; Drug Price Competition and Patent Term Restoration Act of 1984; Prescription Drug Marketing Act of 1987; & the Prescription Drug User Fee Act.

6. Explain the requirements set forth in the Poison Prevention Packaging Act.
7. Explain the information required on a prescription label, and distinguish label from labeling.
8. Explain what is required of pharmacists when ordering controlled substances and when dispensing, refilling, and transferring prescriptions for controlled substances, according to the federal Controlled Substances Act.
 - a. a. Describe controlled substances ordering, inventory control, dispensing and destruction.
 - b. b. Distinguish CSOS from DEA Form 222.
 - c. c. Identify that prescription pads must be purchased from approved vendors.
9. Describe the composition of the Florida board of pharmacy, and its function in regulating the profession of pharmacy.
10. Understand what pharmacy permits are required for entities to sell, purchase and dispense (including reverse distributors)
11. Apply ethical principles in case studies involving a community pharmacy setting.

Course Pre-requisites

1. Successful completion of Block 1, 2, and 3 courses.

Course Co-requisites

1. There are no co-requisites for this course.

Required Textbooks/Readings

1. Aboud RS, Burns KA. Pharmacy Practice and the Law, 9th edition. Jones & Bartlett Learning, LLC. Burlington, MA (Available: February 1, 2019). ISBN 978-1284154979. (8th edition is also acceptable for this course – both page numbers will be posted).
 - Not available via HSC Library
 - Assigned pages in the course schedule above are for the hardcopy version of the textbook. Students may buy an e-copy of the textbook, but the faculty does not possess an e-copy of the textbook, so we cannot post the correct page numbers. We will post the correct topics for each assignment on the course webpage, so that students with an e-book can determine what the assignments are for their version of the textbook. We will also post a copy of the table of content of the hardcopy text for reference.
2. All other required readings will be posted in Canvas.

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 reading materials will be posted in the Canvas site.

Other Required Learning Resources

See canvas for legal glossary

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.]

Assessment Item	Grade Percentage
iRATs [4] – single lowest score dropped 3 @ 8.3%	25%
tRATs [4] 4 @ 2.5% each	10%
Pre ALS-assignments (MS forms answers) 4 @ 01.25% each	05%
In Class ALS assignments (MS forms answers) 4 @ 1.25% each	05%
Pharmacy Law Video Assignment – team submission	05%
Final Exam	50%
Total	100%

Table 1.1 Evaluation and Grading Above

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.

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

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

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/>

Course Specific Policies

- QUIZ Questions: Do not post quiz questions on the discussion boards, please email Dr. Doty directly instead. doty@cop.ufl.edu
- MORE than ONE absence: More than one absence from the Active Learning Sessions (whether excused or unexcused) will require a make-up assignment.

Late Assignment Policy

- Assignments submitted after their due date/time will be given half credit. Requests for additional time/ excuse for late submissions will be handled individually.

Makeup Assignment Policy

- More than one absence (excused or not) will result in a make up assignment. *It will not be easier than being in class.*

Respect for Diversity

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:

Randell E. Doty, Pharm.D.

Email: doty@cop.ufl.edu

Office: HPNP 2333

Phone: 352-294-4984

Office Hours: Please see 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 L. (Bill) Allen, JD, MDiv

Email: wmallen@ufl.edu

Office: College of Medicine, UF-HSC-GNV

Paul Ackerman, B.S. Pharmacy

Email: paackerm@ufl.edu

Office: GNV

Janet Schmittgen, PharmD

Email: jschmittgen@cop.ufl.edu

Office: HPNP 2335

Instructional Designer:

Name: Holly Fremen

- Email: holly.fremen@cop.ufl.edu
- Phone: 352-273-5558

Academic Coordinator Gainesville Campus:

Name: Ashley Williams

- Email: acwilliams@ufl.edu

Absence/Tardy Email: (Visit the course policy site for further instructions)

Educational Coordinators

Name: Katie Orben

- Email: korben06@ufl.edu
- Office: Jacksonville Campus

Name: Andrea Arredondo

- Email: aarredondo1@cop.ufl.edu
- Office: Orlando Campus

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. Video Assignment Rubric

Pharmacy Law Video Team Submission Rubric				
Criteria	Ratings			Pts
Content				1 pts
	1 pts Full Credit Content is clearly related to pharmacy law/ethics.	0 pts No Credit Content is not related to pharmacy law/ethics.		
Team Organization and Effort				1 pts
	2 pts Full Credit Clear organization and effort.	1 pts Partial Credit Somewhat lacking in effort and organization.	0 pts No Credit Not organized or effort was not clearly demonstrated.	
Time				1 pts
	1 pts Full Credit Video is less than 2 minutes long.		0 pts No Credit Video is more than 2 minutes long.	
Peer Review				2 pts
	2 pts Full Credit Review questions answered with thoughtful consideration of their peer’s video	1 pts Partial Credit Review questions answered	0 pts No Credit Review questions not answered	
Total Points: 5				

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.

Dates of Recommended Study	Mod#	Activity	Unit Topic	Hours	Learning Objectives	Responsible
	1	Module	Module 1: Introduction to Pharmacy Ethics and Law		1-4	Bill Allen, Randell E Doty
3/6/23	1	Video Lecture	Course Introduction			
3/6/23	1.1	Video Lecture	Watch: Pharmacy Ethics: Why Knowing Law Is Not Enough	0.3		Bill Allen
3/6/23	1.2	Video Lecture	Watch: Legislative and Judicial Processes	0.5		Bill Allen
3/7/23	1	Reading	Read: Reading from Required Textbook - See Canvas for Details	0.6		Bill Allen
3/7/23	1	Reading	Read: Assigned Florida Statutes • 465.004 Board of Pharmacy • 465.005 Authority to make rules	0.1		Bill Allen
3/8/23	1	Assignment Graded	Pre ALS 1 Assignment			Randell E Doty
3/21/23	1	Active Learning Session--VC	Active Learning Session 1:	2	1-3, 12	Bill Allen, Randell E Doty

3/21/23	1	Quiz In-class Graded	iRAT/tRAT Module 1			
3/21/23	1	Assignment Graded	In Class ALS 1 Assignments			Randell E Doty
	2	Module	Module 2: Food, Drug, and Cosmetic Act – History and Prohibition of Adulteration and Misbranding		5-7	Janet L Schmittgen
3/22/23	2.1	Video Lecture	Watch: Historical Overview of the Federal Food, Drug, and Cosmetic Act	0.75		Janet L Schmittgen
3/22/23	2.2	Video Lecture	Watch: Defining and Distinguishing Drugs From Foods, Dietary Supplements, Devices, and Cosmetics	0.5		Janet L Schmittgen
3/23/23	2.3	Video Lecture	Watch: Adulteration & Misbranding; Labeling, Product Recalls, Pregnancy Warning, & Black-box Warning	0.5		Janet L Schmittgen
3/23/23	2	Reading	Read: Reading from Required Textbook - See Canvas for Details	0.5		Janet L Schmittgen
3/24/23	2	Reading	Read: Assigned Florida Statutes • 499.006 Adulterated drug or device	0.15		Janet L Schmittgen

			• 499.007 Misbranded drug or device			
3/27/23	2	Assignment Graded	Pre ALS 2 Assignment			Randell E Doty
4/4/23	2	Active Learning Session-- VC	Active Learning Session 2:	2	4-5, 12	Bill Allen, Janet L Schmittgen, Paul Ackerman, Randell E Doty
4/4/23	2	Quiz In- class Graded	iRAT/tRAT Module 2			
4/4/23	2	Assignment Graded	In Class ALS 2 Assignments			Randell E Doty
	3	Module	Module 3: Prescription vs. OTC Drugs, Generic Substitution, and Filling Prescriptions, Prescription Drug Labeling, Prescription Formats, Pharmacy Interns and Technicians, and Categories of Pharmacy Permits		5-7	Bill Allen, Paul Ackerman
4/5/23	3.1	Video Lecture	Watch: Prescription vs. OTC Drugs, Generic Substitution, and Filling Prescriptions	0.3		Paul Ackerman
4/5/23	3	Reading	Read: Reading from Required Textbook -	0.8		Paul Ackerman

			See Canvas for Details			
4/6/23	3	Reading	Read: Assigned Florida Statutes and Florida Admin. Code	0.7		Paul Ackerman
4/7/23	3.2	Video Lecture	Watch: Categories of Pharmacy Permits	0.65		Bill Allen
4/7/23	3	Reading	Read: Reading from Required Textbook - See Canvas for Details	0.25		Bill Allen
4/7/23	3	Reading	Read: Written, Electronic, Oral prescriptions, Requirements for Pharmacy Interns and Technicians, and Prescription Labeling	0.6		Bill Allen
4/10/23	3	Assignment Graded	Pre ALS 3 Assignment			Randell E Doty
4/18/23	3	Active Learning Session--VC	Active Learning Session 3: Module 3 RATs	2	4, 6-9, 12	Bill Allen, Randell E Doty
4/18/23	3	Quiz In-class Graded	iRAT/tRAT Module 3			
4/18/23	3	Assignment Graded	In Class ALS 3 Assignments			Randell E Doty
	4	Module	Module 4: Dispensing of Controlled Substances		9-11	Randell E Doty
4/19/23	4.1	Video Lecture	Watch: Controlled Substance Dispensing: Record Keeping and	0.5		Randell E Doty

			DEA Form 222			
4/19/23	4.2	Video Lecture	Watch: Florida Law Updates	0.5		Bill Allen
4/19/23	4	Reading	Read: Reading from Required Textbook - See Canvas for Details	1		Randell E Doty
4/20/23	4	Assignment Graded	Pre ALS 4 Assignment			Randell E Doty
Due:4/21/23		Assignment Graded	Assignment: Pharmacy Law Video Part 1- Team Submission			Randell E Doty
4/25/23	4	Active Learning Session--VC	Active Learning Session 4:	2	4	Bill Allen, Randell E Doty
4/25/23	4	Quiz In-class Graded	iRAT/tRAT Module 4			Randell E Doty
4/25/23	4	Assignment Graded	In Class ALS 4 Assignments			Randell E Doty
Due:4/27/23		Assignment Graded	Assignment: Pharmacy Law Video Part 2- Video Review			
5/2/23 at 10:00am	All	Exam	Final Exam		All	
			Total Hours:	17.2		