

# PHA5703 Principles of Pharmacy Law and Ethics

Spring, 2021

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: Please see 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:

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. Describe controlled substances ordering, inventory control, dispensing and destruction.
  - b. Distinguish CSOS from DEA Form 222.
  - 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.

## 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

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

N/A

## 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	25%
tRATs [4]	10%
Class Participation (MS forms answers)	05%
Pharmacy Law Video Assignment – team submission	05%
Final Exam	55%
<b>Total</b>	<b>100%</b>

*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

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](mailto: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.

## 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](mailto: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](mailto:wmallen@ufl.edu)

Office: College of Medicine, UF-HSC-GNV

### Paul Ackerman, B.S. Pharmacy

Email: [paackerm@ufl.edu](mailto:paackerm@ufl.edu)

Office: GNV

### Janet Schmittgen, RPh

Email: [jschmittgen@cop.ufl.edu](mailto:jschmittgen@cop.ufl.edu)

Office: HPNP 2335

## Instructional Designer:

Name: Holly Fremen

- Email: [holly.fremen@cop.ufl.edu](mailto:holly.fremen@cop.ufl.edu)
- Office: HPNP 4309
- Phone: 352-273-5558

## Academic Coordinator Gainesville Campus:

Name: Natalie Hasty

- Email: [nataliehasty@cop.ufl.edu](mailto:nataliehasty@cop.ufl.edu)
- Office: HPNP 4312
- Phone: 352-273-6002

Absence/Tardy Email: [absent1pd@cop.ufl.edu](mailto:absent1pd@cop.ufl.edu) (Visit the course policy site for further instructions)

## Educational Coordinators

Name: McKenzie Wallen

- Email: [mwallen@cop.ufl.edu](mailto:mwallen@cop.ufl.edu)
- Office: Jacksonville Campus

Name: Iverta Allen

- Email: [iallen1@cop.ufl.edu](mailto:iallen1@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 Examplify and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.

## 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 Study	Mod#	Activity	Unit Topic	Contact Time [hr.]a	Syllabus Learning Objectives	Responsible
03/9/21	1	Module	Module 1: Introduction to Pharmacy Ethics and Law		1-4	Bill Allen
03/10/21	1.1	Video Lecture	Watch: Pharmacy Ethics: Why Knowing Law Is Not Enough	0.3		Bill Allen
03/11/21	1.2	Video Lecture	Watch: Legislative and Judicial Processes	0.5		Bill Allen
03/12/21	1	Reading	Read: Reading from Required Textbook - See Canvas for Details	0.6		Bill Allen
03/16/21	1	Reading	Read: Assigned Florida Statutes • 465.004 Board of Pharmacy • 465.005 Authority to make rules	0.1		Bill Allen
03/19/21 1:55pm to 3:50pm	1	Active Learning Session--VC	Active Learning Session 1:	2	1-3, 12	Bill Allen, Randell E Doty
03/19/21	1	Quiz In-class Graded	iRAT/tRAT Module 1			
03/21/21	2	Module	Module 2: Filling Prescriptions: Adulteration and Misbranding, RX drugs, OTCs and Generics		5-7	Janet L Schmittgen
03/21/21	2.1	Video Lecture	Watch: Historical Overview of the Federal Food, Drug, and Cosmetic Art	0.5		Janet L Schmittgen
03/22/21	2.2	Video Lecture	Watch: Defining and Distinguishing Drugs From Foods, Dietary Supplements,	0.35		Janet L Schmittgen

			Devices, and Cosmetics			
03/23/21	2	Reading	Read: Reading from Required Textbook - See Canvas for Details	0.5		Janet L Schmittgen
03/23/21	2	Reading	Read: Assigned Florida Statutes • 499.006 Adulterated drug or device • 499.007 Misbranded drug or device	0.15		Janet L Schmittgen
03/25/21	2.3	Video Lecture	Watch: Prescription vs. OTC Drugs, Generic Substitution, and Filling Prescriptions	0.3		Paul Ackerman
03/25/21	2	Reading	Read: Reading from Required Textbook - See Canvas for Details	0.8		Paul Ackerman
04/02/21	2	Reading	Read: Assigned Florida Statutes and Florida Admin. Code	0.7		Paul Ackerman
04/02/21 1:55pm to 3:50pm	2	Active Learning Session-- VC	Active Learning Session 2:	2	4-5, 12	Bill Allen, Janet L Schmittgen, Paul Ackerman, Randell E Doty
04/02/21	2	Quiz In- class Graded	iRAT/tRAT Module 2			
04/05/21	3	Module	Module 3: Prescription Drug Labeling, Prescription Formats, Pharmacy Interns and Technicians,		7-8	Bill Allen
04/05/21	3.1	Video Lecture	Watch: Categories of Pharmacy Permits	0.65		Bill Allen
04/05/21	3	Reading	Read: Reading from Required Textbook - See Canvas for Details	0.25		Bill Allen
04/06/21	3	Reading	Read: Written, Electronic, Oral	0.6		Bill Allen



			prescriptions, Requirements for Pharmacy Interns and Technicians, and Prescription Labeling			
04/07/21 10:40am to 12:30pm	3	Active Learning Session--VC	Active Learning Session 3:	2	4, 6-9, 12	Bill Allen, Randell E Doty
04/07/21	3	Quiz In-class Graded	iRAT/tRAT Module 3			
04/08/21	4	Module	Module 4: Dispensing of Controlled Substances		9-11	Randell E Doty
04/08/21	4.1	Video Lecture	Watch: Controlled Substance Dispensing: Record Keeping and DEA Form 222	0.5		Randell E Doty
04/09/21	4.2	Video Lecture	Watch: Florida Law Updates	0.5		Bill Allen
04/11/21	4	Reading	Read: Reading from Required Textbook - See Canvas for Details	1		Randell E Doty
04/13/21 1:55pm to 3:50pm	4	Active Learning Session--VC	Active Learning Session 4:	2	4	Bill Allen, Randell E Doty
04/13/21	4	Quiz In-class Graded	iRAT/tRAT Module 4			Randell E Doty
04/15/21 at 5:00pm		Assignment Graded	Assignment: Pharmacy Law Video - Team Submission			Randell E Doty
04/20/21 8:30AM to 10:30AM	All	Exam	Final Exam		All	
				16.3		