

PHA5239 Applications of Pharmacy Law and Ethics

Fall 2020

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 Leader

Randell Doty, PharmD,

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

Office Hours: Thursday 10 – 11 am during course dates.

Please see Canvas course for Zoom link.

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. EPA E4. 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 of pharmaceutical products (prescription and non-prescription).
9. Describe the requirements and application procedure for the registration, licensure, certification, or permitting of a practice setting or business entity.
10. Outline the operational requirements for a registered, licensed, certified, or permitted pharmacy practice setting.
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.
12. Recognize the requirements for a finding of pharmacy malpractice, risk management strategies, as well as drug product liability.

Course Pre-requisites

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

Course Co-requisites

1. PHA5165L Professional Practice Skills Laboratory V

Course Outline

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. The course map can be found in the appendices to this syllabus.

Date [Recommended dates for independent study]	Delivery Date	Time	Mod#	Unit Topic	Contact Time [hr.]	Responsible	Syllabus Learning Objectives
				1 Module 1: New drug approval, marketing unapproved drugs, human subjects research ethics, and advertising by manufacturers and pharmacies		Bill Allen	1,11
8/17/2020				Read: Textbook pp. 62-83, 119-120	0.92	Bill Allen	
8/17/2020				1.1 Watch: The Ethics of Research with Human Subjects	0.33	Bill Allen	
8/19/2020				1.2 Watch: Advertising by Manufacturers and Pharmacies	0.25	Bill Allen	
	8/24/2020	1:55 pm - 3:50 pm		Active Learning Session 1 (online)	1.95	Randell E Doty	
				2 Module 2: Prescription drug labelling, compounding, & Prescription Drug Marketing Act of 1987		Randell E Doty	1, 5, 6, 11
8/24/2020				Read: Textbook pp. 121-130	0.3	Randell E Doty	
8/25/2020				Read: Textbook pp. 136-141	0.35	Randell E Doty	
8/26/2020				2.1 Watch: Florida rules on labeling, compounding, and drug samples	0.5	Randell E Doty	
8/27/2020				2.2 Watch: Florida rules on storage, distribution, and recordkeeping and drug samples	0.5	Randell E Doty	
	8/31/2020	1:55 pm - 3:50 pm		Active Learning Session 2 (online)	1.95	Randell E Doty	
				3 Module 3: Closed System of Controlled Substances		Bill Allen	8
9/4/2020				Read: Textbook pp. 161-176	0.83	Bill Allen	
9/7/2020				3.1 Watch: Pharmacy inspections, opioid treatment programs, and laws related to the Controlled Substances Act.	0.67	Bill Allen	
	9/8/2020	1:55 pm - 3:50 pm		Active Learning Session 3 (hybrid)	1.95	Randell E Doty	
				4 Module 4: State Regulation of Pharmacy Practice, Part I – Examination, licensing, and continuing education		Bill Allen	8
9/9/2020				4.1 Watch: Pharmacy Licensing, Regulation, and Discipline	0.5	Bill Allen	
				4.2 Watch: Legal changes in 2019-2020	0.15	Randell E Doty	
9/10/2020				Read: See Canvas	1	Bill Allen	
				5 Module 5: State Regulation of Pharmacy Practice, Part II – Automated, Institutional Pharmacies, and Technicians and Interns		Bill Allen	1,8
9/11/2020				5.1 Watch: Standards of Practice, Repository Programs, State Hospital Pharmacy licensure issues, and State regulation of long term care	0.83	Bill Allen	

9/11/2020 Read: Florida Statutes and Florida Administrative Codes posted under module 5 on Canvas **0.67** Bill Allen

9/14/2020 1:55 pm - 3:50 pm Active Learning Session 4 (hybrid) **1.95** Randell E Doty

6 Module 6: Federal Regulation of Pharmacy Practice, Part I Randell E Doty

9/15/2020 Read: Textbook pp. 241-246 **0.33** Randell E Doty

9/16/2020 Read: Textbook pp. 256-269 **0.67** Randell E Doty

9/17/2020 6.1 Watch: Florida rules on patient counseling, records, drug therapy management, ordering lab tests, & drugs that may be ordered by pharmacists **0.5** Randell E Doty

9/17/2020 10–11 am Office hour Randell E Doty

9/18/2020 8:30 am - 10:00 am Exam 1: Modules 1-4 **1.5** Randell E Doty 1, 3, 5, 6, 8-11

9/21/2020 1:55 pm - 3:50 pm Active Learning Session 5 (online) **1.95** Randell E Doty

7 Module 7: Federal Regulation of Pharmacy Practice, Part II Bill Allen 6, 11

9/22/2020 Read: Textbook pp. 247-255 **0.42** Bill Allen

9/23/2020 Read: Textbook pp. 278-286 **0.58** Bill Allen

9/28/2020 7.1 Watch: 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

9/29/2020 1:55 pm - 3:50 pm Active Learning Session 6 (online) **1.95** Randell E Doty

8 Module 8: State Regulation of Pharmacy Practice, Part III – Pharmacy Permits, Closure/Transfer Ownership, Special Pharmacies Randell E Doty 9, 10

9/30/2020 8.1 Watch: Self-Regulation in Pharmacy, Approaches to Regulation, and State Boards of Pharmacy **0.33** Randell E Doty

8.2 Watch: House Bill 389 update **0.15** Randell E Doty

Text 301- 303, 304-307, 308-312 – optional – optional Randell E Doty

10/1/2020 Read: Florida Administrative Codes 64B16 28100 through 64B16 28900 on Canvas under Module 8 **1.17** Randell E Doty

10/5/2020 1:55 pm - 3:50 pm Active Learning Session 7 (hybrid) **1.95** Randell E Doty

9 Module 9: Professional Pharmacist Liability, Risk Management, & Product Liability Bill Allen 12

10/9/2020 Read: Textbook pp. 335-350 **1** Bill Allen

10/12/2020 9.1 Watch: Pharmacist as Risk Manager, Malpractice Insurance, and Drug Product Liability **0.5** Bill Allen

10/13/2020 1:55 pm - 3:50 pm 9 Active Learning Session 8 (online) **1.95** Randell E Doty

10/18/2020	10–11 am	Office hour	Randell E Doty
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10/19/2020	8:30 am - 10:00 am	Exam 2: Modules 1-9	1.5 Randell E Doty
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Total Contact Time in Course: 33.05

Required Textbooks/Readings

1. Aboud 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.
2. Florida Statutes
 - Available online: <http://www.leg.state.fl.us/statutes/>
3. Florida Administrative Code
 - Available online: <https://www.flrules.org/>
4. Florida Department of Business and Professional Regulation
 - Available online: <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 may 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.]

Assessment Item	Grade Percentage
iRATs [7]	10%
tRATs [7]	10%
Participation	10%
Exam 1	30%
Exam 2	40%
Total	100%

Table 1. Grading Scale

Percentage Range	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 [Pharm.D. Course Policies](#) carefully, at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/course-policies/>

Course Evaluation Process

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at <https://evaluations.ufl.edu>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://evaluations.ufl.edu/results/>.

Appendix A. Course Directory

Teaching Partnership Leaders/Course Directors:

Randell Doty, PharmD,

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

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

- Email: wmallen@ufl.edu
- Office: G1-20 (Stetson – Medicine Wing)
- Phone: (352) 273-5155

Questions to Ask:

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

Instructional Designer:

Name: Elliot Tordoff

Office: HPNP 4309

Email: etordoff@cop.ufl.edu

Phone: 352-294-5215

Academic Coordinator:

Name: Misti Merrill

Office: HPNP 4312

Phone: 352-273-5617

Absent/Tardy Email: absent3pd@cop.ufl.edu

Educational Coordinators:

McKenzie Wallen

Email: mwallen@cop.ufl.edu

Office: Jacksonville Campus

Iverta Allen

Email: iallen1@cop.ufl.edu

Office: Orlando Campus

Questions to Ask:

- Issues related to course policies (absences, make-up exams, missed assignments)
- Absence 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 grades
- Assistance with ExamSoft®
 - Students at distant campuses may contact Educational Coordinator for use of SofTest and assistance during exams.
 - The Academic Coordinator is the contact person for issues related to posting ExamSoft grade

Other Teaching Partnership Faculty Members:

Paul Ackerman, B.S., Pharmacy

Email: paackerm@cop.ufl.edu