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 Leader

Randell E. Doty, Pharm.D.
- Email: doty@cop.ufl.edu
- Office: HPNP 2333
- Phone: 352-294-4984
- Office Hours: By appointment ONLY.

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 what a prescription is and the obligations of pharmacy personnel in processing prescriptions.
2. Explain the dispensing requirements for prescriptions, including those involving generic substitution.
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).


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. Identify the various classifications of pharmacy permittees in the state of Florida, and the activities that may be performed in these different pharmacies.
   a. 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
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.
<table>
<thead>
<tr>
<th>Date and Time</th>
<th>Mod#</th>
<th>Unit Topic</th>
<th>Contact Time [hr.]a</th>
<th>Responsible</th>
<th>Syllabus Learning Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/14/19</td>
<td>1</td>
<td>Module 1: Introduction to Pharmacy Ethics and Law</td>
<td>Bill Allen</td>
<td>1-4</td>
<td></td>
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<tr>
<td>03/14/19</td>
<td>1.1</td>
<td>Watch: Pharmacy Ethics: Why Knowing Law Is Not Enough</td>
<td>0.3</td>
<td>Bill Allen</td>
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<tr>
<td>03/14/19</td>
<td>1.2</td>
<td>Watch: Legislative and Judicial Processes</td>
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<td>Bill Allen</td>
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<tr>
<td>03/14/19</td>
<td>1</td>
<td>Read: Reading from Required Textbook - See Canvas for Details</td>
<td>0.6</td>
<td>Bill Allen</td>
<td></td>
</tr>
<tr>
<td>03/14/19</td>
<td>1</td>
<td>Read: Assigned Florida Statutes</td>
<td>0.1</td>
<td>Bill Allen</td>
<td></td>
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<tr>
<td>03/20/2019 10:40-12:35pm</td>
<td>1</td>
<td>Active Learning Session 1:</td>
<td>2</td>
<td>Bill Allen, Randell E Doty</td>
<td>1-3, 12</td>
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<tr>
<td>03/20/19</td>
<td>1</td>
<td>iRAT/TRAT Module 1</td>
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<td>03/21/19</td>
<td>2</td>
<td>Module 2: Food, Drug, and Cosmetic Act – History and Prohibition of Adulteration and Misbranding</td>
<td>Janet L Schmittgen</td>
<td>5-7</td>
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<tr>
<td>03/21/19</td>
<td>2.1</td>
<td>Watch: Historical Overview of the Federal Food, Drug, and Cosmetic Art</td>
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<td>Janet L Schmittgen</td>
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<td>Watch: Defining and Distinguishing Drugs From Foods, Dietary Supplements, Devices, and Cosmetics</td>
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<td>03/26/19</td>
<td>3</td>
<td>Module 3: Prescription vs. OTC Drugs, Generic Substitution, and Filling Prescriptions</td>
<td>Paul Ackerman</td>
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<td>03/26/19</td>
<td>3.1</td>
<td>Watch: Prescription vs. OTC Drugs, Generic Substitution, and Filling Prescriptions</td>
<td>0.3</td>
<td>Paul Ackerman</td>
<td></td>
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<tr>
<td>Date and Time</td>
<td>Mod#</td>
<td>Unit Topic</td>
<td>Contact Time [hr.]</td>
<td>Responsible</td>
<td>Syllabus Learning Objectives</td>
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<td>03/26/19</td>
<td>3</td>
<td>Read: Reading from Required Textbook - See Canvas for Details</td>
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<td>Paul Ackerman</td>
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<td>03/26/19</td>
<td>3</td>
<td>Read: Assigned Florida Statutes and Florida Admin. Code</td>
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<td>Paul Ackerman</td>
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<td>03/27/2019 10:40-12:35pm</td>
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<td>Active Learning Session 2:</td>
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<td>Allen, Schmittgen, Ackerman, Doty</td>
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<td>03/27/19</td>
<td>2-3</td>
<td>iRAT/TRAT Module 2 and 3</td>
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<td>03/27/19</td>
<td>4</td>
<td>Module 4: Prescription Drug Labeling, Prescription Formats, Pharmacy Interns and Technicians, and Categories of Pharmacy Permits</td>
<td>Bill Allen</td>
<td>7-8</td>
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<td>4.1</td>
<td>Watch: Categories of Pharmacy Permits</td>
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<td>Bill Allen</td>
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<td>03/27/19</td>
<td>4</td>
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<td>0.25</td>
<td>Bill Allen</td>
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<tr>
<td>03/27/19</td>
<td>4</td>
<td>Read: Written, Electronic, Oral prescriptions, Requirements for Pharmacy Interns and Technicians, and Prescription Labeling</td>
<td>0.6</td>
<td>Bill Allen</td>
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<tr>
<td>4/5/2019 10:40-12:35pm</td>
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<td>Active Learning Session 3: Module 4 RATs</td>
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<td>Bill Allen, Randell E Doty</td>
<td>4, 6-9, 12</td>
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<td>4</td>
<td>iRAT/TRAT Module 4</td>
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<td>04/05/19</td>
<td>5</td>
<td>Module 5: Dispensing of Controlled Substances</td>
<td>Randell E Doty</td>
<td>9-10</td>
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<td>04/05/19</td>
<td>5.1</td>
<td>Watch: Controlled Substance Dispensing: Record Keeping and DEA Form 222</td>
<td>0.5</td>
<td>Randell E Doty</td>
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<tr>
<td>04/05/19</td>
<td>5</td>
<td>Read: Reading from Required Textbook - See Canvas for Details</td>
<td>1</td>
<td>Randell E Doty</td>
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<td>Active Learning Session 4:</td>
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<td>iRAT/TRAT Module 5</td>
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<td>6</td>
<td>Module 6: Florida Law Updates</td>
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<td>Watch: Florida Law Updates</td>
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<td>Bill Allen</td>
<td></td>
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<tr>
<td>04/10/19</td>
<td>6</td>
<td>Read: Reading from Required Textbook - See Canvas for Details</td>
<td>0.1</td>
<td>Bill Allen</td>
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</tbody>
</table>
### Required Textbooks/Readings

   - 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.

2. All other required readings will be posted in Canvas.

Use [UF VPN to access UF Libraries Resources](http://library.ufl.edu/) 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://library.ufl.edu/](http://library.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.

<table>
<thead>
<tr>
<th>Assessment Item</th>
<th>Grade Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>iRATs [4] – single lowest score dropped</td>
<td>25%</td>
</tr>
<tr>
<td>tRATs [4]</td>
<td>25%</td>
</tr>
<tr>
<td>Class Participation and Professionalism</td>
<td>10%</td>
</tr>
<tr>
<td>Final Exam</td>
<td>40%</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
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Table 1. Grading Scale

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 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/
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

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

Instructional Designer:
Sarah A. Burgess, M.Ed
Email: sburgess@cop.ufl.edu
Office: HPNP 4309
Phone: 352-273-9492

Academic Coordinator:
Holly Fremen
Email: holly.fremen@cop.ufl.edu
Office: HPNP 4312
Phone: 352-273-5558
Absence/Tardy Email: absent1pd@cop.ufl.edu (Visit the course policy site for further instructions)

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 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.)
Other Teaching Partnership Faculty Members:

Paul Ackerman, B.S. Pharmacy
Email: paackerm@ufl.edu
Office: GNV

Janet Schmittgen, RPh
Email: jschmittgen@cop.ufl.edu
Office: HPNP 2335

William L. (Bill) Allen, JD, MDiv
Email: wmalen@ufl.edu
Office: College of Medicine, UF-HSC-GNV