

Course Number and Title: PYPC 5110 - Pharmacy Law and Ethics

Credit Hours: 2

Prerequisites: First year PYDI Standing

Corequisites: None

Course Description:

Defines basic legal and ethical principles of pharmaceutical care and their effect on the patient drug use process.

Date: November 12, 2004

Reading Materials:

- *Strauss's Federal Drug Laws and Examination Review*, 5th Edition Revised, Steven Strauss, Ph.D., R. PH.
- *Pharmacists Manual*, DEA Publication [This manual is being furnished by the Birmingham Office of the Drug Enforcement Administration].
- *Code of Alabama, 1975* §34-23-1, et seq., Pharmacists and Pharmacies.
- *Code of Alabama, 1975* §20-2-1, et seq., Controlled Substances.
- *Rules of the Alabama State Board of Pharmacy*.

Note: *Code of Alabama 1975* materials and *Rules of Alabama State Board of Pharmacy* are available for download at Alabama State Board of Pharmacy web site, www.albop.com.

Pharmacist's Manual is also available from the DEA web site, www.usdoj.gov/dea.

Code of Federal Regulations is available at www.access.gpo.gov/nara/cfr/index.html.

Course Ability Based Outcomes

1. Manage the Pharmacy Within the Organization's Business Plan

Course Objectives:

1. Display appropriate knowledge of Federal, State and Administrative Pharmacy Law.
2. Know and practice the ethical professional standards governing the pharmacy profession.
3. Provide improved patient pharmaceutical care through legal and ethical avenues.

4. Improve professional relationships/communications through legal and ethical avenues.

Course Content

Week	Topic
1	Course overview including review of referenced texts and supplemental materials. Review of Syllabus. Introduction to Pharmacy Law, the Legal System and Ethics.
2	Analysis of Pharmacy Law including Federal law and State law [Civil vs. Criminal]. Administrative Laws and how they affect pharmacists. Chapters 1-3 <i>Strauss</i> .
3	Test 1 The Controlled Substances Act – the first two lectures regarding the controlled substances act. <i>Pharmacist's Manual</i> , DEA Publication, Chapter 4 <i>Strauss</i> .
4	The Controlled Substances Act. <i>Pharmacist's Manual</i> , DEA Publication, Chapter 4 <i>Strauss</i> .
5	Test 2 Summarize Controlled Substances Act including Questions & Answers session. Liability under the Controlled Substances Act, Criminal vs. Administrative. Pharmacy Inspections. <i>Pharmacist's Manual</i> , DEA Publication, Chapter 4 <i>Strauss</i> .
6	The Food and Drug Administration. The Food Drug & Cosmetic Act including history of the Act. Durham-Humphrey Amendment and Kefauver- Harris Amendment. How the drug thalidomide affected the Act and public's perception of drugs. Chapters 9 & 22 <i>Strauss</i> .
7	Midterm Exam.
8	Adulteration vs. Misbranding; Child resistant packaging; Tamper resistant packaging and New Drug Applications. Chapter 5 <i>Strauss</i> .
9	Test 3 Medical Devices, Drug Recalls and Postal Regulations. Chapters 6, 7, 9 & 11 <i>Strauss</i> .
10	HIPPA, National Drug Identification Numbers, Expiration Dating, Foreign prescriptions and Ipecac Syrup. Chapters 8, 10, 23 and 25 <i>Strauss</i> .

- 11 **Test 4.**
 Prescription Marketing Act of 1987, Anabolic Steroids, Cosmetics and the Orange Book.
 Chapters 12, 13, 14 and 16 *Strauss*.
- 12 Rx to OTC switch, Compounding and Manufacturing. Introduction to State Pharmacy Law.
 Chapters 18 and 26 *Strauss*. *Code of Alabama 1975*, Titles 20 and 34; *Regulations of the Alabama Board of Pharmacy*.
- 13 State Pharmacy Law. Why are there both State and Federal Laws regulating Pharmacy? How do regulations of the Alabama Board of Pharmacy apply to Federal and State Law?
Code of Alabama 1975, Titles 20 and 34; *Regulations of the Alabama Board of Pharmacy*.
- 14 Alabama Pharmacy Law, including ethical considerations and obligations.
Code of Alabama 1975, Titles 20 and 34; *Regulations of the Alabama Board of Pharmacy*.
- 15 Alabama Pharmacy Law (Continued)
Code of Alabama 1975, Titles 20 and 34; *Regulations of the Alabama Board of Pharmacy*.

Comprehensive Final Exam

Methods of Evaluation

Students will be evaluated on a number of activities. The points earned on each activity will count toward the final course grade. The activities and their weights are as follows:

1. **Tests** – (each of the 4 tests is worth **10%**) **40%**.
2. **Mid-term Exam** **30%**
3. **Comprehensive Final Exam** **30%**

GRADING

Final grades will be determined using a scale of:

- A = 90% and higher
- B = 80-89%
- C = 70-79%
- D = 60-69%
- F = 59 and below

Policy Statements

Late Assignments: Assignments turned in past the deadline date will receive a 10% reduction in grade for each day late.

Examinations: The exams and tests will be drawn from the lectures, assigned readings, handouts, class discussions, and guest presentations.

Grading: Scores for all graded elements will be available as soon as possible on the course website.

Students may challenge any graded element by

1. Submitting a written evidenced-based challenge with appropriate supporting documentation to back up the challenge. The appropriate supporting documentation consists of a photocopy of the reference that was used as a basis for the challenge with the applicable text highlighted.
2. Faculty must receive the challenge within two (2) business days of the graded material being made available.
3. The item in question along with the evidenced-based challenged will be reviewed by the question author or other faculty member. The review committee may DECREASE the points awarded for the original response, MAINTAIN the points awarded for the original response, or INCREASE the points awarded for the original response based on the evidence provided. The decision of this committee will be final.
4. Only serious, professionally worded, evidence-based challenges will be considered.

Conduct and Academic Dishonesty: A professional demeanor is expected at all times during large group and team activity sessions. For the benefit of your classmates, all cell phones, pagers, and other electronic communication devices that may disrupt the class must be turned off prior to the start of class. Failure to do so may result in confiscation of the disruptive item(s). Students engaging in disruptive behavior may be asked to leave the classroom.

The student is responsible for reading and abiding by the provisions of the Auburn University Harrison School of Pharmacy Honor Code (the Honor Code). Violations of the Honor Code include but are not limited to the following:

- Printing, duplicating, recreating, or saving to a file any test question, exam question, or unauthorized homework file.
- Working on a test, exam, or any individually graded assignments with the assistance of any one else.
- Taking a test, exam, or completing any graded assignment using another student's ID.

A student is responsible for reporting to the course coordinator any student whom he/she observes engaging in one of these activities and any student who indicates to that he/she has engaged in one of these activities.

Class Attendance and Missed Work

Attendance Policy

1. The student is expected to attend and participate in all lectures.
2. The student is expected to carry out all assigned work and to take examinations during the class period designated by the instructor.

3. The regularly accepted time for class to begin is __: __ __M. If the instructor does not convene class within fifteen minutes after the hour, it may be assumed that class is canceled for that day.
4. It is the University policy that all classes will be as scheduled on the last day before and the first day after holiday periods designated by the University.
5. Unresolved problems regarding class attendance, grading policies or other issues involving the class should be discussed with the instructor. If the student is not satisfied with the results of these discussions, he or she should follow the Auburn University School of Pharmacy procedures for handling course-related disputes.

Make-Up Work

1. Arrangements to make up missed work due to excused absences are to be initiated by the student.
2. A student will be allowed to make up any missed exams as long as the instructor is notified prior to the exam. Such absences must be for legitimate, documented purposes as indicated in the Auburn University Handbook. Make-up exams will be taken at the convenience of the instructor and most likely will not take place during regularly scheduled class time.
3. No students will be allowed to take an exam prior to the scheduled date and time.

Special Needs:

It is the policy of Auburn University to provide accessibility to its programs and activities and reasonable accommodation for persons defined as having disabilities under Section 504 of the Rehabilitation Act of 1973, as amended, and the Americans with Disabilities Act of 1990.

Students should contact the instructor at the beginning of the semester so that accommodations can be arranged. Students should also contact the Program for Students with Disabilities 1244 Haley Center, phone: (334) 844-2096.