

PMDU 530: Pharmacy Jurisprudence
School of Pharmacy
Department of Pharmacy Practice
Northeastern University
Summer 2006

Course Description:

The pharmacy law course will examine the U.S. and Massachusetts laws regulating the practice of pharmacy and drug manufacture, distribution, and use. The course will also provide students opportunities to apply legal principles and broader professional knowledge and analyze regulatory issues and situations facing pharmacy practitioners.

Course Goals and Objectives:

Course Goals

One goal of the pharmacy law course is for students to come away understanding the regulations affecting the entire process of development and delivery of medications to patients. A second goal of the course is to integrate legal principles and cases into situations that can occur in pharmacy practice.

Course Objectives

Upon successful completion of this course, students will be able to:

1. Identify and describe U.S. and Massachusetts laws regulating pharmacy practice, drug manufacture, distribution, and use.
2. Interpret U.S. and Massachusetts laws regulating pharmacy practice, drug manufacture, distribution, and use.
3. Describe the relationships between groups, organizations, and processes involved in the regulation of drugs and pharmacy practice.
4. Analyze pharmacy practice issues and situations using legal principles, cases and knowledge of the profession.
5. Integrate different sources of current information on U.S. and Massachusetts laws across a variety of pharmacy practice situations.
6. Search for and identify legal and regulatory information and apply it to specific pharmacy practice situations.

Course Coordinator:

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Learning Resources: TBA**Credit Hours:** 3.0 Semester Hours**Clock Hours:** 150 minutes/week**Lecture:**

Tuesdays: 11:30 – 12:45 pm
Wednesdays: 1:30 – 2:45 pm

Required Texts:

Aboud RR (2005) Pharmacy Practice and the Law, 4th Edition. Sudbury, MA: Jones and Bartlett Publishers.

Massachusetts Pharmacy Package. Obtained at State House.

Suggested Readings:

Fink JL, Vivian JC, Reid KK (eds) (2006) Pharmacy Law Digest, 40th Ed. St. Louis, MO: Facts and Comparisons

Pavlan R. Pharmacy Law State/Federal for Massachusetts and Supplement

Prerequisites or Permission Statement: This course is required in the doctor of pharmacy program; Health Care Systems is a pre-requisite.

Policy Regarding the Use of Taping of Lectures/Cell Phones and Palm Pilots:

University policy dictates that students must seek the instructor's permission to tape record class lectures. All cell phones and palm pilots should be turned off during lectures, laboratory sessions and during examinations

Academic Honesty Statement

Northeastern University is committed to the principles of intellectual honesty and integrity. All members of the Northeastern community are expected to maintain complete honesty in all academic work, presenting only that which is their own work on tests and assignments. If you have questions regarding the definitions of cheating or plagiarism, consult the Northeastern University Student Handbook and/or contact your professor prior to submitting work for evaluation.

Plagiarism is intentionally or unintentionally using the ideas or writings of another person without properly presenting the information and giving credit to the source. Plagiarism will not be tolerated. Plagiarized work will receive a grade of **F** and may result in the student failing the course.

Cheating will also not be tolerated. Any evidence of cheating on a test or assignment will result in an F for that work, may result in the student failing the course and/or expulsion from the program or University. The student's actions may also be brought to the attention of the Northeastern University Student Judicial Hearing Board.

Any member of the academic community who witnesses an act of academic dishonesty should report it to the appropriate faculty member or to the Director of Judicial Affairs. The charge will be investigated and if sufficient evidence is presented, the case will be referred to the Northeastern University Student Judicial Hearing Board.

Statement Concerning Students With Special Needs

Students with special needs (e.g., disabled, Deaf, or hard of hearing) are encouraged to contact the Disability Resource Center (DRC) to register and request services. Students must notify the instructor at the beginning of the semester if they plan to use DRC services throughout the course.

Course Grading Criteria:

1. Three exams: two in-class exams and a final exam. Students will be allotted the same amount of time per question as on the Multi-State Pharmacy Jurisprudence Exam, MJPE (1.3 minutes per question). Thus, students will be allotted 65 minutes for a 50-item exam.

First Exam: 100 pts (50 multiple choice questions)

Second Exam: 100 pts (50 multiple choice questions)

Third Exam: 150 points (50 multiple choice questions)

Exams will be cumulative and in multiple choice format using scantron forms; all students must bring a #2 pencil to all exams. Exam questions will be written in the format used in the MPJE.

2. Assignments:

Case Analyses (3 @ 20 pts.): 60 pts
Standards & Liability Paper: 45 pts
Debate Presentation: 45 pt

3. Total Points: 500 pts

A	$\geq 93\%$	≥ 465.00 points
A -	90 – 92.9% =	450.00 points – 464.99 points
B +	87 – 89.9% =	435.00 points – 449.99 points
B	83 – 86.9% =	415.00 points – 434.99 points
B -	80 – 82.9% =	400.00 points – 414.99 points
C +	77 – 79.9% =	385.00 points – 399.99 points
C	73 – 76.9% =	365.00 points – 384.99 points
C -	70 – 72.9% =	350.00 points – 364.99 points
D +	67 – 69.9% =	335.00 points – 349.99 points
D	63 – 66.9% =	315.00 points – 334.99 points
D -	60 – 62.9% =	300.00 points – 314.99 points
F	$< 60\%$	≤ 299.99 points

There will be **three unannounced** quizzes worth 3 points each (total: 9 points) for extra credit. These points will be added to the students total number of points for the course (i.e., if a student has 400 points total and 6 points in extra credit, they will receive a total of 406 points).

A minimum of **73% (a C)** is needed to pass the course. **The above point scale will be held tightly when computing grades.**

Note:

- (1) The course instructors reserve the right to modify the syllabus and classroom activities given needs to change the allocation of time to various topics and last-minute issues in the administration of the course. For example, **additional readings may be assigned during the semester.**
- (2) The course is likely to involve the use of the interactive Classroom Performance System (CPS) technology. This will require you to register for access to the system as it applies to this course and bring your response pads.

Table 1: Lecture Outline			
Date	Week #	Topic	Reading Assignment
05/09/06 & 05/10/06	1 NR	Course Instruction; Professional decision making; Introduction to law and legal systems; legal terminology, Ethics & Ethical Decision-Making	Abood: Pp. 1-35
05/16/06 & 05/17/06	2 NR	Federal Legislation: Food, Drug, Cosmetic Act, Acts & Amendments, Drug Approval Process & Related Legislation, Federal vs. State Law; Misbranding, Adulteration, Manufacturing Requirements, DESI drugs	Abood: Pp. 37-100
05/23/06 & 05/24/06	3 NR	Cont. on Federal Law; State Pharmacy Examining Board: Composition, Mission, Licensure of Pharmacies, Pharmacist Interns, Pharmacists, Wholesalers; Grievance Procedures, National Association of Boards of Pharmacy	Abood: Pp: 275- 311
05/30/06 & 05/31/06	4 NR	Regulations related to practice of pharmacy- Authority to Prescribe, Requirement for Written vs. Oral Prescriptions, Patient Records, Health Insurance Portability and Accountability Act (HIPPA); Case 1 Due	Abood: Pp: 233- 240
06/06/06 & 06/07/06	5 NR	Cont. of regulations related to practice of pharmacy; Regulations related to prescription processing-Preparing, Packaging, Labeling, Dispensing, Patient Counseling (OBRA vs. State Regs); Speaker: Chuck Young, Executive Secretary of State Board of Pharmacy	Abood: Pp: 227-233
06/13/06 & 06/14/06	6 NR	Exam 1 , Miscellaneous prescription processing issues: Compounding, Syringes, Poisons, Prescription Samples, Medication Leaflets, Drug Importation	
06/20/06 & 06/21/06	7 NR	Regulations related to prescription processing of specific medications and practice environments- hospitals, nursing homes, nuclear pharmacy Case 2 Due	Abood: Pp: 240- 251
06/27/06 & 06/28/06	8 PG	Controlled Substances Act, Amendments, Related Laws, Registrations under the Controlled Substance Act, Changes in Registrations, Opioid Treatment Programs	Abood: Pp: 145-183
07/05/06	9 PG	Controlled Substances Act: Prescribing and Dispensing, DEA Form 222	Abood: Pp: 185-200, 206-226
07/11/06 & 07/12/06	10 PG	Controlled Substances Act: Record Keeping, Inventory Maintenance, Security Requirements, Case 3 Due	Abood: Pp: 200-206
07/18/06 & 07/19/06	11 PG	Exam 2 ; Introduction to Civil Liability: Criminal vs. Civil, Harms and Torts, Negligence, Duty Breached, Damages, Direct Causation	Abood: 313-364
07/25/06 & 07/26/06	12 PG	Cont. of Civil Liability, Response to Negligence Claims, Limits of Responsibility, Pharmacist Responsibilities & Risks	Abood: 313-364
08/01/06 & 08/02/06	13 NR&PG	Debates 1 & 2	
08/08/06 & 08/09/06	14 NR&PG	Debates 3 & 4 Standards & Liability Paper Due	

Exam 3: During Finals Week