

PHAR 580
Pharmacy Law

Spring 2006

2 credits

Tuesday: 8-8:50 AM
Thursday 9-10:50 AM

Dr. Francis Palumbo
Judge John Fader

This course involves an examination of the legal and regulatory issues pertaining to drugs and devices and the practice of pharmacy. Students will learn the various laws and regulations which will govern their usual daily activities in a variety of practice sites.

SPECIFIC COURSE OBJECTIVES:

1. Know the basic federal laws that create a framework for the regulation of foods, drugs, cosmetics and medical devices. The principal focus will be on drug laws and regulations.
2. Know the federal and state laws governing the marketing, prescribing and dispensing of controlled dangerous substances.
3. Know the state laws governing the practice of pharmacy and delivery of pharmaceutical care.

CONDUCT OF THE COURSE AND GRADING:

This is basically a lecture course supplemented by the textbooks and, perhaps, some handouts or class discussions, where appropriate. There will be two examinations, each worth 100 points. There may be additional unannounced quizzes (approximately 10 points each). The total quiz points will be added to the denominator for determining the final grade. For example, if you have two exams and two 10 point quizzes, your grade will be based upon the points you earned over 220 points. There will be NO makeups of unannounced quizzes under any circumstances. The number of unannounced quizzes is at the discretion of Dr. Palumbo and Judge Fader. Please keep up with the material.

Any issues regarding an examination must be brought to the coursemaster's attention within 10 working days of posting of grades or the opportunity will be lost.

Grade ranges: A = 90-100%
 B = 80-89
 C = 70-79
 D = 60-69
 F = below 60%

TEXTS

Both of the following are required:

1. Abood RR. Pharmacy Practice and the Law, 4th. Edition. Boston: Jones and Bartlett Publishers, Inc. 2005.

2. Pharmacy Laws and regulations for the State of Maryland. Maryland Pharmacists Association.

Latest Edition. This book is available only from the Maryland Pharmacists Association. You must go to the association offices at Lombard and Penn and purchase this book. The books will not be ready for purchase until a few weeks after the start of the course. We will make an announcement at that time.

The following text is recommended:

Reiss BS, Hall GD. Guide to federal pharmacy law, 3rd edition. Delmar, NY. Apothecary Press.

SCHEDULE REVISED 2-21-06

Schedule
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| | | | | Readings (Additional readings may be assigned during classes) |
|---------------|------|----|---|---|
| 1. Tu, Feb 14 | 8-9 | FP | Intro to FDCA | A 37-42 |
| 2. Th, Feb 16 | | | No Classes-Legislative Day | |
| 2. Tu, Feb 21 | 8-9 | FP | Definitions (Food, drug, cosmetic, Medical device, etc) Official Compendia | A 42-51; 71-75; 63-68; |
| 3. Th, Feb 23 | 9-11 | FP | Film Dietary Supplements | |
| 4. Tu, Feb 28 | 8-9 | FP | Premarket Clearance & 1962 Amendments / DESI, OTC Drugs | 102-104 A 68-69 118-120 102-107 |
| 5. Th, Mar 2 | 9-11 | FP | Premarket Clearance (cont) Drug Advertising Prohibited Acts Prescription Drug Marketing Act, Reimportation/Counterfeiting | A 75-83 51-60 119-122 |
| 6. Tu, Mar 7 | 8-9 | FP | Patent Term Restoration Act Generic substitution Orphan Drug Act | A 40, 68-71 MLR A 68-71 116-119, 286-287 111-112 |
| 7. Th, Mar 9 | 9-11 | JF | FDA Authority (injunctions, etc) Labeling & packaging requirements | A 50-51, 104-105 59-63, 109-111 250 |

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|----------------|------|----|---|-----------------------------|
| | | | Use of Alcohol | |
| | | | Federal Caustic Poison Act | |
| | | | Federal Hazardous substances act | |
| | | | Poison Prevention Packaging Act | A 123-125 |
| | | | Consumer Product Safety Act | |
| | | | Federal Anti-Tampering Act | A 55 |
| 8. Tu, Mar 14 | 8-9 | FP | Health Insurance Portability and Accountability Act | A 233-240 |
| 9. Th, Mar 16 | 9-11 | JF | Mid Term Exam | |
| 11. Tu, Mar 28 | 8-9 | JF | Maryland Pharmacy Practice Act Board of Pharmacy Pharmacist licensure requirements | MLR A 275-295 |
| 12. Th, Mar 30 | 9-11 | JF | Suspension/revocation Pharmacy licensure requirements General requirements for pharmacy operations (hours, etc) | MLR |
| 13. Tu, Apr 4 | 8-9 | JF | Controlled Dangerous Substances | MLR A 145-211 |
| 14. Th, Apr 6 | 9-11 | JF | Controlled Dangerous Substances, contin Opioid Treatment Programs | A 166-168 |
| 15. Tu, Apr 11 | 8-9 | JF | Prescription requirements- general. Processing the prescription | MLR |
| 16. Th, Apr 13 | 9-11 | JF | Hospital Pharmacy | MLR A 258-261 288-289 |
| | | | Long Term Care Facilities | A 289-290 248-251 |

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|----------------|------|----|--|-----------------------------|
| 17. Tu, Apr 18 | 8-9 | JF | Prescription files Pharmacy inspections | MLR A 161-166 |
| 18. Th, Apr 20 | 9-11 | JF | Pharmacy equipment/books Mailing prescriptions Prescriptive Authority/ Collaborative practice | MLR A 108-109 MLR |
| 19. Tu, Apr 25 | 8-9 | FP | FDA registration Pharmacist Compounding | MLR A 112-116 |
| 20. Th, Apr 27 | 9-11 | FP | OBRA 90 Negligence | A 287 227-233 |
| 21. Tu, May 2 | 8-9 | FP | Veterinary drugs | TBA |
| 22. Th, May 4 | 9-11 | | Final Exam | |

* A refers to the Abood text (4th. ed)

* MLR refers to Pharmacy Laws and regulations for the State of Maryland

FP= F. Palumbo

JF = J. Fader

