

PHARMACY 310- PHARMACY LAW SPRING 2006

Lecture: Tuesday, Thursday, 10:40am to noon in SB 114 **unless noted**

Course Coordinator: Lori Morin Office SB 340 4080

Laboratory: Tuesday or Thursday 1:10pm to 3:10pm or 3:10pm to 5pm in SB 229

Lab Coordinator: Kristen Robbins SB 318 4693

Instructors: Genine Thormahlen SB 218 4056

Arleann Santoro SB 225 6070

COURSE DESCRIPTION:

This is an introductory course in the legal aspects of pharmacy practice that includes a lab emphasizing the technical aspects of drug dispensing and patient communication in simulated pharmacy practices.

COURSE GOALS:

At the conclusion of this course you should have a working knowledge of the laws and rules pertaining to pharmacy practice that will help you become a “legal” practitioner. There are times that the law will not provide a specific answer. In these cases, you will need to use experience and ethical grounding to do what you believe is the best under the circumstances. By the course’s completion, you should have a working knowledge of and ability to apply or demonstrate the following:

Important legal terminology

The Federal Register and other government publications

A history of pharmacy law

How laws and rules affect pharmacy practice

The Food, Drug and Cosmetic Act and its Amendments

The Controlled Substances Act of 1970 and its Rules

Inspections

The Poison Prevention Packaging Act

The Tamper Resistant Packaging Act

Montana State Laws and Regulations

Pharmacist liability in practice, error reduction

Confidentiality and HIPAA

Other pertinent laws and rules related to pharmacy practice

60 ~~of the~~ top 100 prescription medications (trade name, generic name, and use)

Counseling information for selected classes of medications

Counseling experience

Intro to parenteral medication preparation and administration

Intro to sterile technique guidelines for practice
You will also acquire technical skills needed to safely, accurately, and legally fill prescriptions.

Skills or knowledge you should obtain in your lab work include:

Ability to fill prescriptions using commercial drug products in a simulated practice setting.
Ability to detect and properly handle prescription errors.
Demonstrate knowledge about the products you dispense.
Demonstrate knowledge and skills required to properly utilize the PDX computerized production system.
Demonstrate knowledge of parenteral dosage forms and the references required to safely produce such compounds.
Demonstrate aseptic skills used in preparing sterile medications for parenteral administration.
Demonstrate counseling on prescription drugs.
With the use of reference books, computer programs, and personal digital assistants (PDAs), you will be able to locate, gather, and convey drug information.

TEXTS:

- A. Pharmacy Law text- *Guide to Federal Pharmacy Law- 4th Edition. Barry S. Reiss and Gary D. Hall.*
- B. Pharmacy Law Digest- in lab and Learning Support Services (LSS)
- C. Montana State law booklet- provided in class
- D. *Clinical Pharmacology* - Internet application provided to you early in 2005. **You must be signed up for this at the start of this class.**

Other pamphlets may be provided from time to time.

READINGS: The course will not exactly follow the text or the statutes and rules from Montana law. I will try to give you assigned readings **prior to the lecture on the subject**. If so, I expect you to read them. In addition, you should check your mailbox and Blackboard **DAILY**. Many items will be distributed prior to lecture. You will be expected to have read the material assigned or distributed **PRIOR** to attending class. Quizzes at the start of class or lab to test your reading knowledge will be given.

By the end of the semester you will have the material to develop a HOW-TO manual covering the various aspects of legal pharmacy practice. You will be able to add to the manual in future classes so when you are ready to take the Pharmacy Law exam for licensing you will have a complete study guide.

LECTURE SCHEDULE: *The intent is to finish before term's end. However, this is an approximate schedule, as it may take longer than anticipated to cover a particular topic. A more detailed schedule will be handed out later.*

Topic

orientation to ambulatory and sterile compounded prescriptions and aseptic technique
introduction to federal and state law and the major acts that relate to practice.
negligence, liability, errors, confidentiality
drug types, names, quality, recalls, labels and labeling
drug packaging, mailing, specific drug programs
controlled drugs
ADRs, DIs
internship
Montana State law, licensing, continuing education

I will be giving you a day-to-day schedule soon, as there are a few days that I need to be gone.

LABORATORY SCHEDULE:

Jan. —	24 and 26	No labs
Jan & Feb:	31 and 2	Orientation, reading the Rx, and PDX training (Read handout before class).
-Feb. _____	—7 and 9	Drug Reference (Facts and Comparison, Clinical _____ Pharmacology on-line, PDAs)
Feb. _____	14 and 16	Introduction to sterile compounding
Feb. _____	21 and 23	First prescription lab <u>VIDEO TAPING BEGINS</u>
Feb & Mar	28 and 2	Second prescription lab
Mar. _____	7 and 9	Third prescription lab
Mar. _____	14 and 16	Fourth prescription lab
Mar. _____	21 and 23	Fifth prescription lab
Mar. _____	29 and 31	<u>SPRING BREAK- NO LAB THIS WEEK</u>
Apr. _____	4 and 6	Sixth prescription lab
Apr. _____	11 and 13	Seventh prescription lab
Apr. _____	18 and 20	Eighth prescription lab
Apr. _____	25 and 27	Wrap up including counting contest, reading illegible Rx's, _____ Rx jeopardy

LABORATORY REQUIREMENTS AND OPERATION:

1. Attend all lab meetings. If unable to attend, please call before the lab session so arrangements can be made for a make-up lab.
2. Bring a blank **videotape** to the **first** lab. The tape should have your name on it.
3. Wear a clean white lab coat.
4. Dress appropriately. Shorts are only acceptable if they extend below your lab coat. NO hats of any kind.
5. No eating or drinking in the lab.
6. Clean your work area at the end of every session.
7. Turn you cell phone to silent; take only emergency phone calls in the hall.

DISPENSING PRACTICE:

In the initial dispensing lab, you will be paired with a partner. Partners will be changed later in the semester. The dispensing portion of the lab will consist of filling new prescriptions, **most of which** are from the 60 drugs you ~~will be~~ **are**-learning and sterile product preparations. You will, as in practice, fill drugs not on the list. It is incumbent upon you to learn enough about the drug to safely fill the prescription (proper dose, directions, use). Refill prescriptions will also be assigned. When you complete your prescriptions (new or refill), you will provide these to your partner who will check your prescriptions and record any errors they find. When you and your partner have completed review of each other's prescriptions, you will ask one of the instructors to check your work. The instructor will check your prescriptions and collect the check sheet you prepared. You are graded on your prescriptions and your ability to detect problems in your partner's prescriptions.

In addition, in 4 of the ~~89~~ dispensing labs, you will counsel your partner on a medication from one of four drug classes: antibiotic, antihypertensive, antidepressant, or analgesic. These counsels will be videotaped and you will "grade" your own counseling prior to submitting it to the instructors for review and grade adjustment. Counseling information for each class of drug will be provided to you.

GRADING:

Each new prescription (**including sterile compounds**) is worth 7 points and each refill worth 3 points. You **lose** points for prescription errors or missing errors on prescriptions you check.

The video counseling sessions are self-graded (20 pts. each). Your instructor will review your grade and make comments. **The instructor may either raise or lower your grade.**

TESTING:

There will be six graded lecture quizzes as listed on the test schedule. These are **cumulative** and may test material from **any class** prior to this class. Each quiz will be worth about 25 points. Roughly 75 % of each test will be on new material. The final exam could be worth up to 200 points and will cover the key aspects of the entire course including the lab.

You must achieve a passing score in the laboratory, and on the AVERAGE of the lecture QUIZZES AND FINAL. That is, your total score for each of these sections must not be less than 73% (see below). When combined, the lab is worth 33% of your total grade.

ASSIGNMENTS:

Quizzes - 6 at 25 points each = 135 points

Lab - Total of 407 points: (-20 pts for-~~For~~ each counseling video (80), 7 ptspoints for each new/iv prescription (126), filled, and 3 ptspoints for each refill (6), 10 pts PDA worksheet (10), 5pts for each drug question (20), 60 pts for monograph book (60), 6 quizzes (105)filled.

Final- 200 points (100 points law, 100 points lab)

Drug names assignment- 20 points

Class participation- 25 points

Senior Partner Assignment-25 points

GRADING SCALE:

91 and above is an A

From 82 to 90 is a B

From 73 to 81 is a C

In addition, extra credit assignments may be offered. Scores for these are used at the instructor's discretion to augment your grade. The +/- system may be used when assigning ~~Pharmacy~~ final grades. We would like you to continue work with your senior partner from ~~Pharmacy~~ 309. An appropriate assignment will be announced.

The course and/or lab coordinator may adjust the grading scale and points assigned for any activity.

All students must practice academic honesty. Academic misconduct is subject to an academic penalty by the course instructor and/or a disciplinary sanction by the University.

All students need to be familiar with the Student Conduct Code. The Code is available for review online at

<http://www.umt.edu/SA/VPSA/index.cfm/page/1321>.

CLASS ATTENDANCE: Expected, please call Lori at 243-4080 in advance if you are unable to attend lecture or Kristen at 243-4693 if you must miss lab. All labs **MUST** be made up prior to the end of the semester.