New Concepts, Topics, and Issues in Pharmacy Practice
PHM 383K (Unique # 58570)
Spring 2019
Syllabus

Instructors
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Class Meeting Time and Room
Mondays 4:00pm to 6:45pm
PHR 2.208

Course Purpose and Objectives
The purpose of this course is to increase student awareness and understanding of contemporary issues related to pharmacy practice, pharmacy education, the pharmaceutical industry and the health care system, in general. More specifically, the class will cover current issues related to:

- pharmacy practice in community, institutional, and other settings;
- existing payment systems;
- emerging practice and payment models;
- legislative, regulatory, and political issues affecting pharmacy practice;
- the pharmaceutical industry;
- the provision of health care services in the U.S. and globally;
- pharmacy education; and
- other relevant aspects of the health care system.
The course objectives are:

(1) **to help students become more familiar with and more proficient in discussing different perspectives on contemporary issues facing pharmacy and health care.**

For example, students will be able to discuss the pros and cons of novel therapies and the implications for patients, prescribers, pharmacists, and payers. The course gives students the opportunity to express their views verbally in a non-threatening environment. Students will gain experience in organizing their thoughts and engaging in the discussion even when others in the room may have voiced a different opinion or position.

(2) **to help students become more aware of and informed about information sources they may not have used before.**

Course readings will come from lay and professional sources including journals, newspapers, reports, newsletters, web sites (e.g., professional and trade associations, government agencies), and other sources. Guests/experts also may join the class to present their perspectives and expertise on a topic area.

(3) **to help students become more proficient in gathering and organizing information regarding assigned current topics, presenting summaries of the information, and leading discussion of the topics.**

During the semester, students will identify a topic of interest, perform a literature search, and prepare a presentation to be given toward the end of the semester. The students will lead a discussion of the topic after giving their presentation. This gives students an opportunity to explore a topic of interest more deeply and to think about the best ways to present the information and to prepare questions that will stimulate discussion.

Overall, this course is intended to be an enjoyable learning experience—one where you want to be there to learn and you look forward to coming to class.

**Student Requirements / Activities**

**Attendance**

- **Class attendance is required.** Because this course is discussion-based, students must attend in order to benefit from and contribute to the discussions. If you cannot attend class (due to illness, death in family, religious holy day, etc.) you must notify the instructor as soon as possible, preferably before the class session meets. Failure to inform the instructor of your absence in a timely manner may result in a penalty of 10 points per absence.
Readings for Class Discussions

- For most class meetings, readings will be assigned by the instructors.
- For two class meetings, students will present a summary of an article of their choosing and lead the discussion on that article.
- No readings will be assigned for the week(s) of student presentations.

Readiness Assessment Quizzes

- A short readiness assessment quiz (RAQ, typically 4-5 questions) will be given at the beginning of each class meeting except on the days when students present the articles they have selected, and on student presentation day(s) at the end of the semester. The quiz will cover the readings assigned by the instructors for discussion during that class meeting. No RAQs will be given on days when articles chosen by students are discussed.
- The purpose of the RAQ is to encourage students to complete the readings so that they can participate fully in the discussions, and to serve as a mechanism to reward students for their efforts outside of the classroom.
- Students who miss the readiness assessment quiz must make up the missed quiz within a week of the missed class, unless other arrangements are made with the instructor (due to extenuating circumstances). Failure to make up the missed quiz will result in a score of 0 for the quiz.

Class Discussions / Participation

- At or soon after each class meeting (except on student presentation day(s) at the end of the semester), readings will be assigned for the following class meeting.
- Because the course is primarily discussion based, students must be prepared and must participate in class discussions. Students are encouraged to find and read material in addition to the assigned material to become more familiar with the issues.
- Students are also encouraged to develop and bring their own questions to ask during the discussions.
- The instructors may call upon students to express their opinions.
- Each class session may cover a variety of issues or focus on just one or two topics.

Student End-of-Semester Presentations

- At the end of the semester, students will give a formal classroom presentation and lead the discussion on a contemporary pharmacy topic area.
- Each student will develop and give a presentation lasting about 25 minutes, then lead discussion on the topic for about 5 minutes (for a total of 30 minutes). Please do not exceed 30 minutes.
• The instructors will provide a list of potential presentation topics and work with students to identify other appropriate topics not on the list at the students’ request. **Topics must be selected and approved by Dr. Lawson or Dr. Moczygemba by April 1, 2019. Topics cannot be duplicated.**

• For each presentation, the presenter must prepare a comprehensive handout for the students and instructors (this can be your slide deck or a Word document) and develop questions as an aid in leading the discussion.

• Students will be randomly assigned a date for their presentation. These dates can be changed if you make arrangements with another student in the class and inform Dr. Lawson of the change in advance.

• Grading of the presentation will be based on the following areas:

| Points | Content of presentation and references | 35 |
| | Organization of presentation | 5 |
| | Delivery | 10 |
| | Leading discussion | 15 |
| | Handout materials for the presentation | 5 |
| | TOTAL | 70 |

**Student Evaluation and Grading**

Quizzes will be given at the start of the class period. The quiz will cover the day’s required reading assignments. Ten points will be allocated for each quiz.

**Course Point Allocation**

| Points | Participation in class discussions | 50 |
| | Quizzes (assuming 9 quizzes @ 10 points each)* | 90 |
| | Student-selected articles (2 @ 15 points each) | 30 |
| | End-of-semester presentation | 70 |
| | TOTAL** | 240 |

* 9 quizzes are planned, but this number may change. The total points may vary depending on the number of quizzes given.

** There is no final exam in the course.
Grading Scale:

<table>
<thead>
<tr>
<th>Letter Grade</th>
<th>Course Average (Percent)</th>
<th>Grade Points</th>
<th>Letter Grade</th>
<th>Course Average (Percent)</th>
<th>Grade Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>93% – 100%</td>
<td>4.0</td>
<td>C+</td>
<td>77% – 79%</td>
<td>2.33</td>
</tr>
<tr>
<td>A-</td>
<td>90% – 92%</td>
<td>3.67</td>
<td>C</td>
<td>73% – 76%</td>
<td>2.0</td>
</tr>
<tr>
<td>B+</td>
<td>87% – 89%</td>
<td>3.33</td>
<td>C-</td>
<td>70% – 72%</td>
<td>1.67</td>
</tr>
<tr>
<td>B</td>
<td>83% – 86%</td>
<td>3.0</td>
<td>D+</td>
<td>68% – 69%</td>
<td>1.33</td>
</tr>
<tr>
<td>B-</td>
<td>80% – 82%</td>
<td>2.67</td>
<td>D</td>
<td>66% – 67%</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>D-</td>
<td>65%</td>
<td>0.67</td>
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<td></td>
<td></td>
<td></td>
<td>F</td>
<td>&lt; 65%</td>
<td>0.0</td>
</tr>
</tbody>
</table>

(Note for letter grade reporting: x.45% to x.99% will be rounded to the higher whole number. x.01% to x.44% will be rounded to the lower whole number.)

Examples of Possible Class Presentation / Discussion Topics

Note: Some of the topics could be classified into more than one category.

Pharmacy Practice
- Expansion of pharmacists’ services
- Provider status
- Opportunities for pharmacists and use of social media for patient care
- Misuse/abuse of prescription drugs
- Medication errors by pharmacists
- Patient safety
- Changing patient demographics
- Compounding vs. manufacturing
- Pharmacists’ roles in disasters
- Pharmacists’ roles in bioterrorism
- Opioid crisis / provision of naloxone
- Technicians’ roles
- New therapeutic guidelines (e.g., hypertension, lipid disorders)
- Collaborative practice agreements

Specialty Pharmaceuticals / Bio-Similars
- Growth in utilization of and expenditures for specialty pharmaceuticals
- Distribution channels for specialty pharmaceuticals
- Issues with bio-similar pharmaceuticals
- Approval of bio-similar drugs
Payment Systems / PBM s
- Issues regarding the transparency of pharmacy benefit management firms (PBMs)
- Pharmacy reimbursement issues (e.g., the switch to actual acquisition cost for product cost instead of using estimated acquisition cost)
- Direct and Indirect Remuneration (DIR) Fees
- Open, preferred drug list and closed formularies and drug switching by PBMs and the role of rebates
- Ethical issues in managed care
- Value-based payment models / Payment based on accountability
- High / increasing cost of drugs

Medicare
- Governmental price negotiations for Part D prescriptions
- Medicare Part D issues (MTM, Patient Costs, etc.)

Medicaid
- Expansion of Medicaid

Pharmaceutical Industry / FDA
- Reasons for the increase in generic drug prices
- Drug price discrepancies between countries, impact of lower drug prices in some countries on U.S. drug prices—who pays for the research?
- Drug shortages—causes and possible corrections, FDA involvement
- Authorized generics—what are they and the pros and cons
- Role of FDA and drug safety
- Use of RFID and bar codes for product authentication—patient/consumer privacy issues
- Prescription drug direct-to-consumer advertising—pros and cons
- Payment to physicians by drug industry—reporting the payments made to health care providers by industry
- Impact of generic drug user fees
- Off-label promotion for pharmaceuticals
- Marketing and promotional techniques used by pharmaceutical manufacturers—Freedom of Speech Decision
- Pharmaceutical pricing arrangements used by the drug industry
- Pharmaceutical industry’s payment to generic companies for NOT manufacturing generic drugs
- Required serialization of drug products under the Drug Quality and Security act of 2013
- Drug research and development / drug pipeline
- Ethical issues in the pharmaceutical industry
- 21st Century Cures Act
Healthcare Reform / Emerging Healthcare Delivery Models / ACOs / PCMHs
- Future of the Affordable Care Act / Healthcare reform efforts
- Pharmacies'/pharmacists' roles in ACOs, PCMHs, and other care models
- Health Care Reform: Impact on Pharmacy
- EHRs, EMRs, HIT

Regulatory / Legislative Issues
- Pharmacist refusal to dispense emergency contraceptives and legislative efforts to prohibit pharmacists refusal decisions
- Drug safety and the role of FDA and State Boards of Pharmacy — who regulates pharmaceutical compounders?
- Switching of prescription drugs to OTC status, i.e. birth control pills to OTC status
- Extent of drug price regulations outside of the U.S. and the impact on the U.S. market
- Provider status

Clinical Trials / Research
- Enrolling indigent people who reside in developing countries in clinical trials
- Stem cell research controversies
- Access to investigational new drugs for people who are in desperate need
- Drug researchers, physicians and industry executives leaking confidential research information to the press and investors
- Advantages and disadvantages of releasing clinical trial data to the public
- “Ghost” authorship for medical publications
- Ethical issues in research / conflicts of interest / data fabrication

Pharmacy Education and Workforce Issues
- Changing accreditation standards
- Increasing number of pharmacy schools
- Future demand for pharmacists
- Future training for pharmacists
- Required residencies for pharmacists providing direct patient care
- Pharmacy curricula

Others
- End-of-life care
- Immunizations
- Pharmacogenomics / gene therapy
**Course Policies and Procedures**

**Recordings and Computer Use**

1. Students are **NOT allowed** to video record or audio record discussions and presentations while in the class.

2. Students are **NOT allowed** to use personal computers or electronic devices during the class, during discussion sessions or student presentations unless authorized or directed by the instructor. Students giving presentations are allowed to use computers.

**Attendance**

3. Because the course is structured around discussion, attendance is required.

**Scholastic Integrity**

4. The “Statement of Scholastic Integrity of the College of Pharmacy” reads as follows: “Pharmacy practitioners enjoy a special trust and authority based upon the profession’s commitment to a code of ethical behavior in its management of client affairs. The inculcation of a sense of responsible professional behavior is a critical component of professional education, and high standards of ethical conduct are expected of pharmacy students. Students who violate University rules on scholastic dishonesty are subject to disciplinary penalties including failure of the course involved and dismissal from the college and/or the University. Since dishonesty harms the individual, fellow students, and the integrity of the University and the College of Pharmacy, policies on scholastic dishonesty are strictly enforced."

Each student in the course is expected to abide by the University of Texas Honor Code: “As a student of The University of Texas at Austin, I shall abide by the core values of the University and uphold academic integrity.”

Students are expected to work independently on all examinations and written assignments unless otherwise specified by the instructors. Any student caught cheating will be given a zero on the exam/assignment and other penalties may be assessed. Any student suspected of dishonesty will be reported to the Dean of the College of Pharmacy and to the UT Dean of Students, as per University regulations. Students are expected to have read and to understand what constitutes scholastic dishonesty and the relevant procedures as published in the current issue of the General Information Catalog. Please refer to the Student Conduct and Academic Integrity website ([http://deanofstudents.utexas.edu/conduct/](http://deanofstudents.utexas.edu/conduct/)) for the official University policies and procedures on academic integrity.
Emergency Procedures (http://www.utexas.edu/emergency)

5. Occupants of buildings on The University of Texas at Austin campus are required to evacuate buildings when a fire alarm is activated or an official announcement is given.

6. Evacuation procedures require orderly exiting and assembly outside.

7. Familiarize yourself with all exit doors of each classroom and building you may occupy. Remember that the nearest exit door may not be the one you used when entering the building.

8. Students requiring assistance in evacuation shall inform their instructor in writing during the first week of class.

9. During an evacuation — follow the instructions of faculty or class instructors.

10. Do not re-enter a building unless given instructions by the following: Austin Fire Department, The University of Texas at Austin Police Department, or the Fire Prevention Services.

11. CAMPUS CARRY
    Students should familiarize themselves with the information provided by the University regarding the implementation of “Campus Carry” legislation. You will find an information sheet specifically for students (as well as sheets for parents, visitors, faculty, and staff) at http://campuscarry.utexas.edu/info-sheets."

12. LOCKDOWN:
    The directive “Lockdown” is used to protect occupants in proximity of an immediate threat by limiting access to buildings and rooms. If no specific locations are given, all buildings should initiate lockdown procedures. Should you discover that there is a violent or potentially violent person in your building or area, DO NOT CONFRONT THE PERSON UNLESS THERE IS NO OTHER OPTION TO SAVE YOUR LIFE.

13. SHELTER-IN-PLACE
    For weather:
    1. Go to the lowest level of the building if possible.
    2. Stay away from the windows.
    3. Go to interior hallways and rooms.
    4. Use arms to protect head and neck in a “drop and tuck” position.
    5. Monitor emergency communications for specific instructions (www.utexas.edu/emergency).
**For environmental incidents (chemical, biological, or radiological releases):**

1. Go inside the nearest building.
2. Close all doors, windows, and other inlets from the outside.
3. Shut down the fresh air intake or HVAC system if possible.

**Academic Accommodations**

14. “The University of Texas at Austin provides upon request appropriate academic accommodations for qualified students with disabilities.” All University rules concerning accommodations must be followed, including the student arranging for special accommodations prior to each examination. In the absence of such prearrangement, the instructors will assume that the student is not requesting special accommodations for that exam, and the student will be expected to take the exam with the rest of the class at the regularly schedule time and location.” For more information, contact the Division of Diversity and Community Engagement, Services for Students with Disabilities, 512-471-6259 (voice) or 1-866-329-3986 (video phone) (http://diversity.utexas.edu/disability/).

**Canvas and E-Mail:**

15. The official Canvas web site for this course can be accessed through UTDirect or via http://courses.utexas.edu. On this site, you can access the course syllabus, selected readings, grades, and other course resources. E-mail is recognized as an official mode of university correspondence; therefore, you are responsible for reading your e-mail for university and course-related information and announcements.

**Religious Holy Days**

16. According to UT Austin policy, you must notify the course coordinator of your pending absence at least fourteen days prior to the date of observance of a religious holy day. If you must miss a class, an examination, a work assignment, or a project in order to observe a religious holy day, you will be given an opportunity to complete the missed work within a reasonable time after the absence.
Behavior Concerns Advice Line (BCAL)

17. If you are worried about someone who is acting differently, you may use the Behavior Concerns Advice Line to discuss by phone your concerns about another individual’s behavior. This service is provided through a partnership among the Office of the Dean of Students, the Counseling and Mental Health Center (CMHC), the Employee Assistance Program (EAP), and The University of Texas Police Department (UTPD). Call 512-232-5050 or visit http://www.utexas.edu/safety/bcal.

Counseling and Mental Health Center

18. The Counseling and Mental Health Center (CMHC) provides counseling, psychiatric, consultation, and prevention services that facilitate students’ academic and life goals and enhance their personal growth and well-being. https://cmhc.utexas.edu/

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## Class Schedule (Spring 2019)

<table>
<thead>
<tr>
<th>#</th>
<th>Date</th>
<th>Topic</th>
<th>Instructors/Notes</th>
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<tbody>
<tr>
<td>1</td>
<td>1/28</td>
<td>Course Introduction</td>
<td>KL, TM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exploring Topics of Interest</td>
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<tr>
<td>2</td>
<td>2/4</td>
<td>RAQ1 / Discussion of Readings</td>
<td>KL</td>
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<tr>
<td>3</td>
<td>2/11</td>
<td>RAQ2 / Discussion of Readings</td>
<td>KL</td>
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<tr>
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<td>Ask students to provide 1 reading each by 2/18 for discussion on 2/25</td>
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<tr>
<td>4</td>
<td>2/18</td>
<td>RAQ3 / Discussion of Readings</td>
<td>TM</td>
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<tr>
<td>5</td>
<td>2/25</td>
<td>Discussion of Student-Selected Readings</td>
<td>KL, TM</td>
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<tr>
<td>6</td>
<td>3/4</td>
<td>RAQ4 / Discussion of Readings</td>
<td>KL</td>
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<td>7</td>
<td>3/11</td>
<td>RAQ5 / Discussion of Readings</td>
<td>TM</td>
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<td>3/18</td>
<td>Spring Break</td>
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<td>8</td>
<td>3/25</td>
<td>RAQ6 / Discussion of Readings</td>
<td>KL</td>
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<td>Ask students to provide 1 reading each by 4/1 for discussion on 4/8</td>
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<tr>
<td>9</td>
<td>4/1</td>
<td>RAQ7 / Discussion of Readings</td>
<td>TM</td>
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<tr>
<td></td>
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<td>Presentation topics must be finalized</td>
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<tr>
<td>10</td>
<td>4/8</td>
<td>Discussion of Student-Selected Readings</td>
<td>KL, TM</td>
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<tr>
<td>11</td>
<td>4/15</td>
<td>RAQ8 / Discussion of Readings</td>
<td>TM</td>
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<tr>
<td>12</td>
<td>4/22</td>
<td>RAQ9 / Discussion of Readings</td>
<td>KL</td>
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<tr>
<td>13</td>
<td>4/29</td>
<td>Student Presentations</td>
<td>KL, TM</td>
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<td>Students 1-5</td>
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<tr>
<td>14</td>
<td>5/6</td>
<td>Student Presentations</td>
<td>KL, TM</td>
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<td>Course / Instructor Survey in class Open discussion, careers, etc.</td>
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<tr>
<td></td>
<td></td>
<td>Students 6-8</td>
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