Course Coordinator: Diane B. Ginsburg, Ph.D., M.S., R.Ph., FASHP
Pronouns: She/Her/Hers
Email: diane.ginsburg@austin.utexas.edu
Phone: (512) 471-3631
Office: PHR 5.110D
Office Hours: by appointment

Course Unique Number(s): 80719

Classroom(s): Online Asynchronous

Class Days/Times: Online Asynchronous

Teaching Assistants: None

Academic Assistants/Advanced Academic Assistants: None

Course Information

Course Description:
“Pharmaceutical Diversion” is when a controlled substance is removed from the closed system of distribution. One of the methods of diversion is illegal dispensing of prescriptions. Pharmacists play an integral role in combating the opioid crisis through fulfilling their corresponding responsibility when evaluating and dispensing prescription drug orders. In addition to pharmacy practice, pharmacists work collaboratively with the Drug Enforcement Association (DEA) and Department of Justice (DOJ) to evaluate alleged violations of federal and state-controlled substances acts, analysis of data and evidence during investigations, and during enforcement through expert opinion and testimony.

This course will introduce students to types of violations of federal and state-controlled substances laws and rules, identification of “red flags” and the pharmacist’s responsibility, methods and analysis of drug diversion cases, and the pharmacist’s role in enforcement. Students will be involved in analyzing data and evidence, providing an expert opinion based on the analysis, and testimony in a simulated hearing. The final product will be the development of an expert report based on the analysis of a specific pharmacy “pill mill” case.

Course Prerequisites/Co-Requisites:
Enrolled in the College of Pharmacy or admission to the Pharm.D. program or by approval of the course coordinator.
**Course Learning Objectives (CAPE Objectives):**
1. Identify and describe violations of the Texas and Federal Controlled Substances Acts. (1.1)
2. Categorize the violations and what type of enforcement actions may be taken by the Drug Enforcement Administration (DEA), Department of Justice (DOJ), and the Texas State Board of Pharmacy (TSBP) including administrative, civil and criminal actions. (1.1)
3. Analyze pharmacy data to determine areas of potential violations of the Texas and Federal Controlled Substances Acts. (1.1)
4. Develop and present an expert report based on the analysis of a specific pharmacy “pill mill” case. (1.1)

**Course Success:**
Course participants will participate in online asynchronous presentations, homework assignments, and case study analysis. Assigned readings will be from pharmacy law textbooks, articles, and export reports.

Teams of two students/team will work together to review and analyze case data, prepare an export report, and provide testimony in a simulated hearing. Student teams will sign up for individual sessions with the course coordinator for presentation of their expert report and provide testimony including state examination and respondent/defense counsel cross examination. Course participants will participate in a simulated hearing. A U.S. Attorney with the DEA will preside over the case.

The course will require preparation and submission of a written expert report. Students may contact the University Writing Center [https://uwc.utexas.edu](https://uwc.utexas.edu) to schedule a free appointment for writing consultation. Students will be required to present their report during a simulated hearing. The Sanger Learning Center provides consultation on public speaking skills. Students may schedule a free appointment with a trained speech student consultant to assist with preparation of materials, presentation rehearsal, and receive helpful feedback. For more information, you can contact the Sanger Learning Center at [https://ugs.utexas.edu/slc/support](https://ugs.utexas.edu/slc/support).

Each weekly presentation will have a a component of a case to be analyzed and submitted. Questions will be included with the case the students must address based on their analysis. Participants will receive a participation grade (0% or 100%) for answering all questions associated with the weekly case and a numeric grade (0% to 100%) for correct answers to the case questions. The presentation, case analysis and questions will be handled according to the following weekly schedule:

<table>
<thead>
<tr>
<th>Mondays by 5:00 p.m.</th>
<th>Fridays by 11:59 p.m.</th>
<th>Sundays by 11:59 p.m.</th>
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</thead>
<tbody>
<tr>
<td>Presentation posted</td>
<td>Case Study Analysis &amp; Questions Due</td>
<td>Answers to Case Study Posted</td>
</tr>
<tr>
<td>Case Study Posted</td>
<td></td>
<td></td>
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</tbody>
</table>

**Course Website:**
This course uses Canvas, a Web-based course management system in which a password-protected site is created for each course. Canvas will be used to distribute course materials, to communicate, and to post grades. Canvas is available at [http://canvas.utexas.edu](http://canvas.utexas.edu). Support is provided by the ITS Help Desk at 475-9400 Monday through Friday 8 am to 6 pm.
Optional Course Activities
Course registrants are encouraged to participate in weekly office hours. During these meetings, students may ask questions about the weekly presentations or case analysis. The coordinator may discuss case studies to demonstrate application of concepts covered in the weekly presentation. Discussion of assigned cases, final report preparation, and hearing testimony will also be reviewed. These meetings will also be used to obtain timely feedback about the course content and format. It is very important to the course coordinator that this course is informative and helpful to participants.

Course Communications:
Official course communications will take place in class, through e-mail and on the course Canvas website. Students are advised to configure their Canvas settings to forward course announcements to their official e-mail address. Canvas uses only the e-mail address listed on the official University of Texas directory, so please check the University’s online directory to ensure your e-mail address is listed correctly.

Course Video Recordings:
A video capture system will be used in this course. The video streams are offered as a supplement to lecture attendance, not as a substitute. Therefore, if technical problems preclude recording the lecture, the lecture will not be re-recorded, but students are still responsible for the content of the lecture. Lecture recordings will be available to you for the balance of the semester unless otherwise specified. Do not expect to have access after the semester is over.

Faculty and students utilizing class video recordings should be careful to not compromise the privacy of either themselves or other users (http://registrar.utexas.edu/students/records/ferpa), or the rights of the presenter. Students are free to make their own recordings of lectures unless specifically prohibited from doing so by the presenter. Any additional distribution of College- or student-generated recordings (regardless of format) is prohibited without the written and signed permission of the presenter and students identifiable on the recording. Likewise, all course materials developed by the faculty member (handouts, PowerPoints, etc.) are the intellectual property of that faculty member and cannot be distributed further without the permission of that faculty member.

Viewing video-streamed recordings of lectures can be streamed on campus or can be viewed off-campus using a DSL broadband connection. Your faculty are not in a position to troubleshoot your video-streaming problems, so please do not ask them to do so; rather, you should access the LRC ’s help website at https://www.utexas.edu/pharmacy/help/ to address those problems. You will find additional information about the lecture capture system or can report technical issues at http://sites.utexas.edu/phr-lrc/
Course Policies

Course Grading Policies:
The semester grade will consist of points accumulated through weekly case study analysis submissions, final report submission, and simulated hearing. Weekly case study analysis are to be completed independently. The final case report and simulated testimony will be done as a team. Weighting for each category is based on the number of items in that category.

<table>
<thead>
<tr>
<th>Weekly Case Study Analysis</th>
<th>40 Points (5 points each)</th>
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</thead>
<tbody>
<tr>
<td>Final Case Report (Team Project)</td>
<td>35 Points</td>
</tr>
<tr>
<td>Simulated Testimony (Team Project)</td>
<td>25 Points</td>
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For all of these, the participant’s grade will be reduced by 25% each day that any of the above assignments are late (including the weekly case study analysis). After it is late for four days, the participant will not receive points for the assignment.

Course Grade:
Letter grades will be assigned according to the following scale:

<table>
<thead>
<tr>
<th>Score</th>
<th>Letter Grade</th>
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<tbody>
<tr>
<td>89.50-100</td>
<td>A</td>
</tr>
<tr>
<td>79.50-89.49</td>
<td>B</td>
</tr>
<tr>
<td>69.50-79.49</td>
<td>C</td>
</tr>
<tr>
<td>64.50-69.49</td>
<td>D</td>
</tr>
<tr>
<td>&lt;64.50</td>
<td>F</td>
</tr>
</tbody>
</table>

Final averages at .5 or above will be rounded to the next highest grade, e.g., 89.5 = 90% = A for the course. Final averages at .4 or below will not be rounded, e.g., 89.4 = 89.4% = B for the course.

Attendance:
Class Attendance:
Participants must complete weekly case study analysis by the due date. The case study analysis will be due by Friday at 11:59 p.m. In addition, participants are encouraged to participate in the weekly office hours.

Excused Absences:
The only absences that will be considered excused are for religious holy days or extenuating circumstances due to an emergency. If you plan to miss class due to observance of a religious holiday, please let the course coordinator know at least two weeks in advance, preferably at the beginning of the semester. You will not be penalized for this absence, although you will still be responsible for any work you will miss on that day if applicable. Check with the course coordinator for details or arrangements.

Attendance at Professional Meetings:
It is the student’s responsibility to ASK permission IN ADVANCE if they plan to attend a professional meeting that would necessitate missing an exam, assignment, or other required course activity. It is at the discretion of
the course coordinator as to whether to grant permission and allow the student to make up any missed work.

**Required Materials:**
There is not a required textbook for this course. Students will be assigned readings, articles, and reports which will be posted in Canvas.

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**Course Assignment Policies**

**Course Assignments:**
Students will be assigned readings each week to provide background for information covered during weekly presentations. The readings will provide necessary information for the students to complete the weekly case study analysis. Students are expected to complete the weekly case study analysis independently. Students will work in teams of two to complete an analysis of case with extensive violations of the Texas and Federal Controlled Substances Acts. Student teams will prepare a final expert report based on their analysis of the case. The student teams will participate in a simulated hearing and provide testimony as an expert witness in the case.

**Academic Integrity:**
Students who violate University rules on academic dishonesty are subject to disciplinary penalties, including the possibility of failure in the course and/or dismissal from the University. See College Policies and Information, and University Policies and Information for more details.

**Religious Holy Days**
If you will miss a class, an examination, a work assignment or a project in order to observe a religious holy day, you must notify the course coordinator the first week of class so that arrangements for all such students can be made for the full semester.

**Services for Students with Disabilities:**
Students with disabilities may request appropriate academic accommodations from the Division of Diversity and Community Engagement, Services for Students with Disabilities at 471-6259 (voice) or 232-2937 (video phone) or https://diversity.utexas.edu/disability/. 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, it will be assumed that the student is not requesting special accommodations for that exam, and will be expected to take the exam with the rest of the class at the regularly scheduled exam time.

Please provide a copy of the letter to the course coordinator and the office of the Associate Dean for Academic Affairs as soon as possible after receipt.
### Course Schedule

<table>
<thead>
<tr>
<th>Week/Date</th>
<th>Presentation Topics</th>
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<tbody>
<tr>
<td><strong>Week #1</strong>&lt;br&gt;6/8/20</td>
<td>Orientation and Course Overview&lt;br&gt;Opioid Crisis – Statistics&lt;br&gt;Role of Pharmacists in Enforcement</td>
</tr>
<tr>
<td><strong>Week #2</strong>&lt;br&gt;6/15/20</td>
<td>Federal and Texas Controlled Substances Laws and Rules&lt;br&gt;Diversion – Federal Definition and Components&lt;br&gt;Drugs Involved in Diversion Cases&lt;br&gt;DEA’s Role in Diversion Investigation &amp; Enforcement (Dunn)</td>
</tr>
<tr>
<td><strong>Week #3</strong>&lt;br&gt;6/22/20</td>
<td>Corresponding Responsibility&lt;br&gt;“The Pharmacist” documentary</td>
</tr>
<tr>
<td><strong>Week #4</strong>&lt;br&gt;6/29/20</td>
<td>Red Flags&lt;br&gt;NABP Video</td>
</tr>
<tr>
<td><strong>Week #5</strong>&lt;br&gt;7/6/20</td>
<td>Prescription Drug Monitoring Program (PDMP)&lt;br&gt;Automation of Reports and Consolidated Order Systems (ARCOS)&lt;br&gt;Pharmacist Analysis – Expert Report Components&lt;br&gt;Team Case Assigned</td>
</tr>
<tr>
<td><strong>Week #6</strong>&lt;br&gt;7/13/20</td>
<td>Investigation Process&lt;br&gt;Surveillance&lt;br&gt;Media Reports</td>
</tr>
<tr>
<td><strong>Week #7</strong>&lt;br&gt;7/20/20</td>
<td>Three-Legged Stool – Players involved in Drug Diversion Cases&lt;br&gt;Data Sources – Banking Records</td>
</tr>
<tr>
<td><strong>Week #8</strong>&lt;br&gt;7/27/20</td>
<td>Team Expert Reports Due&lt;br&gt;Hearing Simulations – Team Testimony&lt;br&gt;Final Case Simulation</td>
</tr>
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</table>

### Pre-Class Preparation

<table>
<thead>
<tr>
<th>Week/Date</th>
<th>Pre-Class Preparation – Complete prior to each week’s class</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Week #1</strong>&lt;br&gt;6/8/20</td>
<td>Orientation and Course Overview&lt;br&gt;Opioid Crisis – Statistics&lt;br&gt;Role of Pharmacists in Enforcement</td>
</tr>
<tr>
<td><strong>Week #2</strong>&lt;br&gt;6/15/20</td>
<td>Review Federal &amp; Texas Controlled Substances Act document&lt;br&gt;Review Diversion – Federal Definition and Components PowerPoint presentation&lt;br&gt;Review Drugs Involved in Diversion Cases document&lt;br&gt;Review “TSBP Fraudulent Official Prescription Form” document</td>
</tr>
<tr>
<td><strong>Week #3</strong>&lt;br&gt;6/22/20</td>
<td>“The Pharmacist” documentary&lt;br&gt;Watch the 4 part video series on Netflix&lt;br&gt;“Professional Responsibility of Pharmacists” – review Rule 291.29&lt;br&gt;Review TSBP Information on Abuse and Misuse of Prescription Drugs - <a href="https://www.pharmacy.texas.gov/SB144.asp">https://www.pharmacy.texas.gov/SB144.asp</a>&lt;br&gt;Review “Corresponding Responsibility” document</td>
</tr>
</tbody>
</table>
| Week #5  | 7/6/20 | Review Prescription Drug Monitoring Program (PDMP) document  
|         |        | Review Automation of Reports and Consolidated Order Systems (ARCOS) document  
|         |        | Review Pharmacist Analysis – Expert Report Components draft report  
|         |        | **Team Case Assigned**  
| Week #6  | 7/13/20 | Review Investigation Process Analysis description  
|         |        | Surveillance – Review information provided regarding how surveillance is conducted  
|         |        | Review Media Reports regarding pill mill cases  
| Week #7  | 7/20/20 | Three-Legged Stool – Players involved in Drug Diversion Cases – Review wholesaler information provided including online reports  
|         |        | Review Data Sources – Banking Records document  
| Week #8  | 7/27/20 | **Team Expert Reports Due**  
|         |        | Hearing Simulations – Team Testimony – Schedule will be provided  
|         |        | Final Case Simulation  
|         |        | Part IV (4:47 minutes)- [https://youtu.be/c5H70QuSt-E](https://youtu.be/c5H70QuSt-E)  
|         |        | Red Flags – Review TSBP “You might be a pill mill if...“ checklist |