Course Purpose:
This course is designed to provide an understanding of state licensure and standards setting for healthcare professions and practice sites. In particular, students study how, what and under what circumstances administrative boards determine and enforce items such as: Initial and continuing competence of practitioners; professional misconduct; role of professional self-regulation. The course also explores federal initiatives to regulate healthcare professionals and practice sites and the role of non-governmental organizations and influences on practice regulation.

Course Faculty and Office Hours

Course Instructors and Coordinators:
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University Coordinator:
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Clinical Associate Professor
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Main Phone: 352-273-6264 | FAX: 352-273-6270 Direct Phone:
352-273-5657 | Email: tsmith@cop.ufl.edu College Website: http://www.cop.ufl.edu

Office Hours
Students may contact either Ken Baker or Cody Wiberg at anytime through email or mobile phone (1st number above). Students may request a telephone appointment, which will be arranged at a mutually convenient time. Communication is encouraged.

- Place and Time of Class Sessions
  - Class time: Sunday & Wednesday 8 pm to 9:30 pm EST
Any special notes (e.g., exceptions to the normal class schedule)
- Sunday, September 2, although not a holiday, is the Labor Day Weekend. In the past we have found this causes problems in attendance and attention. This class will be required, but pre-recorded and can be viewed any time up to the next class. It will not be live on September 2. There may be a special assignment given based upon the recorded lecture, which would be due prior to the following class.
- Should a class be unavailable for any reason at the regular time, the class shall be recorded and all students will be required to attend the recorded lecture. There may be a special assignment given based upon the recorded lecture, which would be due prior to the following class.

All class are via Internet through University system.

Course Objectives

Upon completion of this course, the student will:

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

1. Describe the traditional market failures that justify government regulation of pharmaceutical products and services.
2. Describe the four “tiers” of drug risk evaluation and regulation.
3. Distinguish between state paternalism and personal paternalism, and describe each concept.
4. List the significant events that have occurred in the history of professional regulation during the 20th Century, and explain how each event is an example of either “direct regulation” or “indirect regulation.”
5. Explain the implications of the dispensing “exemption” from otherwise relevant misbranding provisions of the Food Drug and Cosmetic Act.
6. Discuss the distinction between “manufacturing” and “compounding” under relevant pharmacy laws.
7. Describe the significance of official drug labeling under state law.
8. Explain the challenge faced by regulators who must restrict availability of unreasonably harmful drugs, but not restrict availability of beneficial drugs.
9. Discuss the implications for pharmacy practice of the prospective and retrospective drug use review provisions mandated under the OBRA-90 legislation.
10. Explain, and distinguish, “thing responsibility” and “agent responsibility.”
11. Explain, and distinguish, the following four types of error: technical, judgmental, normative and quasi-normative.
12. Explain how pharmaceutical outcomes regulation differs from the traditional pharmaceutical regulation that focuses on structure and process.
13. Discuss the basic rationale that justifies professional licensure of pharmacists.
14. Explain the legal basis of pharmaceutical care, with its foundation in the power model of pharmacist responsibility.
15. Describe how exposure to civil liability operates as a regulatory mechanism in parallel with state administrative regulation.
16. Discuss opportunities and responsibilities in the use of the Internet for drug distribution and health care.
17. Describe the process for discipline of a state licensed health care professional and health care institution.
18. List regulatory approaches that can effectively assure the integrity of the nation’s drug supply.

Course Structure & Outline

Course Structure.

a) Learning activities video lectures;
b) students are required to complete all assignments and complete all exams, which will use the “turn-it-in” platform through Sakai

c) Multiple self-directed learning activities are required (eg, videos, readings, web-based learning)
d) Students are expected to participate in live discussions during class and participate as directed in assignments in discussion board activities
e) All class sessions are live voice to voice and the students are expected to have completed all posted assignments and participate in discussion.

Course Outline/Activities. See outline of classes and assignments in Appendix A posted on Sakai. All assignments are subject to change as posted on Sakai to take advantage of most current topics by state boards and federal agencies as they may affect state regulations.

Textbooks

- Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (August 2011) available free for download in Word from www.nabp.net
- NABP Newsletters – available for download free from NABP: www.nabp.net
  - National Pharmacy Compliance News (all 2012 quarterly editions)
  - One state News letter – latest issue (for discussion board and class discussion)
- Additional resources will be assigned via University’s internet learning platform (Sakai)

Active Learning Requirements

Students are expected to attend each class and actively participate in live class discussion as well as discussion board questions and subjects each week. Ten percent of the grade is through class participation which includes discussion board as well as unannounced quizzes.

Student Evaluation & Grading

Evaluation Methods

Tests:
There will be a midterm essay exam and a final comprehensive multiple choice or true/false exam. Requirements for the essay will be provided along with the test. The students will be given not less than
one week to complete and turn in the midterm essay. Essays will be graded on content, style and grammar.

**Grading Scale**

**Evaluation Techniques:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class participation &amp; quizzes</td>
<td>10%</td>
</tr>
<tr>
<td>Midterm</td>
<td>40%</td>
</tr>
<tr>
<td>Final</td>
<td>50%</td>
</tr>
</tbody>
</table>

**Grading:**

A: 93-100
A-: 90-92.9
B+: 87-89.9
B: 80-86.9
C+: 77-79.9
C: 73-76.9
C-: 70-72.9
D: 65-69.9
E: < 65

**Class Attendance Policy**

It is understood that students in this class may hold full time jobs, which may provide themselves learning experiences valuable to the class and the student’s education. If a student is unable to attend a class he or she must listen to the recorded lecture and complete all assignments. Repeated lack of attendance may affect class participation grade.

**Quiz/Exam Policy**

There will be a midterm essay exam and a final comprehensive multiple choice or true/false exam. Requirements for the essay will be provided along with the test. The students will be given not less than one week to complete and turn in the midterm essay. Essays will be graded on content, style and grammar. Students are encouraged to make an appointment to discuss grading on any test.

**Make-up Quiz/Exam Policy**

Students are given several days to complete the final exam (Thursday to the following Sunday). The students will be given not less than one week to complete and turn in the midterm essay. Should any student be unable to take an exam or quiz or assignment within the required time, they are encouraged to discuss this with an instructor prior to or after due date.
Policy on Old Quizzes and Assignments
Students are not provided old quizzes/assignments.

Assignment Deadlines
Students are given several days to complete all assignments. Should any student be unable to take an assignment within the required time, they are encouraged to discuss this with an instructor prior to or after due date. Points may be subtracted for late assignments or tests.

General College of Pharmacy Course Policies
The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

Complaints
Should you have any complaints with your experience in this course please visit:
http://www.distancelearning.ufl.edu/student-complaints to submit a complaint.

Other Course Information
Additional information will be available through Sakai and announcements during the course. In an attempt to discuss timely and current problems involving state regulation assignments and topics are always subject to change. Students are expected to visit Sakai regularly to note any changes.
# PHA 6278 State Regulation of Drugs & Pharmacy
## Appendix A

### Classes are on **Sunday** [8 pm to 9:30 pm EST] & **Wednesday** [8 pm to 9:30 pm EST]. All times are given as Eastern Time, unless specifically stated otherwise. Should any class be scheduled on a University of Florida holiday, it will be recorded before the scheduled day and will be available at any time prior to the next scheduled class.

**Note:** Assignments are subject to being updated on Sakai, e-Mail and orally in class.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Subject</th>
<th>Dates</th>
<th>Reading Assignments</th>
<th>Video Assignments</th>
<th>Learning Responsibilities</th>
</tr>
</thead>
</table>
| Week I     | State Regulation of Practice v. Federal Regulation of Product            | 8/19 to 8/25  | - Baron, Licensure of Health Professionals  
-Weekly written assignment  
-Discussion board                                                                 |  
| Week II    | The Process of Professional Regulation                                   | 8/26 to 9/1   | - OIG Report, State Pharmacy Board’s Oversight  
- Wiederholt, The Wisconsin Self-Inspection Project  
-Weekly written assignment  
-Discussion board                                                                 |  
| Week III   | State Disciplinary Action                                                | 9/2 to 9/8    | - OIG Report, State Discipline of Pharmacists  
- Jost, Consumers, Complaints and Professional Discipline  
- Murtough, Unprofessional or Immoral Conduct                                                                                                                  | Video Lecture: Assuring Professional Competence                                    | -Elluminate classes 9/5 (no live class on 9/2 – but you must view a recorded class)  
-Weekly written assignment  
-Discussion board                                                                                                                                       |  
| Week IV    | Regulating Professionalism                                               | 9/9 to 9/15   | - Carmichael, The Changing Role of Pharmacy Practice  
- Massaro, Constitutional Limitations on State-Imposed Continuing Competency  
- Smearman, Drawing the Line: The Legal, Ethical and Public Policy Implications of Refusal Clauses for Pharmacists                                                                 | Video Lecture: Regulating for Outcomes                                            | -Elluminate classes 9/9 & 9/12  
-Discussion board                                                                                                                                          |  
| Midterm    |                                                                          |               | **Midterm Exam**                                                                                                                                         | Video Lecture:                                                                   | -Elluminate classes 9/16 & 9/19  
-Weekly written assignment  
-Discussion board                                                                                                                                       |  
| Week V     | Drug Distribution                                                        | 9/16 to 9/22  | - Ascione, Historical Overview of Generic Medication Policy  
- Spring, Sales v. Safety  
- Johnson, PBMs: Ripe for Regulation                                                                                                                         | Video Lecture: Practices that Affect the Pharmaceutical Product                   | -Elluminate classes 9/23 & 9/26  
-Weekly written assignment  
-Discussion board                                                                                                                                       |  
| Week VI    | Product Integrity                                                       | 9/23 to 9/29  | - Liang, Parallel Trade in Pharmaceuticals  
- Kleiman, State Regulation of Canadian Pharmacies  
- Pollock, Blame Canada (And the Rest of the World)                                                                                                            | Video Lecture: Protecting the Pipeline                                            | -Elluminate classes 9/30 & 10/3  
-Weekly written assignment  
-Discussion board                                                                                                                                       |  
| Week VII   | eRegulation                                                              | 9/30 to 10/6  | - Ridgely, Pharmacy, Facsimile and Cyberspace  
- Ayers, Prescribing a Cure for Online Pharmacies  
- Brushwood, Responsive Regulation of Internet Pharmacy                                                                                                     | Video Lecture: Adapting to an Electronic World                                   | -Elluminate classes 10/7: A review of topics covered and new areas of interest in the future. See Sakai for assignments |  
<p>| Week       | FINAL WRAP UP                                                            | 10/7:         | <strong>FINAL WRAP UP</strong>                                                                                                                                          |                                                                                | <strong>FINAL WRAP UP</strong>                                                                 |</p>
<table>
<thead>
<tr>
<th>VIII &amp; DISCUSSION</th>
<th>and/or readings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Multiple choice</td>
<td>Posted 10/3, 9:00AM; Due 10/7, Midnight EST</td>
</tr>
</tbody>
</table>