Structure, Process and Outcomes of Regulation II

PHA6935

Course Purpose:
This course emphasizes the role of the legislative, executive and judicial branches of state and federal government in the establishment of standards for pharmacy practice and drug distribution. It also places special emphasis on the administrative rule making process. Additionally, the course focuses on the purpose of government agencies, the approach to standards setting by each type of agency, and the effects of regulation on public health.

Course Faculty and Office Hours:

*Professor and Course Coordinator:*
Variates

*Office Hours:*
By appointment only. Students may request a telephone appointment time which will be arranged at a mutually convenient time. Communication is encouraged.

Place and Time of Class Sessions:
- Class time: Varies
- All classes are via Internet through the University system.

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

1. Discuss the primary purpose of state boards of pharmacy in the licensure of pharmacists.
2. Discuss the role of regulators as educators versus enforcers.
4. Evaluate the effectiveness of licensure as a control on quality in health care.
5. Explain Sparrow’s 4 tiers of “business results” in terms of health care.
6. Distinguish the following terms: profession, occupation, job, career, and calling.
7. Describe the changes that enabled the medical profession to control pharmaceutical information.
8. Discuss the relationship of trust within medication distribution and use.
9. Distinguish the various types of responsibility (technical, judgmental, normative, agent).
10. Discuss the legal status of clinical practice standards.
11. Describe the elements of a “culture of safety.”
12. Explain how it is regulators within a given agency can know whether the agency has successfully promoted a culture of safety.
13. Describe the roles courts may play in reviewing evaluations of quality in medical practice.
14. Describe the standard of care for the proper utilization of medications.
15. Discuss the shortcomings of the use of medical malpractice as an effective mechanism for
quality assurance.
16. Describe the requirements for experimentation with human subjects.
17. Describe Sparrow’s 6 steps of regulatory accountability
18. Discuss Brennan and Berwick’s 5 approaches to quality
19. Discuss possible reforms in health care regulation.

Pre-Requisite Knowledge and Skills:
Structure, Process, and Outcomes of Regulation I serves as a prerequisite for this course.

Course Structure & Outline/Activities:

Course Structure:
Multiple self-directed learning activities are required (e.g., prerecorded lecture videos for homework, readings that involve critical thinking, and discussion board participation), and each week students come to class in Big Blue Button to discuss the materials assigned for the given week.

Course Outline/Activities
The outline of course activities is listed at the end of this document in Appendix B.

Textbooks and Videos:

Required Text:
• Varies

Supplemental Reading Assignments (provided through online reserve):
• Varies

Commercially Available Videos:
• Varies

Prerecorded Video Lectures:
• Varies

Active Learning Requirements:
During each live, in-class session, students are required to answer poll questions over the material assigned for that class. Class discussions are heavily based upon students’ responses to these questions. Students are also highly encouraged to participate on the weekly course discussion boards by deliberating and chatting about core concepts assigned for the given week. Full credit for class participation requires four postings weekly on discussion board; two postings must be original threads, and two must be responsive postings in a thread started by someone else. Each of these postings should be relevant to the class and original to the student. Full credit for class participation also requires attendance at every class, adequate preparation for class, and appropriate participation in class.
**Student Evaluation & Grading:**

**Evaluation Methods:**

- Quizzes (3) 25%
- Assignments (2) 25%
- Class Participation AND Discussion Board 10%
- Final (cumulative): 40%

**Grading Scale:**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Score Range</th>
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<tbody>
<tr>
<td>A</td>
<td>95 - 100</td>
</tr>
<tr>
<td>A-</td>
<td>90 - 94</td>
</tr>
<tr>
<td>B+</td>
<td>86 - 89</td>
</tr>
<tr>
<td>B</td>
<td>83 - 85</td>
</tr>
<tr>
<td>B-</td>
<td>80 - 82</td>
</tr>
<tr>
<td>C+</td>
<td>76 - 79</td>
</tr>
<tr>
<td>C</td>
<td>73 - 75</td>
</tr>
<tr>
<td>C-</td>
<td>70 - 72</td>
</tr>
<tr>
<td>D+</td>
<td>66 - 69</td>
</tr>
<tr>
<td>D</td>
<td>63 - 65</td>
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<tr>
<td>D-</td>
<td>60 - 62</td>
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<tr>
<td>E</td>
<td>&lt; 60</td>
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</tbody>
</table>

- See link regarding minus grades: [http://www.isis.ufl.edu/minusgrades.html](http://www.isis.ufl.edu/minusgrades.html).
- See link regarding University grading policies: [https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx#averaging](https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx#averaging).

**Class Attendance Policy:**

Students will have an opportunity to be involved in this course through class discussion. It is therefore essential that students read all assigned course materials, watch and listen to all prerecorded videos, as well as attend each and every class. **Attendance in live class sessions is mandatory.** Students should, whenever possible, anticipate upcoming absences and speak with the professors to make prior arrangements for make-up work. Students must contact the course coordinator (cc'ing the faculty member who taught the missed class session) as soon as possible following any unanticipated absence.

**Quiz/Assignment/Exam Policy:**

**Quizzes:**

- There are 3 total quizzes.
- Quizzes consist of 10 multiple-choice/true-false questions over the material assigned for
the given week. Students will have **20 minutes** to complete the quiz.

- Quiz scores are revealed upon submission. Quiz keys will be made available once all students have completed the quiz.

**Assignments:**

- Assignments (2 total) will be posted at 8:00 pm Eastern, and are due by 6:00 pm Eastern the following week on assigned days. Assignments are found under the 'Assignments' tab on Canvas.
- Responses to these assignments must be in essay format. Formatting instructions are provided in the 'Directions' section atop each assignment.
- Assignments are designed to provide students the opportunity to critically analyze an issue(s). These assignments foreshadow what students will see on exams.
- Please submit by uploading your response as a Word attachment. If you have any difficulty uploading your paper to Canvas - don't panic; simply email it to the Professor.
- Students who feel their writing skills are in need of improvement should contact the Professor very early on in order to discuss an improvement plan.

**Exam:**

- There is one **cumulative** final exam in this course.
- Please be sure to set aside at least 6-8 hours over the weekend to work on your exam.
- Accessing the exam early allows for an opportunity to address unforeseen technical glitches in a timely manner.
- Exams consist of four questions, similar to the assignments
- Exams are found under the 'Assignments' tab on Canvas.
- Please submit by uploading your responses to each of the four questions as a **single** Word attachment (with your name included). If you have any difficulty uploading your exam to Canvas - don't panic; simply email it to the Professor.
- Exam comments will be returned to students in a timely fashion.

**Make-up Quiz/Exam Policy:**

**Quizzes:**

- Generally, make-up quizzes will not be offered. However, the Professor will entertain a student's request to make-up a quiz, and make his decisions based on the student's special, unforeseeable circumstances.

**Exam:**

- Students who must miss the final exam due to an excused absence only shall notify the Professor before the exam to ensure an opportunity to make up the missed work. Failure to do so will render the student unable to make up the missed exam regardless of the reason. Exceptions for extreme circumstances, however, may be granted.
- Excused absences include auto accident, illness (documentation required), death or illness of family members, etc.
- Students with unexcused absences will not be permitted to submit an exam beyond the due date/time. Such individuals, however, shall notify the Professor of their absences.
- Format of a make-up exam is at the discretion of the faculty.
- A make-up exam must be completed within a reasonable time frame (generally no later than one week after the scheduled exam date).
Policy on Old Exams, Quizzes and Assignments:

- Previously administered quizzes, assignments, or exams will not be made available to students.

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: http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf

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.

Appendix A: Directions for Contacting Faculty & Course Faculty List

Directions for Contacting Course Faculty:
- Please post on the discussion board questions regarding the substantive material covered in this course.
- Please contact the Professor for personal or professional matters that may affect your performance in this course.
- Please contact the Professor directly for questions about the assignments.
- Please contact popsupport@ahc.ufl.edu for technical issues involving either Canvas or Big Blue Button at any time of the day or night.

Appendix B: Schedule of Course Activities/Topics:

<table>
<thead>
<tr>
<th>Topic</th>
<th>Reading Assignment</th>
<th>Video Assignment</th>
<th>Learning Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module I</td>
<td>- Chapters 7 &amp; 8.</td>
<td>- Licensure as Assessment of Competence</td>
<td>- Discussion Board - Quiz 1</td>
</tr>
<tr>
<td>Regulating Health</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Professions | - Chapter 10.  
- Chapter 3.  
- Case:  
- The Quality Gap | - Assignment 1  

| Module II  
Regulatory Responses to Medical Error | - Chapters 10 & 11  
- Chapter 3  
- Chapter 8  
- Case:  
- Liability for Harm from Defective Products  
- A Questionable Doctor | - Discussion Board  
- Quiz 2  

| Module III  
Liability as Regulation of Health Care & The Future of Health Care Regulation | - Chapters 16, 17  
- Chapter 8  
- Case:  
- Principles of Legal Liability  
- Chapters 19 & 20  
- Chapter 7 | - Discussion Board  
- Quiz 3  

| Cumulative Final Exam |
regulatory agencies actually improve the level of care provided to patients? Is a regulatory agency an arm of the profession it regulates or is it an arm of the government? Should we resign ourselves to the reality that some people simply will receive better products and services than others, and that there is really nothing to be done about it?

Week’s Activities:

- Read text Chapter 10.
- Read text Chapter 3.
- View Video: The Quality Gap.

Module Assessments:

- Do not forget to post regularly on the discussion board.
- Take the Quiz.
- Submit Assignment.

MODULE II

Overview of Class:

The purpose of this class is to provide an overview of actions taken by regulatory agencies in response to public concern over the increased incidence of medical error.

As you study for this class, ask yourself how a regulatory agency can approach problem solving when a public mandate for change is issued. How can management of a regulatory agency assure that changes in policy are purposeful and not counterproductive? Does mandatory continuous quality improvement effectively replace punishment of error?

Week’s Activities:

- Read assigned text Chapters 10 & 11.
- Read text Chapter 3.
- View Video Lecture: Liability for Harm from Defective Products.

Overview of Class:

The purpose of this class is to reflect on the standard of medical practice, and ask whether a practice that is unusual is below the standard and therefore in error.

As you study for this class, reflect on how standards of medical practice are developed. Do the majority of practitioners set the standard? What if there is a substantial minority opinion—is anyone in the minority necessarily wrong in the way they practice? How can the public evaluate the quality of medical practice? What role do the courts play in reviewing evaluations of quality in medical practice?

Week’s Activities:
• Read assigned Report.
• Read Case.
• View Video: A Questionable Doctor.

Module Assessments:

• Do not forget to post regularly on the discussion board.
• Take the Quiz.
• Submit Assignment 2.

MODULE III

Overview of Class:

The purpose of this class is to (1) provide an overview of medical malpractice liability as a mechanism to assure and improve the quality of health care and (2) consider how an individual or group of individuals can meet its professional duty to patients, when there are competing interests.

As you study for this class:

• Ask yourself how those in regulation can evaluate those being regulated. Is it really possible for those who do not practice a profession on a day-to-day basis to know what can and cannot be done within a health care practice? How can the discretion of a reviewer of quality be used judiciously to allow for variations in quality? What does it mean to be “negligent” in the practice of a profession?
• As you study for this class, ask yourself at what point a health care professional has a responsibility to set aside her/his interests and risk the loss of a job as a matter of principle in the defense of a patient’s best interests. How certain can a health care professional be that a particular course of action is the right course of action? When should a fellow health care professional be challenged if science is never absolute and there is no real way to know what approach to care is the best approach?

Week’s Activities:

• Read assigned text Chapters 16, 17.
• Read text Chapter 8.
• Read case.
• View Video Lecture: Principles of Legal Liability.

Overview of Class:

The purpose of this class is to develop proposals for reform in health care regulation. As you study for this class, ask yourself what additional information you would need to know in order to redesign health care regulation to be more effective. How would you go about obtaining that information? Have recent reforms in health care regulation really just be Band-Aids that perpetuate the traditional problems while putting a new coat of paint on the standard regulatory techniques? How can an outcomes orientation become the cornerstone of health care regulation?
Week’s Activities:

- Read assigned text Chapters 19 & 20.
- Read text Chapter 7.

Module Assessments:

- Do not forget to post regularly on the discussion board.
- Take the Quiz.