

COURSE SYLLABUS
PHCY 5210 – Regulating Dangerous Drug Use
2 Credits

Instructor Information:

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Course Information:

This course is delivered in an asynchronous fashion. Pre-recorded lectures are posted to WyoCourses, along with reading assignments. Student-student and student-faculty interaction occurs on the course discussion board around the clock, 24/7. Students are expected to actively participate in online discussions, starting two original threads during each unit and posting three responses within other students' original threads during each unit. There is an online exam during each unit. There is a final exam. This course provides the option for students to prepare either a term paper or a recorded case study presentation, which can raise a student's grade but will not lower a student's grade.

Prerequisites: Enrollment in graduate or professional program or department permission.

Course Description:

Regulatory theory and practice are used to study the authority/responsibilities of three federal agencies that are entrusted to ensure safe, effective, and efficient medication use in the United States. The practices and procedures of the FDA, DEA and CMS are reviewed, describing why healthcare providers should comply with regulatory principles. The goal of the course is to design regulatory compliance systems that facilitate compliance by pharmacy personnel with government regulations that protect the public welfare.

Disability Statement:

If you have a physical, learning, sensory or psychological disability and require accommodations, please let me know as soon as possible. You will need to register with, and provide documentation of your disability to University Disability Support Services (UDSS) in SEO, room 109 Knight Hall.

Objectives/Outcomes/Standards:

- Describe the structures and processes of regulation by the state boards of pharmacy, FDA, DEA and CMS, and the influence of politics on regulatory activities by these agencies.
- Discuss the potential consequences of inappropriately lax or inappropriately harsh enforcement activity by the FDA (the so-called "Goldilocks Principle").
- List the requirements for establishing the level of evidence necessary to support the approval of a new molecular entity under the Food, Drug, and Cosmetic Act.
- List the required elements of approved drug labeling and the effect this labeling has on product promotion and professional practice.
- Describe the traditional role of pharmacy compounding and the regulatory controversies that continue to address the appropriate methods of assuring the safety of pharmacy compounded products.
- Discuss the regulatory distinction between Prescription-Only and OTC drugs.
- Describe the regulatory responsibilities of manufacturers, distributors, and health professionals during the marketing and use of an approved drug.

- List the characteristics of the “closed system” of controlled substance distribution under the Controlled Substance Act.
- Discuss the challenges posed by the recent epidemic of prescription drug abuse, and the appropriate regulatory approach to addressing this epidemic.
- Describe how federal payment systems indirectly restrict and control the use of safe and effective medications through payment conditions established by the Medicare and Medicaid programs.
- Discuss the practices that must be adopted to ensure compliance with the False Claims Act, and with the requirements of the Medicare and Medicaid programs.
- Describe the attributes of programs that can successfully manage regulatory liability for harm caused to patients by adverse drug events.

Readings (written monographs):

- The Food and Drug Administration Regulatory Role
- The Drug Enforcement Administration Regulatory Role
- The State Board of Pharmacy Regulatory Role
- Responsibility and Professionalism in Pharmacy
- Responsive Regulation in Pharmacy
- Regulatory Problem-Solving
- Emerging Challenges in Pharmacy Regulation
- The Regulation/Ethics Interface
- Rx v OTC Classification
- Drug Labeling/Off-Label Use
- Postmarketing Surveillance and Risk Management
- Controlled Substance Prescribing and Dispensing
- Licensure as Assurance of Competence
- Meeting Patient Education Responsibilities
- Compliance with Compounding Standards
- Requirements for Generics, Therapeutic Interchange, and Biosimilars
- Compliance with Drug Abuse Prevention Mandates
- Avoiding Fraud and Abuse Noncompliance
- Compliance with Expanded Expectations of Pharmacists
- Compliance with Managed Care Standards
- Unapproved Drugs
- Research v Innovative Practice
- Off-Label Drug Use & Promotion
- Meeting the “Corresponding Responsibility”
- Failure to Warn
- The Whistleblower

Pre-Recorded Online Lectures:

- Intro to Pharmacy Regulation: The Basics of Why Pharmacy is “The Most Regulated Health Profession”
- Theories of Pharmacy Regulation
- New Drug Approval
- Compliance with Patient Safety Requirements
- Using Regulatory Case Studies As A Learning Tool

Journal Articles and Government Documents

- Borchers et al., The History and Contemporary Challenges of the US Food and Drug Administration
- Mitchell, Deregulating Mandatory Medical Prescription
- Mossialos et al., Expanding the Role of Community Pharmacists: Policymaking in the Absence of Policy-relevant evidence?
- U. S House of Representatives, FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?
- U S Government Accountability Office, Prescription Opioids: Medicate Needs to Expand Oversight Efforts to Reduce the Risk of Harm
- Sawicki, Character, Competence, and The Principles of Medical Discipline
- CQI Compliance Guide for Florida Pharmacies

Legal Cases

- Virginia Consumer Citizens Council v. Virginia State Board of Pharmacy
- Jefferson County Pharmaceutical Association v. Abbott Laboratories
- Thompson v. Western States
- Gonzales v. Oregon
- Sorrell v. IMS Health
- Powers v Thobani
- Jones Total Health Care Pharmacy v. DEA
- Carlson v. Ohio Board of Pharmacy
- Oyler v. Hy-Vee
- United States v. Joseph
- Nguyen v. United States
- United States v. Stepanets

Course Requirements/Assignments:

Each unit in this course requires that students complete the following activities:

- Carefully review the Unit Guide for familiarity with unit learning objectives and responsibilities.
- Download and print the lecture handouts and view the pre-recorded online lectures.
- Download and read the assigned written monographs.
- Participate actively in discussion board (2 original threads and 3 responsive posts minimum).
- Take the unit exam online.

There is a final exam.

Students may choose to complete an optional term paper or online case-based presentation to improve their grade.

Grading Standards:

The final grade in this course will be comprised of:

Ten Unit Exams	50%
Final Exam	25%
Class Participation	25%

Grading:

A:	90-100
B:	80-89
C:	70-79

D: 60-69
F: <60

Students who miss exams or class participation may request an excused absence, which will be granted by the course instructor if warranted. Students who develop conflicts that prohibit their completion of 25% or more of course material should withdraw from the course. Students who satisfactorily complete 75% or more of the course material, and who cannot complete the balance within the confines of the course schedule, may be granted an incomplete, and missing coursework must be completed by the end of the following term.

Attendance/Participation Policy:

University sponsored absences are cleared through the Office of Student Life. Class attendance in this course is mandatory and is fulfilled through active participation on the course discussion board, as well as completion of assigned examinations. Graduate and professional students are subject to an elevated expectation for participation in class discussion board. Graduate and professional students should post original threads early during each unit, respond with encouraging and helpful remarks to posts of other students, and provide explanations of healthcare matters or research issues that may not yet be fully appreciated by undergraduate students enrolled in the cross-listed version of this course.

Academic Honesty:

The University of Wyoming is built upon a strong foundation of integrity, respect and trust. All members of the university community have a responsibility to be honest and the right to expect honesty from others. Any form of academic dishonesty is unacceptable to our community and will not be tolerated [from the University Catalog]. Teachers and students should report suspected violations of standards of academic honesty to the instructor, department head, or dean. Other University regulations can be found at: <http://www.uwyo.edu/generalcounsel/new-regulatory-structure/index.html>)

Course Outline:

Unit 0: Readings and Reflections on Pharmacy Regulation

Assigned Readings	U. S House of Representatives, FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities? U S Government Accountability Office, Prescription Opioids: Medicate Needs to Expand Oversight Efforts to Reduce the Risk of Harm
Case Studies	United States v. Joseph Nguyen v. United States United States v. Stepanets

Unit 00: Readings and Reflections on Pharmacy Regulatory Compliance Strategies

Assigned Readings	Sawicki, Character, Competence, and The Principles of Medical Discipline CQI Compliance Guide for Florida Pharmacies
Case Studies	Jones Total Health Care Pharmacy v. DEA Carlson v. Ohio Board of Pharmacy Oyler v. Hy-Vee

Unit I: The Regulatory Climate of Pharmacy and Pharmaceuticals

Background Articles	<ul style="list-style-type: none"> • Borchers, et al., The History and Contemporary Challenges of the US Food and Drug Administration. • Mitchell, Deregulating Mandatory Medical Prescription • Mossialos et al., Expanding the Role of Community Pharmacists: Policymaking in the Absence of Policy-Relevant Evidence?
Assigned Legal Case	<ul style="list-style-type: none"> • Powers v Thobani
Assigned Videos	<ul style="list-style-type: none"> • The FDA and the Pharmaceutical Industry http://www.youtube.com/watch?v=eevMBleMM2Q • The Abuse of Prescription Drugs http://www.youtube.com/watch?v=ILx8Mo0Edac • Supreme Court of Florida Oral Arguments in Your Druggist v. Powers Case http://wfsu.org/gavel2gavel/selectcase.php?year=2006&month=5 (Enter May, 2006 for date, and click on Your Druggist v. Powers)

Unit II: Pharmacy From the Perspective of the Supreme Court

Assigned Video	Interpreting Supreme Court Cases http://www.youtube.com/watch?v=HTVvZ1Sdkaw
Supreme Court Cases	<ul style="list-style-type: none"> • Virginia Consumer Citizens Council v. Virginia State Board of Pharmacy • Jefferson County Pharmaceutical Assn. v. Abbott Laboratories • Thompson v Western States • Gonzales v Oregon • Sorrell v IMS Health

Unit III: Foundations of Pharmacy Regulation

Video Lecture	<ul style="list-style-type: none"> • Intro to Pharmacy Regulation: The Basics of Why Pharmacy is “The Most Regulated Health Profession”
Monographs	<ul style="list-style-type: none"> • The Food and Drug Administration Regulatory Role • The Drug Enforcement Administration Regulatory Role • The State Board of Pharmacy Regulatory Role • Responsibility and Professionalism in Pharmacy

Unit IV: The Process of Regulation in Pharmacy

Video Lecture	<ul style="list-style-type: none"> • Theories of Pharmacy Regulation
Monographs	<ul style="list-style-type: none"> • Responsive Regulation in Pharmacy • Regulatory Problem-Solving • Emerging Challenges in Pharmacy Regulation • The Regulation/Ethics Interface

Unit V: Contemporary Issues in Pharmacy Regulation

Video Lecture	<ul style="list-style-type: none"> • New Drug Approval
Monographs	<ul style="list-style-type: none"> • Rx v OTC Classification • Drug Labeling/Off-Label Use • Postmarketing Surveillance and Risk Management • Controlled Substance Prescribing and Dispensing

	<ul style="list-style-type: none"> • Licensure as Assurance of Competence • Meeting Patient Education Responsibilities
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Unit VI: Principles of Regulatory Compliance

Video Lecture	<ul style="list-style-type: none"> • Compliance with Patient Safety Requirements
Monographs	<ul style="list-style-type: none"> • Compliance with Compounding Standards • Requirements for Generics, Therapeutic Interchange, and Biosimilars • Compliance with Drug Abuse Prevention Mandates • Avoiding Fraud and Abuse Noncompliance • Compliance with Expanded Expectations of Pharmacists • Compliance with Managed Care Standards

Unit VII: Regulatory Compliance Case Studies

Video Lecture	<ul style="list-style-type: none"> • Using Regulatory Case Studies as a Learning Tool in Pharmacy
Monographs	<ul style="list-style-type: none"> • Unapproved Drugs • Research v Innovative Practice • Off-Label Drug Use & Promotion • Meeting the "Corresponding Responsibility" • Failure to Warn • The Whistleblower

Final Exam

The instructor may make changes to the syllabus as the course proceeds. If necessary, these changes will be announced in class. Substantive changes made to the syllabus shall be communicated in writing to the students.

Optional Paper/Presentation Grading Rubric

Please have your proposal approved before proceeding with your paper or presentation. The proposal should include:

1. the central theme of the paper or project;
2. the context of the subject matter and how it relates to materials from the;
3. a brief outline; and
4. a tentative bibliography.

PROPOSAL	Excellent (A)	Adequate (B)	Inadequate (C)
Content	Theme is well-defined. Proposal addresses subject matter related to material in course. Outline is comprehensive and complete. Bibliography is complete.	Theme is defined but not thoroughly developed. Proposal addresses context without relating context to material in course. Outline is complete. Bibliography included.	Theme is vague. Proposal fails to identify context. Outline is brief and incomplete. Bibliography is missing some major components.
Mechanics of Expression	Proposal is highly polished; no grammar or spelling errors.	Proposal is polished; yet several errors of syntax or other unclear uses of language leave the reader guessing.	Proposal is barely understandable; use of language makes it difficult to interpret what the project will accomplish.

PRESENTATION (If Chosen)	Excellent (A)	Adequate (B)	Inadequate (C)
Content Knowledge	Student demonstrates full knowledge (more than required) with explanations and elaboration.	Student is at ease with content, but fails to elaborate.	Student is uncomfortable with information and is able to answer only rudimentary questions.
Organization	Student presents information in logical, interesting sequence which audience can follow.	Student presents information in logical sequence which audience can follow.	Audience has difficulty following presentation because student jumps around.
Delivery	Student used a clear voice and correct, precise pronunciation of terms.	Student's voice is clear. Student pronounces most words correctly.	Student incorrectly pronounces terms. Audience members have difficulty hearing presentation.
Mechanics of Slide Show Preparation	Presentation slides are highly polished; no grammar or spelling errors.	Presentation is clear; yet there are several grammatical or other errors in slides.	Presentation is poorly designed with slides that do not facilitate audience appreciation of the subject.

TERM PAPER	Excellent (A)	Good (B)	Inadequate (C)
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(If Chosen)			
Content	Theme is well-defined. Paper clearly explains relationship of subject to material in course.	Theme is less well defined. Subject is interesting yet not related to course.	Theme is vague. Difficult to understand the premise or significance of subject.
Research	Excellent background, context, and idea development	Good background, context, and idea development	Unclear background, context, and idea development
Organization	Student presents information in logical, interesting sequence.	Student presents information in logical sequence.	Reader has difficulty following paper due to disorganization.
Comprehensibility	Can understand all of what is being communicated.	Can understand most of what is being communicated.	Can understand less than half of what is being communicated.
Bibliography	Bibliography is complete and appropriately organized.	Bibliography is included but not well organized.	Bibliography is missing major components.
Grammar, Mechanics, Spelling, and Sentence Structure	Paper is highly polished; no grammar or spelling errors.	Paper is polished; with several grammar or spelling errors.	Grammar, misspellings, typos distract the reader to the point of annoyance.

Discussion Board (Class) Preparation/Participation Grading Rubric (20% of Grade)

	Excellent (A)	Good (B)	Inadequate (C)
Contributions	Consistently initiates useful and relevant ideas when participating in the discussion board. A definite leader who contributes major effort and who makes class discussions better.	Usually provides useful ideas when participating in classroom discussion board. A strong student who tries hard but is more of a follower than a leader in discussions.	Inconsistent in providing relevant comments on discussion board. Fails to initiate new threads that stimulate participation by other students.
Attitude	Always respectful of others; has a positive attitude, and does not rudely criticize anyone else's ideas or work. Other students feel safe responding to this student's posts.	Occasionally becomes impatient with ideas or work of others. Usually has a positive attitude toward discussions. Usually treats others and self with respect.	On more than one occasion becomes disrespectful of ideas expressed by others, using insults rather than evidence to express contrary views.
Preparedness & Focus	Consistently stays focused on subject matter assigned for discussion board and achieves identified outcomes. Self-directed and highly motivated. Postings help with understanding of assigned materials.	Usually posts comments that are related to course materials, but occasionally rambles about subjects that are not relevant to the course.	Postings to discussion board are based on general knowledge and common sense, rather than on materials assigned for course.
Quality of Work	Provides work of the highest insight that motivates other students to achieve at a high level.	Provides quality work that is interesting but not consistently insightful.	Does work that reflects little understanding of the course material.