

UNIVERSITY OF WYOMING
PHCY 5210
REGULATING DANGEROUS DRUG USE, 2 Credit Hours

Online Delivery, Primarily Asynchronous Through WyoCourses
Fall, 2020

This Course Meets Daily on the Discussion Board

The First Day of Class is September 13 and the Last Day of Class is December 6 (11 Weeks)

Instructor contact information: Professor David Brushwood, R.Ph., J.D., Phone: 307 766-6120 E-mail: dbrushwo@uwyo.edu, Office(s): HS 292, although your professor does not maintain an office in Laramie and electronic contact through some alternate means is required.

Office Hours: Sunday afternoons online, or at other times by appointment either through telephone or online (Zoom meeting). Please post general questions about course materials to the course discussion board. Personal matters should be addressed directly to the instructor through email or by telephone.

Course prerequisites, co-requisites, enrollment restrictions: Professional or graduate standing, or by permission of the School of Pharmacy.

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 role of state regulatory agencies such as a state department of health and state professional licensure boards will also be reviewed. 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.

General 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 comprehensive exam.

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.

Regulatory Compliance Legal Briefs:

- Virginia Board of Pharmacy v. Virginia Consumer Citizens Council (State restrictions on pharmacy price advertisements)
- Whalen v. Roe (Aggregation and dissemination of information about patient use of controlled substances)
- Oregon v. Gonzales (Federal restrictions on medical practice of state-approved death with dignity)
- Thompson v. Western States (Federal restrictions on pharmacy compounding)
- Sorrell v. IMS (Restrictions on sale of de-identified pharmacy dispensing information)
- Merck Sharp & Dohme v. Albrecht (State v. federal standards for warnings in drug product labeling)
- Drug Approval, Withdrawal, & Recall
- The FDA and Post-Marketing Drug Safety
- Generic Product Approval and Selection
- Marketed Unapproved Drugs
- The Ubiquitous “Misbranding” Violation
- Off-Label Drug Use and Promotion
- Liability for Drug Product Defect
- Compounding Requirements in the Post-NECC Era
- Principles of Self-Regulation in Pharmacy
- Legal Parameters of the Pharmacy Technician Role
- Prospective Drug Use Review in the Shadow of OBRA-90
- Regulatory Standards for Opioid Prescription Screening
- The Legal Mandate for Patient Education by Pharmacists
- Privacy and Confidentiality of Patient Information

Pre-Recorded Online Mini Lectures:

- Ethics in Pharmacy
- Marijuana and CBD
- Fraud and Pharmaceuticals
- Approving New Drugs
- Elements to Assure Safe Use
- Labeling of Pharmaceuticals
- Pharmacy Regulatory Compliance
- Regulating Pharmacy
- Pharmaceutical Products and Suicide Prevention
- Pharmacist Management of Medication Use

Course Requirements/Assignments:

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

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

There is a comprehensive exam

Grading Standards:

The comprehensive grade in this course will be comprised of:

Ten Module Exams	50%
Comprehensive 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.

Course Outline:

- Orientation Module
- Module I: Pharmacy as a Business and Pharmacy as a Profession
 - Online Mini-Lecture: Ethics in Pharmacy
 - Regulatory Compliance Legal Briefs
 - Virginia Board of Pharmacy v. Virginia Consumer Citizens Council (State restrictions on pharmacy price advertisements)
 - Whalen v. Roe (Aggregation and dissemination of information about patient use of controlled substances)
 - Module I Discussion Board
 - Module I Exam
- Module II: State v. Federal Authority
 - Online Mini-Lecture: Marijuana and CBD
 - Regulatory Compliance Legal Briefs
 - Oregon v. Gonzales (Federal restrictions on medical practice of state-approved death with dignity)
 - Thompson v. Western States (Federal restrictions on pharmacy compounding)
 - Module II Discussion Board
 - Module II Exam
- Module III: Products and Profits
 - Online Mini-Lecture: Fraud and Pharmaceuticals
 - Regulatory Compliance Legal Briefs
 - Sorrell v. IMS (Restrictions on sale of de-identified pharmacy dispensing information)
 - Merck Sharp & Dohme v. Albrecht (State v. federal standards for warnings in drug product labeling)
 - Module III Discussion Board
 - Module III Exam
- Module IV: Assuring Drug Safety & Efficacy
 - Online Mini-Lecture: Approving New Drugs
 - Regulatory Compliance Legal Briefs
 - Drug Approval, Withdrawal, & Recall
 - The FDA and Post-Marketing Drug Safety
 - Module IV Discussion Board
 - Module IV Exam
- Module V: Selecting an Approved Product
 - Online Mini-Lecture: Elements to Assure Safe Use
 - Regulatory Compliance Legal Briefs
 - Generic Product Approval and Selection
 - Marketed Unapproved Drugs
 - Module V Discussion Board
 - Module V Exam
- Module VI: Information in Labeling
 - Online Mini-Lecture: Labeling of Pharmaceuticals

- Regulatory Compliance Legal Briefs
 - The Ubiquitous “Misbranding” Violation
 - Off-Label Drug Use and Promotion
- Module VI Discussion Board
- Module VI Exam
- Module VII: Unsafe Pharmaceutical Products
 - Online Mini-Lecture: Pharmacy Regulatory Compliance
 - Regulatory Compliance Legal Briefs
 - Liability for Drug Product Defect
 - Compounding Requirements in the Post-NECC Era
 - Module VII Discussion Board
 - Module VII Exam
- Module VIII: Licensure and Practice Standards
 - Online Mini-Lecture: Regulating Pharmacy
 - Regulatory Compliance Legal Briefs
 - Principles of Self-Regulation in Pharmacy
 - Legal Parameters of the Pharmacy Technician Role
 - Module VIII Discussion Board
 - Module VIII Exam
- Module IX: Unsafe Drug Use
 - Online Mini-Lecture: Pharmaceutical Products and Suicide Prevention
 - Regulatory Compliance Legal Briefs
 - Prospective Drug Use Review in the Shadow of OBRA-90
 - Regulatory Standards for Opioid Prescription Screening
 - Module IX Discussion Board
 - Module IX Exam
- Module X: Information for Patients
 - Online Mini-Lecture: Pharmacist Management of Medication Use
 - Regulatory Compliance Legal Briefs
 - The Legal Mandate for Patient Education by Pharmacists
 - Privacy and Confidentiality of Patient Information
 - Module X Discussion Board
 - Module X Exam
- Comprehensive Exam (Essay, Short Answer)

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.

Classroom Behavior Policy:

At all times, I expect you to treat your presence in the classroom and your enrollment in this course as you would a job. You will be respectful towards you classmates and instructor. Spirited debate and disagreement are to be expected in any classroom and all views will be heard fully, but at all times we will behave civilly and with respect towards one another. Personal attacks, offensive language, name-calling, and dismissive gestures are not warranted in a learning atmosphere. As the instructor, I have the right to dismiss you from the electronic forums and other areas where disruptive behavior occurs.

Classroom Statement on Diversity:

The University of Wyoming values an educational environment that is diverse, equitable, and inclusive. The diversity that students and faculty bring to class, including age, country of origin, culture, disability, economic class, ethnicity, gender identity, immigration status, linguistic, political affiliation, race, religion, sexual orientation, veteran status, worldview, and other social and cultural diversity is valued, respected, and considered a resource for learning.

Disability Support:

The University of Wyoming is committed to providing equitable access to learning opportunities for all students. If you have a disability, including but not limited to physical, learning, sensory or psychological disabilities, and would like to request accommodations in this course due to your disability, , please register with and provide documentation of your disability as soon as possible to Disability Support Services (DSS), Room 128 Knight Hall. You may also contact DSS at (307) 766-3073 or udss@uwyo.edu. It is in the student's best interest to request accommodations within the first week of classes, understanding that accommodations are not retroactive. Visit the DSS website for more information at: www.uwyo.edu/udss

Academic Dishonesty Policies:

Academic dishonesty will not be tolerated in this class. Cases of academic dishonesty will be treated in accordance with UW Regulation 2-114. The penalties for academic dishonesty can include, at my discretion, an "F" on an exam, an "F" on the class component exercise, and/or an "F" in the entire course. Academic dishonesty means anything that represents someone else's ideas as your own without attribution. It is intellectual theft – stealing - and includes (but is not limited to) unapproved assistance on examinations, plagiarism (use of any amount of another person's writings, blog posts, publications, and other materials without attributing that material to that person with citations), or fabrication of referenced information. Facilitation of another person's academic dishonesty is also considered academic dishonesty and will be treated identically.

Duty to Report:

UW faculty are committed to supporting students and upholding the University's non-discrimination policy. Under Title IX, discrimination based upon sex and gender is prohibited. If you experience an incident of sex- or gender-based discrimination, we encourage you to report it. While you may talk to a faculty member, understand that as a "Responsible Employee" of the University, the faculty member MUST report information you share about the incident to the university's Title IX Coordinator (you may choose whether you or anyone involved is identified by name). If you would like to speak with someone who may be able to afford you privacy or confidentiality, there are people who can meet with you.

Faculty can help direct you or you may find info about UW policy and resources at

<http://www.uwyo.edu/reportit>

You do not have to go through the experience alone. Assistance and resources are available, and you are not required to make a formal complaint or participate in an investigation to access them.

Substantive changes to syllabus:

All deadlines, requirements, and course structure is subject to change if deemed necessary by the instructor. Students will be notified verbally in class, on our WyoCourses page announcement, and via email of these changes.

Student Resources:

DISABILITY SUPPORT SERVICES: udss@uwyo.edu, 766-3073, 128 Knight Hall, www.uwyo.edu/udss

COUNSELING CENTER: uccstaff@uwyo.edu, 766-2187, 766-8989 (After hours), 341 Knight Hall, www.uwyo.edu/ucc

ACADEMIC AFFAIRS: 766-4286, 312 Old Main, www.uwyo.edu/acadaffairs

DEAN OF STUDENTS OFFICE: dos@uwyo.edu, 766-3296, 128 Knight Hall, www.uwyo.edu/dos

UW POLICE DEPARTMENT: uwpd@uwyo.edu, 766-5179, 1426 E Flint St, www.uwyo.edu/uwpd

STUDENT CODE OF CONDUCT WEBSITE: www.uwyo.edu/dos/conduct

COVID-19 Policies – during this pandemic, you must abide by all UW policies and public health rules put forward by the City of Laramie (or by Natrona County if at UW-Casper), the University of Wyoming and the State of Wyoming to promote the health and well-being of fellow students and your own personal self-care. The current policy is provided for review at: <https://www.uwyo.edu/alerts/campus-return/index.html>

As with other disruptive behaviors, we have the right to dismiss you from the classroom (Zoom and physical), or other class activities if you fail to abide by these COVID-19 policies. These behaviors will be referred to the Dean of Students Office using the UWYO Cares Reporting Form for Student Code of Conduct processes (https://cm.maxient.com/reportingform.php?UnivofWyoming&layout_id=5).

Syllabus Changes: I will alert you to any possible course format changes in response to UW decisions about community safety during the semester.

HyFlex, Zoom, and WyoCourses expectations:

As with all UW coursework, this course will be educational and useful to you. I will respond to questions, concerns, and feedback in a timely manner.

Your responsibilities:

- Give and receive feedback from me and your classmates respectfully and constructively in all interactions. This includes in Zoom chats, on WyoCourses boards, and within physical classroom spaces.
- Actively engage in civil discourse in a respectful manner. Use professional language in all course related forums.
- Communicate professionally. Whenever you send class-related email or messages, please include a clear, specific subject line and use the body of the email or message to explain the purpose for the email and any attached materials. Conduct yourself professionally.
- Meet assignment deadlines. We expect that you're interacting with course material multiple times during the week.

- Ask for help when you need it. For academic assistance for this course please contact me for available resources. For Dean of Students assistance please see: <https://www.uwyo.edu/dos/student-resources/covid-19-student-resources.html>
- Please let us know if you notice another student who needs help in our (anonymous) WyoCares referral option (<https://www.uwyo.edu/dos/students-concern/index.html>).

Information Technology (IT): If you have any IT related challenges, please contact the UWIT Service Center: <https://uwyo.teamdynamix.com/TDClient/1940/Portal/Requests/ServiceDet?ID=8890>

Discussion Board (Class) Preparation/Participation

Grading Rubric

(25% 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.