

**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](mailto: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 final 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.

**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: Medicare 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
- Oylar 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.

#### **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.

**Course Outline:**

Unit 0: Background Readings and Reflections on Pharmacy Regulation

Assigned Readings	<ul style="list-style-type: none"><li>• U. S House of Representatives, FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?</li><li>• U S Government Accountability Office, Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm</li></ul>
Case Studies	<ul style="list-style-type: none"><li>• United States v. Joseph</li><li>• Nguyen v. United States</li><li>• United States v. Stepanets</li></ul>

Unit 00: Background Readings and Reflections on Pharmacy Regulatory Compliance Strategies

Assigned Readings	<ul style="list-style-type: none"><li>• Sawicki, Character, Competence, and The Principles of Medical Discipline</li><li>• CQI Compliance Guide for Florida Pharmacies</li></ul>
Case Studies	<ul style="list-style-type: none"><li>• Jones Total Health Care Pharmacy v. DEA</li><li>• Carlson v. Ohio Board of Pharmacy</li><li>• Oyler v. Hy-Vee</li></ul>

Unit I: The Regulatory Climate of Pharmacy and Pharmaceuticals

Background Articles	<ul style="list-style-type: none"><li>• Borchers, et al., The History and Contemporary Challenges of the US Food and Drug Administration.</li><li>• Mitchell, Deregulating Mandatory Medical Prescription</li><li>• Mossialos et al., Expanding the Role of Community Pharmacists: Policymaking in the Absence of Policy-Relevant Evidence?</li></ul>
Assigned Legal Case	<ul style="list-style-type: none"><li>• Powers v Thobani</li></ul>
Assigned Videos	<ul style="list-style-type: none"><li>• The FDA and the Pharmaceutical Industry</li></ul>

	<a href="http://www.youtube.com/watch?v=eevMBleMM2Q">http://www.youtube.com/watch?v=eevMBleMM2Q</a> <ul style="list-style-type: none"> <li>• The Abuse of Prescription Drugs</li> </ul> <a href="http://www.youtube.com/watch?v=ILx8Mo0Edac">http://www.youtube.com/watch?v=ILx8Mo0Edac</a> <ul style="list-style-type: none"> <li>• Supreme Court of Florida Oral Arguments in Your Druggist v. Powers Case</li> </ul> <a href="http://wfsu.org/gavel2gavel/selectcase.php?year=2006&amp;month=5">http://wfsu.org/gavel2gavel/selectcase.php?year=2006&amp;month=5</a> (Enter May, 2006 for date, and click on Your Druggist v. Powers)
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Unit II: Pharmacy From the Perspective of the Supreme Court

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

Unit III: Foundations of Pharmacy Regulation

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

Unit IV: The Process of Regulation in Pharmacy

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

Unit V: Contemporary Issues in Pharmacy Regulation

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

	<ul style="list-style-type: none"> <li>• Meeting Patient Education Responsibilities</li> </ul>
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Unit VI: Principles of Regulatory Compliance

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

Unit VII: Regulatory Compliance Case Studies

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

Final 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](mailto: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](http://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](mailto:udss@uwyo.edu), 766-3073, 128 Knight Hall, [www.uwyo.edu/udss](http://www.uwyo.edu/udss)

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

ACADEMIC AFFAIRS: 766-4286, 312 Old Main, [www.uwyo.edu/acadaffairs](http://www.uwyo.edu/acadaffairs)

DEAN OF STUDENTS OFFICE: [dos@uwyo.edu](mailto:dos@uwyo.edu), 766-3296, 128 Knight Hall, [www.uwyo.edu/dos](http://www.uwyo.edu/dos)

UW POLICE DEPARTMENT: [uwpd@uwyo.edu](mailto:uwpd@uwyo.edu), 766-5179, 1426 E Flint St, [www.uwyo.edu/uwpd](http://www.uwyo.edu/uwpd)  
STUDENT CODE OF CONDUCT WEBSITE: [www.uwyo.edu/dos/conduct](http://www.uwyo.edu/dos/conduct)