

UNIVERSITY OF WYOMING

PHCY 5248

THE OPIOID CRISIS, 2 Credit Hours

Asynchronous Online Delivery, Through WyoCourses

This Course Meets Daily on the Discussion Board in WyoCourses

Instructor Contact Information:

Professor David Brushwood, R.Ph., J.D., Phone: 307 766-6120, Email: dbrushwo@uwyo.edu, Office: HS 292. Your professor does not maintain an office in Laramie. Electronic communication through telephone or email (preferred) will always be welcomed.

Office Hours:

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

Course Prerequisites, Co-requisites, and Enrollment restrictions:

This course is open to professional students, and graduate students, with no prerequisites.

Course Description: The responsibility for safe and effective treatment of chronic pain is reviewed. The corollary responsibility for the prevention of opioid abuse is discussed. Regulatory compliance systems are developed to provide a patient-centered and evidence-based approach to deterring opioid abuse.

Student Learning Objectives:

Knowledge-Based Learning Objectives

- Describe the history of opioid use in the United States from the late 1700s through the present day.
- List the core features of the federal Controlled Substances Act, as administered by the federal Drug Enforcement Administration.
- Distinguish between regulatory approaches to controlled substance law that medicalize addiction and abuse and regulatory approaches to controlled substance law that criminalize addiction and abuse.
- Describe the pain management movement that emerged in the late 1900s, leading to enactment by United States Congress of the Pain Relief Promotion Act of 2000.
- Discuss how the “War on Drugs” created challenges to the provision of opioid medications to patients in pain.
- Compare the financial, social, and emotional costs of untreated and undertreated chronic pain with the financial, social, and emotional costs of addiction to opioids.
- Describe how the development, approval, and promotion of OxyContin and other extended release opioids led to tragic consequences that were both foreseeable and unforeseeable.

- Discuss the factors that led to expanded use of opioid pharmaceuticals, and of illicit opioids, creating a crisis of abuse, addiction, and death.
- Evaluate legal case studies related to the responsibilities for opioid distribution on the part of the manufacturer, regulator, distributor, prescriber, pharmacy, and patient.
- Discuss how the evidence-based and outcomes-oriented approach known as “responsive regulation” can reduce opioid misuse/abuse, and enhance the quality of life for patients in pain.

Application-Based Learning Objectives:

- Screen an order for opioid analgesic medication to determine whether the order meets applicable regulatory requirements.
- Counsel a patient on the appropriate use of opioid analgesics, to prevent diversion and/or abuse.
- Consult with other healthcare professionals regarding the legal aspects of opioid analgesic usage.
- Implement a policy for detection and resolution of “red flags” that may signify the illegal use of opioid analgesics.

Practice-Based Learning Objectives:

- Develop a regulatory guidance document for clinical practice compliance with regulations related to opioid analgesics.
- Evaluate a scenario in which a healthcare professional or institution is alleged to have violated regulatory requirements related to the use of opioid analgesics.
- Consult with a regulatory agency in the consideration of new legal requirements that will allow access to opioid analgesics for those patients who need them, but deny access to opioid analgesics for those persons who would divert and/or abuse them.

Required texts, readings, and special tools or materials:

There is no textbook. However, there are background readings that must be downloaded from the internet (these readings are subject to change when they are updated or replaced by more current readings from the same source or from an alternative source). Selections from these documents will be assigned as required reading prior to each of the pre-recorded lectures.

- United States Government Accountability Office. PRESCRIPTION DRUGS OxyContin Abuse and Diversion and Efforts to Address the Problem (2003). <https://www.gao.gov/assets/gao-04-110.pdf>
- United States Department of Health and Human Services. Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths (2015). https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//56406/ib_OpioidInitiative.pdf
- National Institute on Drug Abuse. Misuse of Prescription Drugs Research Report (2020). <https://www.drugabuse.gov/download/37630/misuse-prescription-drugs-research-report.pdf?v=add4ee202a1d1f88f8e1fdd2bb83a5ef>
- United States Food and Drug Administration. FDA’s Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (2018).

https://www.accessdata.fda.gov/drugsatfda_docs/remis/Opioid_analgesic_2018_09_18_FDA_BIueprint.pdf

- Substance Abuse and Mental Health Services Administration. Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (2019). <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf>
- Centers for Disease Control and Prevention. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm
- Drug Enforcement Administration. 2020 National Drug Threat Assessment (2021). https://www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf
- Office of the Inspector General, United States Department of Justice. Review of the Drug Enforcement Administration’s Regulatory and Enforcement Efforts to Control the Diversion of Opioids (2019). <https://oig.justice.gov/reports/2019/e1905.pdf>
- Attorney General of West Virginia. DEA’s Failure to Combat Diversion Cost Lives: Results from the West Virginia Attorney General’s Investigation into the DEA’s Catastrophic Failure to Manage the National Drug Quota System from 2010-2016 (2020). <https://ago.wv.gov/publicresources/Documents/DEA%E2%80%99s%20Failure%20to%20Combat%20Diversion%20Cost%20Lives--Results%20from%20the%20West%20Virginia%20Attorney%20General%E2%80%99s%20%20Investigation.pdf>

There are 10 Pre-Recorded lectures that must be viewed, studied, and discussed on the discussion board:

- The Current Opioid Crisis is Not Unprecedented
- Creating a (Supposedly) Closed System of Distribution for Drugs that are Subject to Abuse
- The Best of Intentions to Help People who Hurt Enjoy Life by Removing Their Pain
- Technology Solves Some Problems and Creates Others Due to the Law of Unintended Consequences
- The “Perfect Storm” Causes an Explosion of Opioid Abuse
- Overview of Manufacturer/Distributor Responsibilities
- Overview of Pharmacy/Prescriber Responsibilities
- Overview of Regulatory Agency Responsibilities
- Overview of Patient and Drug User Responsibilities
- Responsive Regulation as A Collaborative Approach to Regulatory Problem Solving

There are 6 journal articles that must be read, studied, and evaluated on the discussion board:

- Musto, Opium, Cocaine, and Marijuana in American History. Scientific Am. (1991)
- Courtwright, The Controlled Substance Act: How a “Big Tent” Reform Became a Punitive Drug Law. Drug Alcohol Dep. (2014)

- Brennan, The US Congressional “Decade on Pain Control and Research” 2001-2011: A Review. J Pain & Palliative Care Pharm. (2015)
- Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am J Pub Health. (2008)
- Makhinson et al., The iatrogenic opioid crisis: An example of ‘institutional corruption of pharmaceuticals’? J Eval Clin Pract. (2021)
- Califf, et al., A Proactive Response to Prescription Opioid Abuse. NEJM (2016)

General requirements and expectations for the course:

The first five modules of this course, and the final module (Module X), require viewing of an online pre-recorded lecture, reading a posted journal article, participation in the discussion board, and a module exam. In modules VI through IX, there will be student presentations of case studies assigned by the instructor, with discussion of these case study presentations on the discussion board.

Upon completion of all modules, students must take a proctored comprehensive exam.

Final Examination or Final Project Date:

There is no final exam. However, there is a proctored comprehensive exam that must be taken once the course modules have been completed.

Grading Scale and Grading Policies: Attendance and Absence policies.

The final grade in this course will be comprised of:

Ten Unit Exams	30%
Comprehensive Exam	30%
Class Participation	25%
Case Study Presentation	15%

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.

Satisfactory participation in this course requires active posting on the course discussion board for each module (minimum of two posts per module), completion of the module exams, and completion of the proctored cumulative exam.

Classroom Behavior Policy

At all times, treat your presence in the classroom (discussion board) and your enrollment in this course as you would a job. Act professionally, pay attention to instructions and to your student colleagues, complete your work in a timely and professional manner, and treat all deadlines seriously. 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 classroom, study sessions, 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: Statement referring to your duty to report status as instructional personnel under Title IX.

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:

Note: This syllabus is a guide. Circumstances may alter the reading and/or test schedules. You are required to check WyoCourses and your email at least once a week.

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

Schedule of topics, activities, and assessment methods:

Module	Topic	Recorded Lectures	Assigned Articles	Assessment
I	Opioid Crises of the Past	The Current Opioid Crisis is Not Unprecedented	Musto, Opium, Cocaine, and Marijuana in American History. Scientific Am. (1991)	Discussion Bd Case Study Module Exam
II	Comprehensive Federal Regulation of Controlled Substances	Creating a (Supposedly) Closed System of Distribution for Drugs that are Subject to Abuse	Courtwright, The Controlled Substance Act: How a “Big Tent” Reform Became a Punitive Drug Law. Drug Alcohol Dep. (2014)	Discussion Bd Case Study Module Exam
III	The Pain Management Movement	The Best of Intentions to Help People who Hurt Enjoy Life by Removing Their Pain	Brennan, The US Congressional “Decade on Pain Control and Research” 2001-2011: A Review. J Pain & Palliative Care Pharm. (2015)	Discussion Bd Case Study Module Exam
IV	OxyContin and Other ER Opioid Products	Technology Solves Some Problems and Creates Others Due to the Law of Unintended Consequences	Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am J Pub Health. (2008)	Discussion Bd Case Study Module Exam
V	A Public Health Epidemic	The “Perfect Storm” Causes an Explosion of Opioid Abuse	Makhinson et al., The iatrogenic opioid crisis: An example of ‘institutional corruption of pharmaceuticals’? J Eval Clin Pract. (2021)	Discussion Bd Case Study Module Exam
VI	Manufacturer/Distributor Responsibility for the Opioid Crisis	Overview of Manufacturer/Distributor Responsibilities	Legal Cases as Assigned to students by the Instructor	Discussion Bd Case Study Presentations
VII	Pharmacy/Prescriber Responsibility for the Opioid Crisis	Overview of Pharmacy/Prescriber Responsibilities	Legal Cases as Assigned to students by the Instructor	Discussion Bd Case Study Presentations
VIII	Regulatory Agency Responsibility for the Opioid Crisis	Overview of Regulatory Agency Responsibilities	Legal Cases as Assigned to students by the Instructor	Discussion Bd Case Study Presentations
IX	Patient and Drug User Responsibility for the Opioid Crisis	Overview of Patient and Drug User Responsibilities	Legal Cases as Assigned to students by the Instructor	Discussion Bd Case Study Presentations
X	Regulatory Solutions to the Opioid Crisis	Responsive Regulation as A Collaborative Approach to Regulatory Problem Solving	Califf, et al., A Proactive Response to Prescription Opioid Abuse. NEJM (2016)	Discussion Bd Case Study Module Exam
Comp Exam				Proctored Comp Exam

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.

Case Study Assessment Presentation
Grading Rubric
(15% of Grade)

	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 with insightful comments.	Student is uncomfortable with information and addresses 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 uses 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 understanding 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.