

PHCY 5243 The Drug Enforcement Administration
2 Credit Hours

Background:

The current opioid public health crisis represents a complex interplay among patients, the pharmaceutical industry, the medical community, and regulatory agencies. The Drug Enforcement Administration (DEA) is the primary federal agency charged with enforcing the controlled substance laws and regulations of the United States and bring to the criminal justice system those organizations and individuals involved in the illicit drug traffic in the United States. In addition, the DEA recommends and supports non-enforcement programs aimed at reducing the availability of illicit controlled substances. Health professionals who fail to comply with laws and regulations pertaining to controlled substances run a significant risk of incurring regulatory and civil penalties.

Course Description:

Given the declaration of opioid dependence and addiction as a public health emergency in the United States, this course will examine the role and function of the DEA in combating this crisis. Through case law, scholarly publications, and timely articles the course will explore both the powers of the DEA as well as the limitations that have been placed on the Agency. In addition, the course will provide insight into the complexities of the opioid crisis and the challenges facing health professionals and health institutions when working closely with regulators to develop programs that reflect both the best interests of individual patients and the best interests of society. Strategies to provide solutions to the opioid crisis are considered.

Course Purpose:

The purpose of this course is to understand the role of the DEA in national controlled substance management while providing knowledge and skills necessary for the development and implementation of a risk management and regulatory compliance program at the institutional level. Viewed through the lens of the opioid crisis, the course will also provide an opportunity to understand the complexities of this national crisis while simultaneously ensuring that patients with legitimate medical needs are not prevented from obtaining controlled substances when indicated.

Place and Time of Class Sessions:

This is a condensed course that will be taught over a five week period. The course will be taught in a blended fashion, with organized class sessions being combined with heavy reliance on an active discussion board. Learning materials will be posted on WyoCourses and may be accessed at any time. Participation in the discussion board is mandatory. Successful discussion board participation requires one original post and two responsive posts each week. There will be five exams that will start at 7am on Fridays and will end at noon on Sundays.

Course Instructor: David W. Bobb, RPh, MS, JD

Phone: 210-284-8287

Email: dbobb1@uwyo.edu

Office Hours: TBD

Course Objectives:

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

- Briefly discuss the history of drug abuse in the United States, why the DEA was created in the early 1970s, what it was intended to do, and how its mission has expanded to become the entity it is today.
- Identify trends from recent Controlled Substance Act violations the DEA investigates and enforces that typically result in court cases.
- Describe the major components of the DEA’s interpretation of “legitimate medical purpose” under the Controlled Substances Act and the “corresponding responsibility” standard under DEA Regulation 21 C.F.R. § 1306.04(a) (2014), and how they apply to both pharmacists and prescribers.
- Identify the legal and political challenges facing the DEA when investigating and enforcing the drug laws of the United States, especially in the context of the opioid crisis.
- Summarize the complex nature of the current opioid crisis including the multiple organizations, entities, and individuals contributing to the crisis and the limits of DEA and other law enforcement efforts to curb or end the crisis.
- Discuss how the central principle of balance can be applied in the treatment of chronic pain patients and the regulation of controlled substances to meet the needs of both patients and regulatory authorities.
- List the elements of an effective risk reduction strategy that prevents controlled substance diversion.
- Identify current and proposed tools incorporated by local, state, and federal entities to combat the opioid crisis and develop strategies to control the crisis while ensuring legitimate pain patients have access to opioids when indicated.

Course Learning Resources:

- Monographs
 - Drug Enforcement Administration 1970-1975
 - Drug Enforcement Administration: The Early Years
- Journal Articles
 - Beletsky, et al., Today’s fentanyl crisis: Prohibition’s Iron Law, revisited
 - Bowe, Fixing Pharma’s Incentives Problem in the Wake of the U.S. Opioid Crisis
 - Brushwood et al., Legal Liability Perspectives on Abuse-Deterrent Opioids in the Treatment of Chronic Pain
 - Buchmueller and Carey, The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare
 - Compton, et al., Relationship between Nonmedical Prescription Opioid Use and Heroin Use
 - Dave, et al., Mandatory Access Prescription Drug Monitoring Programs and Prescription Drug Abuse
 - Egan, et al., From dispensed to disposed: evaluating the effectiveness of

- disposal programs through a comparison with prescription drug monitoring program data
- Grass, *The Medicine Shoppe v. Loretta Lynch*, et al: Pharmacists and Prescribing Physicians are Equally Liable
 - Jones, et al., Effect of US Drug Enforcement Administration's Rescheduling of Hydrocodone Combination Analgesic Products on Opioid Analgesic Prescribing
 - Kertesz, Turning the tide or riptide? The changing opioid epidemic
 - Linder, et al., Opioid Overdoses: Prosecution Risk and the Need for Naloxone
 - Marlowe et al., Malpractice Liability and Medical Marijuana
 - Penm, et al., Strategies and policies to affect the opioid epidemic: A case study of Ohio
 - Rudd, et al., Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015
 - Newspaper Articles
 - Bernstein, Lenny and Higham, Scott, The Washington Post Investigative Report, *"We felt like our system was hijacked' DEA agents say a huge opioid case ended in a whimper"*
 - Bernstein, Lenny and Higham, Scott, The Washington Post Investigative Report, *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control*
 - Bernstein, Lenny and Higham, Scott, The Washington Post Investigative Report, *The Drug Industry's Triumph over the DEA*
 - Bernstein, Lenny, Fallis, David and Higham, Scott, The Washington Post Investigative Report, *How drugs intended for patients ended up in the hands of illegal users: "No one was doing their job"*
 - Craig, Tim and Lewis, Nicole, The Washington Post, *As opioid overdoses exact a higher price, communities ponder who should be saved*
 - Legal Case Studies

Course Structure & Outline:

This course is comprised of five modules, to be completed over a period of five weeks.

The five modules are:

- The history, structure, and function of the DEA under the Controlled Substances Act.
- How the DEA enforces policy: procedures, cases, and successes in combating illicit drug use in the United States.
- The opioid crisis in the United States: the role of the DEA in prevention and the effectiveness of programs and tools implemented to curb the crisis.
- Government policy and legal challenges the DEA faces in executing the laws designed to reduce illegal opioid use.
- Developing a DEA compliant hospital or pharmacy controlled substance monitoring program to deter theft and misuse while meeting legitimate patient pain medication needs.

Course Schedule:**Week I: History, Structure, and Function of the DEA under the CSA**

- Live class meets on March 14.
- Discussion board is open all week.
- Quiz I opens on Friday at 7am, closes on Sunday at noon.

Week II: How the DEA enforces policy: procedures, cases, and successes in combating illicit drug use in the United States

- Live class meets on March 21.
- Discussion board is open all week.
- Two to three page paper opens on Friday at 7am, closes on Sunday at noon.

Week III: The opioid crisis in the United States: the role of the DEA in prevention, and the effectiveness of programs and tools used to curb the crisis

- Live class meets on March 28.
- Discussion board is open all week.
- Quiz III opens on Friday at 7am, closes on Sunday at noon.

Week IV: Government policy and legal challenges the DEA faces in executing the laws designed to reduce illegal opioid use

- Live class meets on April 4.
- Discussion board is open all week.
- Two to three page paper opens on Thursday at 7am, closes on Sunday at noon.

Week V: Developing a DEA compliant hospital or pharmacy controlled substance monitoring program to deter theft and misuse while meeting legitimate patient pain medication needs.

- Live class meets on April 11.
- Discussion board is open all week.
- Final Exam opens on Friday at 7am, closes on Sunday at noon.

Evaluation Techniques:

Class participation (discussion board)	30%
Quizzes and Papers	40%
Final Exam	30%

Grading:

A:	90.0 – 100.0
B:	80.0 – 89.9
C:	70.0 – 79.9
D:	60.0 – 69.9
F:	<60.0

Class Attendance Policy:

Attendance at scheduled online classes through Big Blue Button is mandatory. The course coordinator will excuse students from class based on a valid reason. Classes will be recorded for later viewing (within two weeks) by students who have been excused from attendance. There is a requirement for weekly postings on the course discussion board. All postings must relate to the general course objectives. All students are

expected to make weekly posts that are relevant to the course based on material that is being completed that week.

Exams/Written Exercises Policy:

Inquiries regarding exams and written exercises should be directed to the course coordinator, preferably prior to the assessment, and always within a week following the assessment.

Make-up Exam Policy:

Students who are excused from an exam will not be required to make up that assessment and their final grade will be calculated without consideration of the missed assessment. Students who are not excused from a missed quiz or exam will receive a grade of zero on that missed assessment. Any student who misses quizzes and/or exams of a sufficient number that indicate the student has not completed enough coursework to achieve the objectives of the course will be given an incomplete (I) grade for the course.

Policy on Old Exams and Assignments:

At the discretion of the instructor, exams and written exercises may be posted, with answers, to the course discussion board.

Academic Dishonesty Statement:

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. 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://uwadmnweb.uwyo.edu/legal/universityregulations.htm>

Disability Support Statement:

The University of Wyoming is an affirmative action/equal opportunity educator and employer. If you have a physical, learning, or psychological disability and require accommodations, please let the instructor 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 330 Knight Hall. The University Disability Support Services website, which may be found at:
<http://uwadmnweb.uwyo.edu/udss/facultyandstaff/tipsforteaching.asp> or you may contact UDSS for more information at (307) 766-6189, TTY: (307) 766-3073

Course Schedule

Mod	Subject	Case Studies	Readings	Interactive Learning	Assessment
I 1 wk	History, Structure, and Function of the DEA under the Controlled Substance Act	-U.S. v. Agyekum	-DEA Origins -The Early Years -DEA History 2009-2013 -Courtwright Article	Lecture: The Opioid Crisis and the DEA: Bad Prescribers, Bad Pharmacists, or Bad Patients? Discussion Board Live Class on 3-14-18	Quiz (multiple choice) Disc Bd Participation
II 1 wk	How the DEA enforces policy: procedures, cases, and successes in combating illicit drug use in the United States	-Masters Pharmaceutical - U.S. v. Almonte-Baez -U.S. v. Okonkwo	-Medicine Shoppe v. Loretta Lynch Article	Lecture: Legitimate Medical Use & Corresponding Responsibility: How Much is Enough? Discussion Board Live Class on 3-21-18	Quiz (multiple choice) Disc Bd Participation
III 1 wk	The opioid crisis in the United States: the role of the DEA in prevention, and the effectiveness of programs and tools used to curb the crisis		-Drug and Opioid OD Deaths -Medical Marijuana -Opioid and Heroin Use -Prohibition's Iron Law -Turning the Tide or Riptide -Who to Treat	Discussion Board Live Class on 3-28-18	Quiz (multiple choice) Disc Bd Participation
IV 1 wk	Government policy and legal challenges the DEA faces in executing the	-Tug Valley v. All Plaintiffs -U.S. v. Utah	-DoJ Opioids 2016 -Hijacked System -Lobbyists -Wholesalers	Discussion Board Live Class on 4-4-18	Short Paper Disc Bd Participation

	laws designed to reduce illegal opioid use				
V 1 wk	Developing a DEA compliant hospital or pharmacy controlled substance monitoring program to deter theft and misuse while meeting legitimate patient pain medication needs.		<ul style="list-style-type: none"> -From Dispensed to Disposed -Effect of PDMPs -Mandatory PDMP -Opioid Strategies – Ohio -Pharma’s Incentives Problem -Compliance Program Corresponding Responsibility -Establishing a Controlled Substance Compliance Program -Best Practices 	<p>Discussion Board</p> <p>Live Class on 4-11-18</p>	<p>Final Exam</p> <p>Disc Bd Participation</p>