

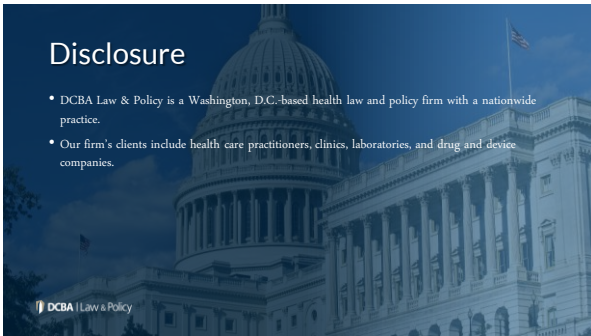


FINDING YOUR FOOTING IN AN EVER CHANGING LANDSCAPE

A LEGAL, REGULATORY, AND PUBLIC HEALTH UPDATE

Shruti Kulkarni, J.D.
International Conference on Opioids | Boston, Massachusetts
June 9, 2019

DCBA | Law & Policy



Disclosure

- DCBA Law & Policy is a Washington, D.C.-based health law and policy firm with a nationwide practice.
- Our firm's clients include health care practitioners, clinics, laboratories, and drug and device companies.

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Learning Objectives

- Evaluate the likely impact of recent and proposed government action on health care, coverage, and professional liability.
- Identify legal and regulatory trends that could impact health care professionals' discretion of practice regimes.
- Summarize the benefits of having written policies and procedures that a practitioner can employ to customize and document care for an individual with pain or opioid use disorder.

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DOJ CRACKDOWN

A horizontal timeline with six circular nodes connected by arrows, detailing the progression of DOJ actions against opioid-related issues:

- DOJ Establishes Opioid Fraud & Abuse Division** - August 2017
- DOJ Issues Prescription Antitrust & Litigation Task Force** - February 2018
- DOJ 60-Day Seize** - April 2018
- DOJ Charges 100 Individuals** - June 2018
- DOJ Issues Prescription Opioid Abuse Task Force** - October 2018
- Federal Prosecution Charge 40 Physicians & Pharmacists** - April 2019

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JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Friday, February 9, 2019

Justice Department Files First of Its Kind Action to Stop Tennessee Pharmacies' Unlawful Dispensing of Opioids

The Justice Department announced an action today to stop three pharmacies, their owners, and their owners' sales from dispensing controlled substance prescriptions, including powerful opioids that have been linked to abuse and diversion. The action is part of a nationwide effort by the department's Prescription Antitrust & Litigation (PAL) Unit. From its inception in 2017, the PAL Unit has worked to ensure the safe and lawful use of controlled substances in the United States. Antitrust & Litigation is a part of the Department of Justice's Civil Division. It is directed by the Chief of the Middle District of Tennessee, D. Christopher Brown, Special Agent in Charge of the U.S. Drug Enforcement Administration's (DEA) Louisville Field Division, and David L. Jackson, Special Agent in Charge of the U.S. Department of Health and Human Services (HHS), Office of Inspector General under the administration.

In a civil complaint filed today in the Middle District of Tennessee, the United States alleges that Collins, Tennessee, defendants, Valley Pharmacy, Inc., John Dale Walker Pharmacy (JDW) Retail and Express Pharmacy of the County (Express), the pharmacies' owner, Thomas West, and pharmacist John Pughon, Michael Griffith, and Larry Lottie were dispensing, and selling hundreds of prescriptions in violation of the Controlled Substances Act and the Public Health Act. According to the United States' complaint, the defendants' unlawful dispensing of opioids has been tied to the deaths of at least two people and numerous others have been hospitalized or unable to receive care within a short time of obtaining controlled substances from the pharmacies.

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New Enforcement Tactics

DEA Criminal & Administrative Actions




Full stories available on centerforinsanity.org


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Continuing Focus on Rx Opioids

- Opioid analgesic prescribing decreased 25 percent between 2012 and 2017.
- Blue tablets (e.g. oxycodone and hydrocodone) are now the most commonly prescribed substances in drug overdose fatalities.
- Policy efforts remain largely focused on restricting access to opioid pain relievers.
- The federal government is seeking to cut nationwide prescription opioid dispensing by an additional one-third by 2021.

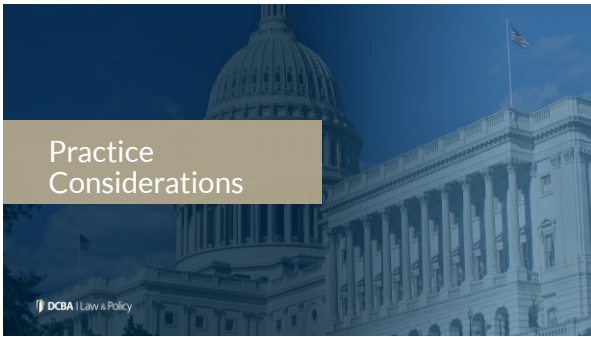


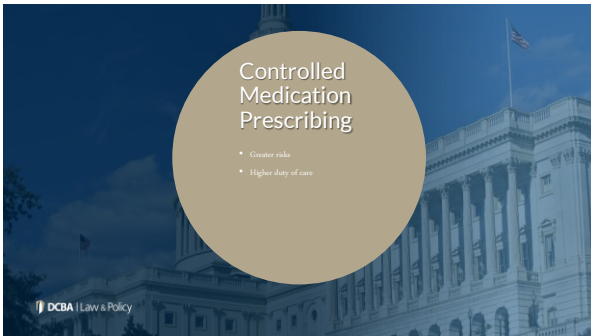


A More Sensible Surge

Requires law enforcement to obtain a referral from a state professional licensing board before instituting, aiding in or conducting a criminal investigation, indictment, or prosecution or civil action against a state licensed health care professional or pharmacist in which medical need or patient care, including the prescribing or dispensing of controlled medications, is at issue.

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Standard of Care

- May be drawn from
 - Government recommendations
 - FDA-approved prescribing information
 - Professional associations' recommendations/guidelines
 - Medical literature
- Facts in proceedings drawn from medical records and witness testimony
 - Deviations from standard of care must be
 - Justified by facts
 - Required by statute
 - Discussed in the medical record

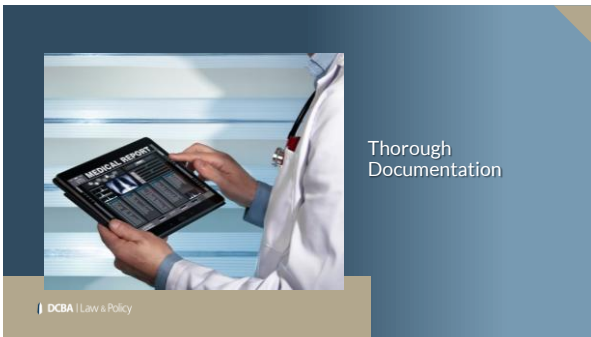
Burns, M.C., PharmD, Journal 2017-2019 | Burns, M.C., Wilson, R., J.D., Ph.D. / Health Care Law 2017-2019 100

Compliance Plan

- Experienced health care legal counsel
- Written policies
- Training
- Monitoring and quality improvement
- Documentation of all medical decisions
- Relationships
 - Law enforcement leaders
 - Reporters
- Engagement in policy & politics

Burns, M.C., PharmD, Journal 2017-2019 | Burns, M.C., Wilson, R., J.D., Ph.D. / Health Care Law 2017-2019 100

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Thorough Documentation

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CDC Clarification, Oregon Stand Down

CDC Issues Key Clarification on Guideline for Prescribing Opioids for Chronic Pain
Agency Clarifies CDC Guideline Not Meant to Limit Access to Appropriate Pain Management for Individuals with Cancer, Sickle Cell Disease

The NEW ENGLAND JOURNAL of MEDICINE

No Shortcuts to Safer Opioid Prescribing
Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., and Roger Chou, M.D.

Oregon's Opioid Tapering Plan Delayed

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OUD Policy

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TIP 63

Medications for Opioid Use Disorder
For Treatment and Relapse Prevention in Outpatient, Residential, and Inpatient Settings

Treatment Improvement Protocol (TIP) #63

Discussing medications that can treat OUD with patients who have this disorder is the clinical standard of care.

TIP 63

SAMHSA

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The New York Times

Opinion

Want to Reduce Opioid Deaths? Get People the Medications They Need

Drugs like buprenorphine could sharply curb the nation's opioid overdose crisis. But federal laws make it difficult for people who need such medications to get them.


By The Editorial Board
The editorial board represents the opinions of the board, its editor and the publisher. It is separate from the newsroom and the Op-Ed section.

March 26, 2019

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X the X Waiver

X the X Waiver



The Mainstreaming Addiction Treatment (MAT) Act

116th Congress

Sponsors: Reps. Paul Tonko (D-NY), Antonio Delgado (D-NY), Ben Ray Lujan (D-NM), Ted Budd (R-NC), Elise Stefanik (R-NY), Mike Turner (R-OH)

"The devastation of America's opioid crisis has touched every part of our country, and access to treatment is a matter of life and death. Our national response needs to rise to meet the unprecedented scale of this crisis."

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FDA Citizen Petition

FDA Blocks New Opioid-Addiction Medications amid Public Health Crisis

<https://www.health.mcgill.ca/2019/04/09/>

Center for U.S. Policy NEWS
April 9, 2019

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Eight Additional Opioid Policy & Practice Trends

- Federal Funding
- Fentanyl-Laced Substances
- Border Seizures
- Integration of Care across Health Settings
- Warm Handoffs and Mobile Medical Services
- Peer Recovery Support Services
- Criminal Justice Programs
 - Pre-Arrest Diversion
 - Treatment in Jails and Prisons
 - Reentry Support
- Comprehensive Treatment and Wraparound Services for All SUDs

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Thank You Questions



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