

512 - OUT OF THE SHADOWS:
Behavioral Health Compliance and
Legal Issues for Every Provider



Presenters



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Overview

- The “Why Now?”: Opioid Epidemic Overview
- Practical Challenges
 - Privacy: 42 CFR Part 2
 - Mandated Reporting / Duty to Warn
 - EMTALA
- Provider-Prescriber Liability and Risk Mitigation
- Questions and Discussion




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Why Now?

- Behavioral Health – mental health and addiction health care services
- ACOs and other integrated care models
- The Opioid Epidemic

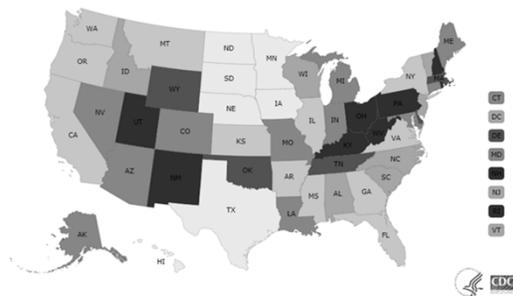
WHY?

Overdose Deaths (2000-2014)

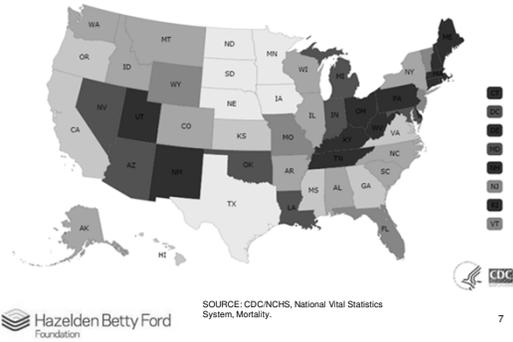


2014: 47,055 United States citizens died from drug overdose. 129 per day.
Source: Haeyon Park and Matthew Block, *New York Times*, *How the Epidemic of Drug Overdose Deaths Ripples Across America*, January 19, 2016

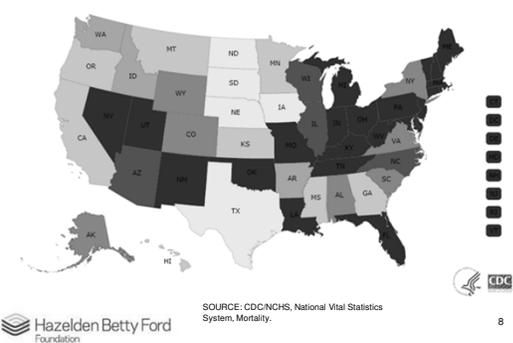
Drug Overdose Deaths by State (2014)



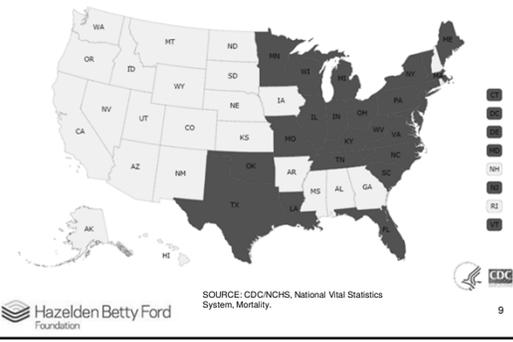
Drug Overdose Deaths by State (2015)



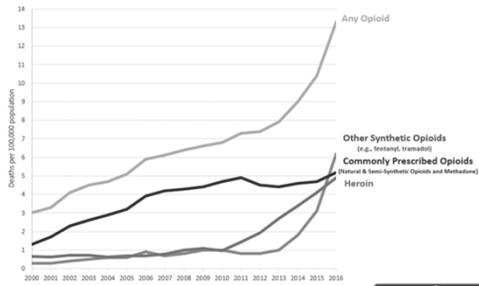
Drug Overdose Deaths by State (2016)



Statistically Significant Overdose Rate Increases (2015-2016)



Opioid Overdose Deaths (2000-2016)

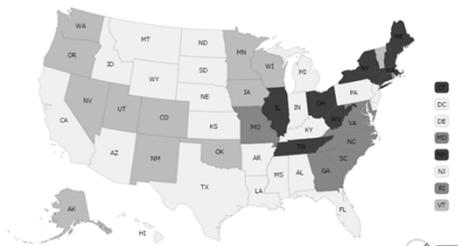


SOURCE: CDC/NCHS, National Vital Statistics System, Mortality, CDC WONDER, Atlanta, GA; US Department of Health and Human Services, CDC, 2017. <https://wonder.cdc.gov/> **www.cdc.gov**

Hazelden Betty Ford Foundation SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. 10

The Rise of Synthetic Opioids

Statistically significant changes in drug overdose death rates involving synthetic opioids (excluding methadone) by select states, United States, 2014 to 2015



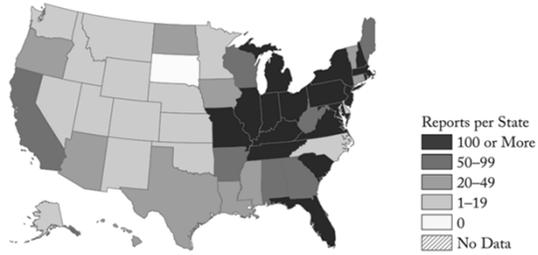
Hazelden Betty Ford Foundation SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. 11

Fentanyl Reports by NFLIS (2001)



Hazelden Betty Ford Foundation SOURCE: DOJ/DEA, Diversion Control Division; National Forensic Laboratory Information System; NFLIS Brief, Fentanyl, 2001-2015. 12

Fentanyl Reports by NFLIS (2015)



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SOURCE: DOJ/DEA, Diversion Control Division; National Forensic Laboratory Information System; NFLIS Brief, Fentanyl, 2001-2015

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Practical Challenges: Privacy

- Addiction: 42 C.F.R. Part 2
- Mental Health
 - States specific statutes and regulations - distinct protections for mental health information
 - Most are above and beyond HIPAA
 - Most stringent standard enforced



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42 C.F.R. Part 2: Introduction

- Limited circumstances under which patient information may be used, disclosed, or re-disclosed
- Much more stringent than HIPAA
 - No treatment, payment or health care operations exceptions
 - Majority of disclosures require written consent
 - Recently updated in 2017 for the first time in decades

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42 C.F.R. Part 2: Applicability

- § 2.12
 - Federally Assisted
 - Definition §2.12(b)
 - Individual or entity who receives federal assistance
 - Examples: 501(c)(3) non-profit, Medicare, Medicaid, DEA license
 - Substance Use Disorder Program
 - Definition of Program: §2.11
 - individual or entity that holds itself out as providing or does provide SUDs diagnosis, treatment, or referral to treatment

42 C.F.R. Part 2: Consent

- Authorization (HIPAA term) called a "consent"
- Written consent only valid if the form includes the required elements (§ 2.31), except:
 - General designation for "treating providers" only
 - Third party payers still require name of entity, but not an individual at the payer
 - All other consents, individual must be named
- Limited exceptions for disclosure without consent (See § 2.51-2.53)
 - Bone Fide Medical Emergency
 - Child Abuse Reporting
 - Audit and Evaluation

42 C.F.R. Part 2: Re-disclosure Prohibition

- Required notice to accompany all disclosures with patient consent (§ 2.32)
- Prohibits re-disclosure without separate consent from patient

Practical Challenge: Mandated Reporting

- Generally state specific requirement:
 - Mandated Reporting:
 - Child abuse / neglect
 - Vulnerable adult abuse
 - Pregnant patient chemical use
 - Duty to Warn, aka *Tarasoff* warning
- Develop policies and procedures
 - How and when?
 - Who does it?



Understand how this interacts with Privacy!

Practical Challenge: EMTALA

- Behavioral health issues trigger EMTALA obligations
 - Examples: drug overdose, suicidal ideation, confusion
- Federal preemption
 - Do not rely on community plans
- ERs need to address behavioral health conditions
 - Covert physical health issue?
 - True mental health crisis?
 - Do you have specialty providers available to screen, examine or treat?



EMTALA

- Examine, stabilize, and treat or transfer challenges
 - Lack of psychiatric or addiction beds
 - Unprepared providers
 - Vague protocols
 - Use of chemical or physical restraints for stabilization
 - Boarding patients
- Build knowledge of community providers
- Review / develop policies and procedures
 - Address screening, examination, and stabilization
 - Protocols to appropriately address common challenges (i.e. adequate medical examination, boarding concerns)
 - Responsible and reasonable transfer protocols and resources

The Pendulum Effect

- **1996:** American Pain Society introduced “Pain as the Fifth Vital Sign”
 - Push for physicians to recognize the importance of properly assessing and treating pain.
- **2000’s:** opioid prescriptions increased 10-fold compared to the 1990’s (decade-over-decade comparison)
- **Today:** Staggering overdose and addiction increases
 - Cost of opioid epidemic is in excess of \$60 billion per year
 - 1,000 emergency room visits per day due to overdoses
 - Natural tendency: find someone to blame

General Trends in Accountability

- Pharmaceutical companies
 - Lawsuits by individuals
 - Lawsuits by county attorneys seeking damages related to public cost of opioid crisis
 - Allege fraud and knowingly false statements regarding the addictive properties of opioids
 - States proposing per-pill tax on opioids
 - Proposed in at least 13 states (MN most recently)

General Trends (continued)

- Prescribing physicians
 - Increased focus by prosecutors
 - Federal Controlled Substances Act
 - 2011: 88 actions against physicians
 - 2014: 371 actions against physicians
 - Increased focus by state medical boards
 - 40% increase in actions against physicians between 2004 and 2014
 - Increased exposure to civil liability

Criminal Liability—the “Bad” Doctors

- Traditional standard for criminal liability under Controlled Substances Act
 - Prove beyond a reasonable doubt that physician knowingly:
 1. Prescribed a controlled substance
 2. Without a legitimate medical purpose
 3. Outside the course of professional practice
 - Just being a negligent doctor not enough
 - Just committing malpractice not enough
 - Doctor must knowingly and intentionally violate standards of professional practice and knowingly and intentionally prescribe without a legitimate medical purpose

“Willful Blindness”

- *U.S. v. Katz* (8th Cir. 2006)
 - Egregious facts
 - Katz’s defense: He was merely a negligent doctor, not a criminal one.
 - Claimed he didn’t *know* the prescriptions he was writing were for non-medical purposes
 - Court: upheld conviction based on “willful blindness” standard
 - Katz may not have *known*, but he turned a blind eye to facts that, if investigated, would have shown the patients had no legitimate medical purpose for seeking the prescribed drugs
 - Convicted of 176 counts of illegal distribution of controlled substances
 - Other jurisdictions have followed suit, applying “willful blindness” in prescribing cases

Civil Liability—the “Negligent” Doctor

- Historic standard:
 - Civil liability for prescribers has typically been limited to malpractice actions where a physician’s negligence harmed an innocent patient
 - Negligence Standard: “What would a reasonably prudent physician in the same position do?”
- “Wrongful conduct rule”
 - “A person cannot maintain an action if, in order to establish his cause of action, he must rely, in whole or in part, on an illegal or immoral act or transaction to which he is a party.”
 - Michigan Supreme Court’s “modern statement” of the wrongful conduct rule in *Orzel v. Scott Drug* (1995)
 - Essentially eliminates any claims by individuals with opioid use disorders, who would have to admit illegal behavior

Tug Valley Pharmacy v. Mingo

- 2015 West Virginia Supreme Court case
- Factual Background:
 - 29 plaintiffs brought claims against 4 doctors, 3 pharmacies, and 1 medical center
 - Plaintiffs claimed that the defendants negligently prescribed and/or dispensed opioids, leading to or continuing plaintiffs' addictions
 - To bring their claims, plaintiffs admitted to some or all of the following criminal activities:
 - Criminal possession of pain medications
 - Criminal distribution of pain medications
 - Fraud, forgery, or deception to acquire opioids
 - Doctor shopping (obtaining prescriptions from multiple doctors)

Tug Valley Pharmacy v. Mingo

- Certified question to West Virginia Sup. Ct.:
 - "May a person maintain an action if, in order to establish the cause of action, the person must rely, in whole or in part, on an illegal or immoral transaction to which the person is a party?"
 - Every time this question had previously been asked of a higher court in the United States in the context of addiction, the answer had been resoundingly "NO"
- What did West Virginia Supreme Court say?
 - Wrongful conduct rule did not apply
 - Rather, "comparative fault" analysis applies—you have to compare the fault of the plaintiff to the fault of defendant.
 - If Defendant is more at fault, plaintiff can recover
 - Allowed plaintiffs to proceed with their claims

Take-away from Tug Valley Pharmacy

- Microcosm of the changing views of addiction?
 - Majority, in addressing comparative fault:
 - "In fact, it may reasonably be argued that wrongdoing by highly trained, licensed professionals, charged with the grave responsibility of the health and welfare of the public, may actually be considered more abhorrent" than the criminal activities of the drug users/seekers
 - **Result:** Jury of peers should determine who is more at fault
 - Dissent, in advocating for the "wrongful conduct rule":
 - "In a state where drug abuse is so prevalent and where its devastating effects are routinely seen in cases brought before this Court, it is simply unconscionable to me that the majority would permit admitted drug abusers to manipulate our justice system to obtain monetary damages to further fund their abuse and addiction."

What does this have to do with Part 2?

- Legal trend: Juries will be given the opportunity to decide who is or is not a “reasonably prudent physician,” and viewpoints on addiction and prescribing are changing
- Prescriber access to information about a patient’s history of substance use disorder may be limited, or totally obscured, by Part 2.
 - But risks related to over-prescribing opioids to a person recovering from an opioid use disorder are even greater
- How can prescribing physicians protect themselves?

CDC Guidelines for Prescribing Opioids

CDC Centers for Disease Control and Prevention
CDC 1610 Clifton Road, NE Atlanta, GA 30333

Morbidity and Mortality Weekly Report (MMWR)
Vol. 65, No. 10, March 12, 2016

CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016

CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Promoting Patient Care and Safety

THE US OPIOID OVERDOSE EPIDEMIC

The United States is in the midst of an epidemic of prescription opioid overdoses. The amount of opioids prescribed and sold in the US quadrupled since 1999, but the worst amount of pain reported by Americans hasn't changed. This epidemic is devastating American lives, families, and communities.

40% More than 40 people die every day from opioid overdoses.

165K More than 165,000 people die every year from overdoses on prescription opioids.

4.3M 4.3 million prescriptions for painkillers are written every day in the United States.

PRESCRIPTION OPIOIDS HAVE BENEFITS AND RISKS

Many Americans suffer from chronic pain. These patients deserve safe and effective pain management. Prescription opioids can help manage some types of pain in the short term. However, we don't have enough information about the benefits of

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Avoiding Potential Prescriber Liability

- Center for Disease Control (CDC) list of recommended practices
 - First ever uniform federal guidelines for prescribing pain killers
 - 12 recommendations within three general categories of guidelines
- Category 1: Determining when to initiate or continue opioids for chronic pain
- Category 2: Opioid selection, dosage, duration, follow-up, and discontinuation
- Category 3: Assessing risk and addressing harms of opioid use

Avoiding Liability Beyond the CDC Guidelines

- The PDMP is your best friend
 - Visit it early and often
- Obtain detailed patient medical histories and perform thorough physical examinations
 - Always ask about potential red flags -- family history, history of addiction, other medications
- Conduct urine testing
- Mandatory opioid training for prescribers (annual CME)
- Train prescribers regarding how to discuss pain with patients, and how to discuss opioid risks
- Provide products for destruction of left-over opioids

Questions and Discussion