

Opioid Crisis:
How to Monitor for Compliance

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Objectives:

- Current status of the opioid crisis nationwide; organizational risks and impact
- Local coverage determination (LCD) for Controlled Substance Monitoring
- What the PDMP tells you
- Auditing and monitoring medical necessity documentation; monitoring your providers' prescription pattern
- Collaboration with prescribers to mitigate risk
- Compliance Officer role: a success story

Current Status of the Opioid Crisis Nationwide

- In 2016, more than 11.5 million Americans, age 12+, have misused prescription opioids.
- In 2016, more than 63,600 overdose deaths occurred, which 66.4% involved an opioid.
- The number of opioid prescriptions dispensed has declined from 2012 to 2016 by 16% to 236 million prescriptions.
- In 2017, executive order signed President's Commission on Combating Drug Addiction and the Opioid Crisis.
- February 2018, government allocation of \$6 billion for opioid programs and initiation of the Prescription Interdiction & Litigation (PIL) Task Force.
- April 2018, 46 states have aligned with CDC's *Guideline for Prescribing Opioids*

- June 2018, government public awareness campaign to combat opioid addiction.
- 2017 & 2018, large pharmacies (CVS, Walmart) have implemented initiatives to reduce the amount of opioids dispensed and to limit the quantity of controlled medications prescribed.
- In 2017, there were still almost 58 opioid prescriptions written for every 100 Americans.
- More than 17% of Americans had at least one opioid prescription filled, with an average of 3.4 opioid prescriptions dispensed per patient.
- Per prescription, the average daily amount was more than 45.3 MME (*morphine milligram equivalent*).
- The average number of days per prescription continues to increase, with an average of 18 days in 2017.

DEATHS IN THE UNITED STATES, PEAK YEAR

72,306	Drug Overdoses, 2017
54,589	Car Accidents, 1972
50,628	HIV/AIDS, 1995
44,193	Suicides, 2015
24,703	Homicides, 1991
16,899	Vietnam War, 1968

Addiction and Substance Abuse Among HCPs

- ▶ Studies in the United States have shown that 10%-15% percent of HCPs will misuse substances during their lifetime, and rates of prescription drug abuse and addiction are 5 times higher among physicians than in the general population, with especially high rates of benzodiazepine and opioid abuse. Physicians are not the only HCPs affected by drug and alcohol abuse.
- ▶ It's estimated that more than 100,000 physicians, nurses, techs and other healthcare employees are drug addicts, according to federal data.

Organizational Risks and Impact

- ▶ Impaired Employees/ Clinicians
- ▶ Patient Care Interruptions
- ▶ Diversion/Theft
- ▶ Forged Prescription
- ▶ HIPAA violations/Identity Thefts
- ▶ **Reputational Damage**
- ▶ Financial Loss
- ▶ Investigations by federal or state agencies
- ▶ Management Liability (The Responsible Corporate Officer Doctrine)

Controlled Substance Monitoring and Drugs of Abuse Testing Local Coverage Determination (LCD)

- ▶ Urine Drug Testing (UDT) is the main tool used to assist clinicians in identifying the presence or absence of drugs or drug classes in the body and making treatment decisions.
- ▶ Objectives of the UDT:
 - ▶ Identifies presence/absence of prescribed medication (potential for abuse, misuse, and diversion)
 - ▶ Identifies undisclosed substances, such as alcohol, un-prescribed medication, or illicit substances
 - ▶ Identifies substances that may add to adverse events or drug-drug interactions
 - ▶ Provides objectivity to the treatment plan, reinforces compliance with the patient, provides documentation for demonstrating patient compliance
 - ▶ Assesses individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications

Controlled Substance Monitoring and Drugs of Abuse Testing Local Coverage Determination *(continued)*

What is the purpose of the LCD?

- ▶ Medicare patients
- ▶ Monitoring for indications - pain management/substance use disorders
- ▶ Frequency of urine drug testing based on risk (high, moderate, low)
- ▶ Medical necessity
- ▶ Types of tests:
 - ▶ Presumptive/Qualitative
 - ▶ Definitive/Quantitative

Controlled Substance Monitoring and Drugs of Abuse Testing
Local Coverage Determination *(continued)*

▶ UDT Medical Necessity Documentation:

- ▶ Patient history, physical examination and previous laboratory findings
- ▶ Clinical assessment and current treatment plan
- ▶ Prescribed medication(s)
- ▶ Risk assessment plan
- ▶ Documentation of results - outside of a patient's self-report, presentation, medical history, or current prescribed medication plan

PDMP - Prescription Drug Monitoring Program

Electronic database used to collect, monitor and analyze prescribing and dispensing of controlled medications by pharmacies and practitioners

- ▶ It is used for education, research, enforcement and abuse prevention
- ▶ PDMP investigations, DEA investigations
 - ▶ Practitioner prescribing practices (what, how much, to who, from whom)
 - ▶ Patient doctor-shopping
 - ▶ Geographic coverage of prescriptions
- ▶ Secure access for practitioner (and delegate)
- ▶ Plan to share data nationally

Monitoring Your Practitioner's Prescribing Pattern

What are you looking for?

- Type of controlled medication (generic or name)
- Volume prescribed
- Morphine milligram equivalent (MME) prescribed
- Frequency of prescription
- Frequency of patient visits
- Who are the patients
- Where are the patients located (>2+ hour distance)
- Does the practitioner have a relationship with a drug/company (potential conflict of interest)

Documenting for Medical Necessity

- ▶ Complete patient history and previous treatment of condition
- ▶ Discussion of treatment options including risks of opioids
- ▶ Establish treatment goals
- ▶ Conservative treatment with alternate therapies prior to prescribing opioid medication
- ▶ Review of prescription drug monitoring program (PDMP) data
- ▶ Monitor with urine drug testing - document results and compliance
- ▶ Assess risk of addiction, abuse, overdose specific to the patient - use a nationally-recognized risk assessment tool - continue to re-assess based on patient's behavior
- ▶ Follow-up and re-assessment of treatment goals and possible medication adjustment or discontinuation of opioid therapy

Collaboration with prescribers to mitigate risk

Mitigate risk with a formal organizational plan, transparency, and development of a culture of accountability

- ▶ Compliance Opioid Crisis Response Committee (COCRC)
 - ▶ Providers
 - ▶ Nursing
 - ▶ Operations
 - ▶ Risk Management
 - ▶ Quality Management
 - ▶ Legal
 - ▶ Compliance
- ▶ Controlled Substances Management Policy
- ▶ Awareness/ Education
 - ▶ General Employees
 - ▶ Providers
 - ▶ Clinical Staff

Collaboration with prescribers to mitigate risk *(continued)*

- ▶ Shared responsibilities
- ▶ Well publicized auditing/ monitoring exercises
- ▶ Prompt/timely response to reports/allegations
- ▶ Collaborative relationship with external agencies: DEA, PD, OPMC, etc.
- ▶ Transparency is essential- Keep leadership looped in
- ▶ Compliance Committee Presentation- Initiatives, Progresses
- ▶ Regular Compliance presence

Compliance Officer Role: A Success Story

- ▶ Planning, approval and execution
- ▶ Multidisciplinary approach
- ▶ Compliance Datamining: Transparency/ Follow ups
- ▶ Regular/frequent Communications across the organization: weekly digest, direct email communications
- ▶ Departmental Meetings
- ▶ Compliance Hotline
- ▶ Compliance Walkthroughs
- ▶ Presentation to Board of Directors and Compliance Committee members

▶ **Results**

Q&A!

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Resources

- ▶ Substance Abuse and Mental Health Services Administration
- ▶ CDC - National Center for Health Statistics
- ▶ Centers for Medicare and Medicaid
- ▶ Centers for Disease Control and Prevention. 2018 Annual Surveillance Report of Drug-Related Risks and Outcomes – United States. Surveillance Special Report 2
- ▶ CNN - *Opioid Crisis Fast Facts*, June 16, 2018
- ▶ Centers for Disease Control and Prevention - Opioid Overdose - Prescription Opioid Data
- ▶ Walmart's Opioid Stewardship Initiative
- ▶ CVS Caremark® Opioid Quantity Limits Pharmacy Reference Guide
- ▶ National Institute on Drug Abuse: Overdose Death Rates
- ▶ CBS News - *Drug overdoses killed more Americans last year than the Vietnam War*, October 17, 2017
