

# 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