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Navigate the Compliance Universe

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Combating the opioid crisis through a compliance lens

by Peiman Saadat, MD, MSc, CHC, CHPC

It was in the late-1990s when the opioid crisis was first mentioned in the United States as a challenge facing the healthcare system. Since then, our industry has faced multiple waves of the same crisis, when the main driver of the crisis shifted from natural opioids to semi- and now synthetic opioids.

Over two decades later, we are still facing the same dilemma but in a larger magnitude. Multiple federal agencies have been tasked to join forces and combat the epidemic from multiple angles. States have adopted new laws and regulations to limit access and provide treatment for patients with opioid addiction.

Compliance professionals have not been spared, and each has taken part in many ways in this matter, from partnering in drug diversion programs to implementing organizational policies and procedures. Many steps taken are retrospective reviews, yet the most impact would obviously come from proactive steps practically available to compliance professionals.

This article aims to provide some practical tools for compliance professionals in the healthcare industry, enabling them to effectively partner with other departments in this fight against the opioid epidemic in the US.

The start and current situation of the crisis

The first wave of opioid overdose deaths began in 1999 with increased prescribed opioids. Generally, there are three major categories of opioids: (1) natural opioids such as morphine and codeine, and semi-synthetic ones like hydrocodone and oxymorphone. This caused the first wave back in the '90s; (2) synthetic opioids such as methadone and fentanyl caused the second wave; and (3) heroin—an illicit, illegally synthesized opioid—caused the third wave alongside fentanyl.

The Centers for Disease Control and Prevention reported more than 932,000 deaths due to opioid overdoses between 1999 and 2020.[1] While in the early years of the 21st century, the most reported opioid overdose deaths were attributed to the prescribed natural and semi-synthetic opioids, the trend has shifted towards synthetic opioids since 2013.

In 2020, 91,799 drug overdose deaths occurred in the US. The number significantly increased in 2021 and reached 106,699 deaths from drug overdoses.[2] According to the latest release, the number soared to 107,477 in the 12-month period ending August 2022.[3]

A survey conducted in 2021 showed that an estimated 3% of survey respondents who were 18 years or older reported misusing opioids.[4]

When it comes to combating the opioid crisis, compliance professionals can play a vital role in cracking down the opioid-related frauds or misconduct, as well as taking a proactive position in educating healthcare professionals on applicable laws and regulations and enforcing policies and procedures.

This article presents the author's professional experience as a compliance officer in a healthcare system around this topic.

When considering a compliance plan to combat the opioid crisis, both proactive and retrospective measures should be considered depending on available resources.

Helping prevent opioid-related misconduct by healthcare professionals

The first step is the probing phase when efforts are focused on identification of opioid-related controls already in place. This shall prevent redundancies and establish proper support from executive leadership within the organization.

A thorough compliance plan should prevent opioid-related fraud/misconduct by healthcare professionals (HCPs) and protect patients against inappropriate opioid dosage causing long-term dependency, accidental overdose, and/or drug interactions.

According to studies conducted in the US, 10%–15% of HCPs will misuse substances during their lifetime, and rates of prescription drug abuse and addiction are five times higher among physicians than in the general population, with benzodiazepine and opioid abuse being particularly prevalent.

There is no single reason why the rate of opioid misuse among HCPs is so much higher than in the general population, but several promising theories have been proposed. According to one such theory, increased access to prescription drugs contributes to higher misuse and addiction rates. According to studies on self-prescribing behaviors, 87% of physicians have prescribed themselves medications, and more than half (55.3%) of HCPs with a prescription for painkillers wrote the prescription themselves.[5]

The following elements would properly support the compliance plan and can be easily adapted into annual compliance work plans. This plan promotes early detection of opioid-related fraud/misconduct by HCPs and implements proactive measures to stop such behaviors. It further creates proper education for HCPs and system alerts to protect the safety of patients receiving opioid prescriptions.

Elements of a compliance plan combatting opioid crisis

- **Policy and procedures.** An absolute must and proactive measure. A well-drafted opioid prescription policy sets the expectations and provides guidelines when HCPs are considering the use of opioids for patients. They should clearly set the limits for prescribing opioids by HCPs, highlighting the importance of informed consent, complete documentation, and periodic evaluation of patients.
- **Transparency and reporting.** Transparency is essential to build trust with other departments, and keeping leadership in the loop would provide the necessary support when needed. Last thing a compliance professional needs is a reportable case to a local licensing authority such as the Office of Professional Medical Conduct in New York state, when no one in the C-suite had been informed about it.
- **Compliance and ethics helpline.** Helplines bring invaluable support to the plan as they can potentially provide firsthand information about suspicious cases of fraud and/or misconduct within the organization.
- **Mandatory education for opioid prescribers.** States have mandatory training programs which require

healthcare providers to take a mandatory prescriber education as part of the mandatory Continuing Medical Education requirements.[6] Additional training sessions can also be added to the annual compliance plan focusing on organizational policies and procedures in place.

- **Prescription drug monitoring programs (PDMPs).** PDMPs store information on the prescriptions and dispenses of controlled substances from ordering providers and pharmacists. PDMPs are a valuable resource for learning about a patient's history of using opioids. PDMP is an electronic database that tracks controlled substance prescriptions in a state.[7] HCPs should check the state-level PDMP to gain insight into patients prior to ordering opioids.
- **Documentation.** A focused documentation review of encounters with opioid prescriptions should be part of an annual compliance audit work plan. Proper documentation is the key to justifying the medical necessity for any prescribed opioids, and the dosage ordered. Proper documentation includes:
    - Complete patient history and previous treatment(s)
    - Complete review of systems and a thorough physical exam
    - Discussion of treatment options with the patient, including risks of opioids
    - Establishing treatment goals
    - Conservative treatment with alternate therapies prior to prescribing opioids
    - Review of PDMP data
    - Monitor with urine drug testing and assess risk of addiction, abuse, and overdose specific to the patient
    - Possible medication adjustment or discontinuation of opioid therapy
- **Compliance data mining.** Access to electronic medical records and other clinical databases provides a unique opportunity for compliance professionals to monitor prescription trends and identify outliers. By combing through the clinical data and identifying the red flags, compliance professionals can narrow down the list of medical records for review. Instituting a monthly opioid-related data mining routine serves the purpose. The following are a few opioid-related data mining metrics:
    - Self-prescribing opioids
    - Prescribing opioids for a household member or a coworker
    - Opioids prescribed when no visits or encounters are on the record
    - Opioid prescription with over 120 tablets
    - Printed opioid prescription
    - Top 10 HCPs with the most opioid prescriptions in the respective month
    - PDMP utilization reports to identify infrequent utilizers
    - Pharmacy utilization reports identify any potential inappropriate relationships between HCPs and pharmacies

- Narcotic utilization reports to identify any misconduct when it comes to storage and dispensing in the facility

Opioid safety alerts.[8] Safety alerts are designed to flag drug interactions, therapeutic duplications, and potentially incorrect drug dosages. Many electronic health record systems can generate safety alerts at the time of the order. There are three main types of opioid-related alerts that can advise ordering providers about best practices. Safety alerts related metrics can also be used for opioid data mining.

- *Seven-day supply limit for opioid-naïve patients:* This alert limits opioid patients who haven't filled an opioid prescription recently (such as within the past 60 days) to a supply of seven days or less, lowering the chance of opioid dependency or abuse.
- *90 morphine milligram equivalent (MME):* This alert triggers when a patient's cumulative MME per day for all of their opioid prescriptions reaches or exceeds 90 MME. Patients who receive more than 90 MME per day are at a much higher risk of developing a dependency on opioids.
- *Concurrent opioid and benzodiazepine use:* Concurrent use of "opioids and benzodiazepines can significantly increase the risk of overdose because both types of drugs can cause mental sedation and suppress breathing."[9]

- **Preventing drug diversion.** Compliance professionals can support the diversion prevention programs by participating in physical walk-throughs and reconciling the narcotic inventories against the logs. The key to drug diversion prevention is "to frequently reconcile and monitor."
- **Preventing forged prescriptions.** The Centers for Medicare & Medicaid Services has mandated Electronic Prescription for Controlled Substances since January 1 for all Schedules II, III, IV, and V controlled substances covered by Medicare Part D.[10] E-prescription requirements have been in place in many states for years. Since March 27, 2016, mandatory electronic prescribing has been a requirement in New York state. While it's practically impossible to forge an electronic prescription, prescription pads are still in use by HCPs. Prescription pads that are stolen or lost could result in fake orders for opioids. Prescription pads need to be kept safe and under strict access control.
- **Opioid-related scams.** In the past few years, a widespread fraud scheme has been in order when scammers impersonate U.S. Drug Enforcement Agency (DEA) agents by calling healthcare facilities or doctor offices, claiming major misconduct related to opioid prescriptions or stolen identity. The caller typically uses an aggressive and demanding tone, refusing to speak to or leave a message with anyone other than the doctor, referencing the doctor's National Provider Identifier and/or state license number. The caller normally gives a fake name and a DEA agent badge number. They threaten to arrest and suspend the doctor's DEA registration. They usually ask for social security number or date of birth and then demand thousands of dollars via wire transfer or in the form of big-box store gift cards. No DEA agent would ever contact physicians by telephone to demand money or any other form of payment to settle an ongoing investigation. DEA will only notify doctors "of a legitimate investigation or legal action in person or by official letter."[11] The best compliance course of action against these scammers is ongoing education and awareness. It's also helpful to block that number and report the incident to the FBI at www.ic3.gov.
- **Reminders on enforcement activities.** Compliance, email communications, and reminders are available tools to educate providers and clinical staff bulletins about recent U.S. Department of Justice settlements, regulatory updates, and new or revised organizational policies and procedures.

- **Collaborative approach.** To mitigate opioid-related risks, healthcare organizations can form a workgroup (such as an opioid crisis response committee) to engage clinical leaders, operations, risk management, quality management, and legal departments to discuss trends, recent cases, future plans, and promote transparency.

Takeaways

- Since the late-1990s, opioid abuse has continued to be prevalent. The healthcare industry must implement proactive and retrospective measures customized to its organization's specifications and available resources.
- An effective compliance monitoring plan to combat the opioid crisis is vitally linked to the providers' and clinicians' support and buy-in. A compliance professional should keep them in the loop when designing such a program and well into the implementation.
- The execution of this plan heavily relies on trust and leadership's buy-in. Orchestrating the efforts amongst various departments with defined roles and responsibilities promotes efficiency and accuracy while diminishing redundancies.
- Mining the data acquired via electronic health record systems is an excellent resource for compliance professionals when conducting opioid-related internal reviews/investigations.
- Consistency is vital to promote a culture of compliance when enforcing laws, regulations, and organizational policies. Design a plan that addresses how to avoid opioid-related fraud/misconduct and promote patient safety.

1 Centers for Disease Control and Prevention, "Death Rate Maps & Graphs: Drug Overdose Deaths Remain High," last reviewed June 2, 2022, https://www.cdc.gov/drugoverdose/deaths/index.html.
2 Centers for Disease Control and Prevention, National Center for Health Statistics, "Drug Overdose Deaths in the United States, 2001–2021," HSHS Data Brief No. 457, December 2022, https://www.cdc.gov/nchs/products/databriefs/db457.htm.
3 The White House, "Dr. Rahul Gupta Releases Statement on CDC's New Overdose Death Data," news release, January 11, 2023, https://www.whitehouse.gov/ondcp/briefing-room/2023/01/11/dr-rahul-gupta-releases-statement-on-cdcs-new-overdose-death-data-2/.
4 Centers for Disease Control and Prevention, The National Institute for Occupational Safety and Health, "Data on Opioids in the Workplace," last reviewed February 24, 2023, https://www.cdc.gov/niosh/topics/opioids/data.html.
5 Butler Center for Research, "Health Care Professionals: Addiction and Treatment," Hazelden Betty Ford Foundation, June 1, 2015, https://www.hazeldenbettyford.org/research-studies/addiction-research/health-care-professionals-substance-abuse.
6 NEJM Knowledge+, "State Requirements for Pain Management CME," accessed June 13, 2023, https://knowledgeplus.nejm.org/cme-moc/pain-management-and-opioids-cme/state-requirements-for-pain-management-cme/.
7 Centers for Disease Control and Prevention, "Prescription Drug Monitoring Programs (PDMPs)," last reviewed May 19, 2021, https://www.cdc.gov/drugoverdose/pdmp/index.html.
8 Medical Learning Network, "A Prescriber's Guide to Medicare Prescription Drug (Part D) Opioid Policies," MLN Fact Sheet, MLN2886155, August 2022, https://www.cms.gov/files/document/mln2886155-prescribers-guide-medicare-prescription-drug-part-d-opioid-policies.pdf.
9 National Institute on Drug Abuse, "Benzodiazepines and Opioids," November 7,

2022, https://nida.nih.gov/research-topics/opioids/benzodiazepines-opioids#:~:text=Combining%20opioids%20and%20benzodiazepines%20can,addition%20to%20impairing%20c

10 Centers for Medicare & Medicaid Services, "E-Prescribing," last modified March 9, 2023, https://www.cms.gov/medicare/e-health/eprescribing.

11 U.S. Drug Enforcement Administration, "Scam Alert," March 19, 2021, https://www.dea.gov/scam-alert.