Government Enforcement in the Age of Opioids
How the Government is Investigating and Prosecuting Opioid Abuse Cases

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Presentation to ASPMN

Slide 2

Conflict of Interest Disclosure

- Randy Harwell is an Assistant US Attorney in Tampa and has no conflict of interest.
- Jason Mehta is a private practice attorney in Tampa and has no conflict of interest.

Presentation Overview

1. Opioid Crisis Background & DOJ Response
2. Notable Recent Law Enforcement Prosecution
3. Best Practices for Compliance
4. Questions
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Opioid Crisis Background

• Every day, more than 115 people in the United States die after overdosing on opioids.

• In 2015, more than 33,000 Americans died as a result of an opioid overdose, including prescription opioids, heroin, and illicitly manufactured fentanyl.

• That same year, an estimated 2 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers, and 591,000 suffered from a heroin use disorder (not mutually exclusive).

3 Waves of the Rise in Opioid Overdose Deaths
DOJ Response to Opioid Crisis

- In response to a rash of deaths and an estimated annual $280 billion economic toll related to the opioid crisis, the Department of Justice (DOJ) established a task force.

- DOJ prioritized the prosecution of those involved with the sale and distribution of illegal opioids.

- To date, these prosecutions have focused on drug-seeking patients, drug dealers, physicians, pharmacies, drug manufacturers, and others in the supply chain.

DOJ Opioid Fraud & Abuse Detection Unit
2018 National Healthcare Fraud Takedown Day

- Last month, DOJ charged 601 defendants across 58 federal districts, including 165 doctors, nurses and other licensed medical professionals, for their alleged participation in health care fraud schemes involving more than $2 billion in false billings.

- Notably, of those charged, 162 defendants, including 76 doctors and several nurses, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics.
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Notable Recent Prosecutions

• While the types of prosecutions – both civilly and criminally – vary, many of the prosecutions are focused on nurses.

• What is notable is that even many well-intentioned nurses are being caught in DOJ's cross-hairs. DOJ is seemingly requiring that nurses take ownership over the opioid crisis – often with significant consequences for failing to do so.

• We walk through some of the more notable trends.

Opioid Diversion Cases

• The most typical cases are those where nurses are seemingly diverting opioids—either by stealing them from patients or otherwise improperly being involved with the prescription of opioids.

• For example, in Denver, two nurses was sentenced to prison sentences when they were found to have stolen opioids from facilities for personal uses.
Other Opioid Diversion Cases

- Last month, a nurse practitioner pled guilty to illegally distributing Schedule III and IV controlled substances.
- According to the plea, the nurse was employed at a substance abuse treatment program. He was alleged to issue prescriptions to patients when he knew there was no legitimate reason to do so—such as prescribing three dosage units of buprenorphine per day to patients.

Pill Mill Cases

- In other typical cases, DOJ is charging physicians, nurses, and pharmacies for running “pill mills” – or locations where opioids are freely dispensed.
- For example, in 2016, a doctor in Huntsville, Alabama was charged with conspiracy to commit healthcare fraud when he saw 80-145 patients a day and freely dispensed opioids, even in the absence of having patient records or conducting patient exams.

Opioid Diversion and Pill Mill Case Take-Aways

- It is clear that physicians and practices that indiscriminately prescribe opioids are capturing special attention from DOJ.
- It is easy to believe that these nurses or practice groups are “rogue” or “bad apples.”
- But even well-meaning nurses – particularly those with high opioid-dependent patients (such as pain management doctors) – can fall on DOJ’s radar screen in this new regulatory and enforcement climate.
Other Enforcement Trends: Kickbacks

• Prosecutors are also targeting nurses who illegally receive harmed kickbacks in exchange for prescribing opioids (and other drugs).

• Of note, last year, a federal jury convicted a nurse in Texas for receiving kickbacks in exchange for falsifying home health certifications and forging physician signatures.

• Nurses ought to be particularly mindful of the risks associated with speaking and accepting fees from pharmaceutical companies for educational sessions.

Lab Toxicology Prosecutions

• DOJ seems increasingly focused on prosecuting nurses, physicians and laboratory owners for their role in kickbacks/medically unnecessary urine toxicology exams.

• For example, following a week-long trial in New Jersey in May 2018, a physician was found guilty of healthcare fraud and violating the Anti-Kickback Statute when he received payment for referring his patients to a specific urine toxicology lab.

• Physicians and nurses with high toxicology referrals would be well-served by reviewing their arrangements with laboratories and making sure that these arrangements are lawful.

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Compliance Strategies

- While no strategy will completely erase government scrutiny, we offer a half-dozen strategies to try to blunt any government investigation.

- These suggestions are not just good for compliance – these are also good suggestions for appropriate clinical decision-making.

- Ultimately, any prosecution will need to show improper intent. By properly adopting strategies like the ones to follow, a provider can show that he/she does not have an improper intent.

Large Aggregate Opioid History Means More File Reviews

- The government appears to be focused on a prescriber’s total aggregate opioid prescription history.

- While this is a misleading statistic, practitioners would be well-suited to know that this is a threshold measure for government prosecutors.

- In particular, we recommend engaging external medical coders or auditors to do file-reviews to ensure the proper necessity of prescriptions.

Ensure Uniquely Tailored Medical Portfolios

- Regardless of DOJ scrutiny, a best practice is to periodically review patient files and ensure that each patient is receiving a uniquely tailored medication portfolio.

- Put another way, the government seems to be focused on practitioners that indiscriminately prescribe opioids to all patients—regardless of condition and history.

- Thus, we recommend that pain-management physicians and nurses periodically self-audit patient files.
Follow-up with Patients and Do Not Be Quick to Prescribe Opioids

- Another metric that the government seems to be focused on is the length of time between a practitioner's first encounter with a patient and the first prescription of opioids.

- As a general matter, the closer in time between the initial encounter and the first opioid prescription, the greater the chance of potential practitioner abuse. There are, of course, exceptions to this rule.

- Thus, we recommend that practitioners understand this metric and carefully evaluate new patients on initial visits. Be sure to document the diligence undertaken before prescribing opioids.

Review Contracts with Toxicology Laboratories

- The federal government is increasingly focusing on the connection between pain management physicians and toxicology laboratories.

- Therefore, a best practice for practitioners is to document in the patient file expressly how the urinalysis was analyzed and how it affected—if at all—the treatment provided to the patient.

- Also, we recommend that pain management practitioners tailor their drug testing panels to reflect patients' individual needs—for example, not all patients need to be tested for all classes of drugs every time they visit.

Know Your Patients

- The government is increasingly looking at practitioners' pattern of prescribing opioids to relatives or members of the same household.

- Again, while there are exceptions, it should be the rare occasion where multiple members of the same address should be receiving opioids.

- Thus, we recommend that practitioners review basic demographic and contact information of patients to ensure that they are not unwittingly being targeted by drug-abusing patients.
**Track Your Patients’ Results**

- Lastly, law enforcement is increasingly *mining states’ autopsy records* to determine whether patients dying of opioid-related overdoses are linked to certain prescribers.

- For example, where many patients dying of overdoses are receiving opioids from the same prescriber, there is potentially, at best, a non-discerning provider or, at worse, a drug diverting prescriber.

- Given this, we recommend that practitioners track their own patients’ (and former patients’) long-term health outcomes. A best practice is to review the patient file to determine whether different treatment options might have prompted different outcomes.