

HCCA Atlanta Regional Compliance Conference

January 26, 2018

THE OPIOID EPIDEMIC: IMPACT ON THE PROVIDER INDUSTRY

KING & SPALDING

Presenters

<p>Stephanie F. Johnson +1 404 572 4629 sfjohnson@kslaw.com King & Spalding</p>	<p>Kimberly New +1 865 456 1813 kimberly@diversionspecialists.com Diversion Specialists</p>
---	---

KING & SPALDING 2

Goals of Session

- **The Opioid Crisis: Background**
- **Government Enforcement Response**
- **Explore Compliance Considerations and Strategies**
 - Diversion Controls
 - Documentation Practices
 - Training and Education
 - Data Analysis and Auditing Strategies
- **Key Takeaways**
- **Questions**

KING & SPALDING 3

The Opioid Crisis: Background

KING & SPALDING 4

Types of Opioids and Opiates

- **Natural Opiates:** Nitrogen-containing base chemical compounds that naturally occur in plants such as the opium poppy.
 - Examples of natural opiates include morphine and codeine
- **Semi-Synthetic Opioids:** Created in labs but derived from natural opiates.
 - Examples of semi-synthetic opiates include hydrocodone, oxycodone, and heroin (made from morphine)
- **Fully Synthetic Opioids:** Completely manmade.
 - Examples of fully synthetic opiates include fentanyl and methadone

KING & SPALDING 5

Examples of Prescription Opioids

- **Hydrocodone:** Used for moderate to severe pain relief, available in liquid and tablet form.
- **Oxycodone:** Used for moderate to severe pain relief, available in immediate release and controlled release formulations.
- **Fentanyl:** Used for chronic pain management, often for end-of-life care, available by injection and skin patch.
- Single-entity vs. combination products

KING & SPALDING 6

What is Drug Abuse?

- Any act that takes a legal prescription drug and uses it for illegal or illicit purposes.
- According to the DEA and the National Survey of Drug Use and Health, the most commonly diverted controlled prescription drugs are opioid pain relievers.
- Diversion can come in many forms, including hospital staff stealing opioids, but also unethical physician prescribing practices can be a form of diversion.

KING & SPALDING

7

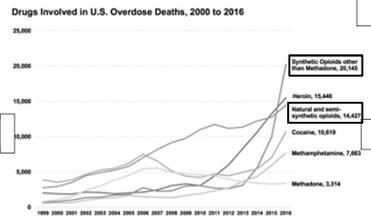
Statistics

- In 2017, among more than 64,000 drug overdose deaths, **about 35,000 deaths** involving opioids (more than 50%).
 - The sharpest increase occurred among deaths related to fentanyl and other synthetic opioids
- The Centers for Disease Control and Prevention estimates that the total “economic burden” of prescription opioid misuse alone in the United States is **\$78.5 billion a year**.
 - Includes the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement

KING & SPALDING

8

Drug Overdose Deaths Involving Opioids



Drugs Involved in U.S. Overdose Deaths* - Among the more than 64,000 drug overdose deaths estimated in 2016, the sharpest increase occurred among deaths related to fentanyl and fentanyl analogs (synthetic opioids) with over 20,000 overdose deaths. Source: CDC WONDER

KING & SPALDING

9

Potential Impact on Healthcare Providers

- Reputational harm
- Financial consequences – civil and regulatory liability
- Licensure considerations

KING & SPALDING

10

Government Enforcement Response

KING & SPALDING

11

Key Regulators

- Department of Justice (DOJ)
- DEA
- State Agencies
- Additional Entities
 - Payors
 - Accrediting Agencies

KING & SPALDING

12

Increased Government Attention

- On May 11, 2017, Attorney General Sessions described the DEA’s 360 Strategy for diversion control:
 - “A lot of drug abuse happens because **legitimate controlled substances are diverted from their lawful purposes**. So DEA is working with drug manufacturers, wholesalers, pharmacies and practitioners to prevent the non-medical abuse of prescription drugs. **We are also targeting and prosecuting dishonest medical providers who violate their oaths by running ‘pill mills’ or otherwise diverting prescription drugs from legitimate uses.**”

Attorneys General Attention

- On September 18, 2017, Attorneys General for 37 states sent a letter to the health insurance industry’s main trade group, America’s Health Insurance Plans, urging its members to reconsider coverage policies that may be fueling the opioid crisis.
- Letter asks insurance industry to revise coverage and payment policies to “encourage healthcare providers to **prioritize non-opioid pain management options** over opioid prescriptions for the treatment of chronic, non-cancer pain.”



Director of Opioid Enforcement and Prevention Efforts

- On **December 20, 2017**, DOJ announced it has created a new senior level position: Director of Opioid Enforcement and Prevention Efforts (Director).
- In its statement, DOJ describes the role: “The Director will be responsible for assisting the Attorney General, Deputy Attorney General, and Department components in formulating and implementing Department initiatives, policies, grants, and programs relating to opioids, and coordinating these efforts with law enforcement.”

New Tools for Enforcement

- Attorney General Sessions has stated that DOJ intends to use data mining efforts to identify potential enforcement targets.
- On August 2, 2017, DOJ announced the creation of a new pilot program, the Opioid Fraud and Abuse Detection Unit, to **focus solely on investigating and prosecuting health care fraud related to prescription opioids.**
- Attorney General Sessions remarked:
 - "This sort of data analytics team can tell us important information about prescription opioids—like which physicians are writing opioid prescriptions at a rate that far exceeds their peers; how many of a doctor's patients died within 60 days of an opioid prescription; the average age of the patients receiving these prescriptions; pharmacies that are dispensing disproportionately large amounts of opioids; and regional hot spots for opioid issues."

Increased Government Attention



FOR IMMEDIATE RELEASE

Friday, January 5, 2018

Attorney General Sessions Applauds China for Restricting Two Fentanyl Precursors

Today Attorney General Jeff Sessions applauded the Chinese government for announcing that it would restrict two chemical precursors to fentanyl.

"Synthetic opioids are killing thousands of people in communities across this nation, and we know that many of these substances originated in China," Attorney General Sessions said. "President Trump and I have repeatedly brought up this issue with the Chinese government, and we are working to restrict the flow of these drugs to our country. I am pleased to see China taking steps that will protect not just their own people from this poison, but the American people, too. I hope that China will continue to take steps like this and eventually schedule all fentanyl analogues, just as the DEA is doing."

Increased Government Attention



FOR IMMEDIATE RELEASE

Thursday, January 11, 2018

Michigan Clinic Office Manager Pleads Guilty to \$131 Million Health Care Fraud Scheme Involving Unnecessary Prescription of Controlled Substances

A Michigan clinic office manager pleaded guilty today for his role in a health care fraud scheme that involved the unnecessary prescription of controlled substances and that resulted in a \$131 million loss to Medicare.

Attorney General Jeff Sessions, Acting Assistant Attorney General John P. Cronan of the Justice Department's Criminal Division, U.S. Attorney Matthew Schneider of the Eastern District of Michigan, Special Agent in Charge David P. Gellos of the FBI's Detroit Division, Special Agent in Charge Lamont Pugh III of the U.S. Department of Health and Human Services Office of Inspector General's (HHS-OIG) Chicago Regional Office and Special Agent in Charge Manny Muriel of Internal Revenue Service-Criminal Investigation (IRS-CI) made the announcement.

Fraud Strike

- On **July 13, 2017**, 412 medical professionals were charged in alleged participation in billing schemes for medically unnecessary prescription drugs and compounded medications.
 - Of those charged, over 120 defendants, including doctors, were charged for their roles in prescribing and distributing opioids.

Payor Strategies

- Incentivize opioid alternatives through reimbursement structures.
- Include conditions for provider plan participation related to opioid prescribing practices.
- Communication and incentive models that promote physician training on CDC Guidelines for Prescribing Opioids for Chronic Pain.
- Use data systems to identify at-risk patients and unusual opioid prescribing trends.

Medical Malpractice Litigation

- *Koon v. Walden*, 2017 WL 4782843 (Mo. Ct. App. Oct. 24, 2017):
 - Missouri appellate court upheld a jury verdict in favor of a patient who became addicted after being over-prescribed opioids.
 - **Punitive damages of \$15 million.**

MDL Litigation: *In re* National Prescription Opiate Litigation

- **Parties:**
 - Multidistrict litigation, consolidating more than 200 suits in the Northern District of Ohio.
 - Plaintiffs include government entities, hospitals and unions.
 - Defendants include pain medication manufacturers and distributors.
- **Allegations:**
 - Plaintiffs allege reckless and negligent sales of prescription opioids.
 - Allegations against makers of opioid pain medications include that they overstated the drugs' benefits and downplayed its risk when marketing to doctors.
 - Allegations against distributors include that they failed to monitor and report suspicious drug orders.

Compliance Considerations and Strategies

Big Picture

- Increased expectations for compliance programs generally.
 - E.g., Risk Assessments
- Increased government focus and whistleblower activity in the industry.
- Opioid crisis is an industry-wide issue; healthcare provider industry should anticipate increased scrutiny.

Specific Strategies to Address Opioid Risks

1. Diversion Controls
2. Documentation Practices
3. Training and Education
4. Data Analysis and Auditing Strategies

1. Diversion Controls

Diversion Controls

Comprehensive Risk Assessment

1. Pharmacy
2. All clinical areas
3. Outpatient areas and retail pharmacies
4. Policy and procedures
5. Surveillance and auditing

Elements of an Effective Diversion Prevention Program

- **Leadership**
 - Diversion Oversight Committee
 - Diversion Specialist
- **Training**
 - Mandatory training of all staff at hire, annually, specialty
- **Monitoring**
 - Auditing and surveillance in all areas that use controlled substances, checks and balances
- **Physical controls**
 - Regular diversion risk rounds, cameras, badge readers, bio-id, prompt discontinuation of access

Addressing Prescribing Practices

- | | |
|--|--|
| <ul style="list-style-type: none"> • Physician Training <ul style="list-style-type: none"> – Clear guidelines for when opioid use is clinically appropriate • Risk Assessment and Treatment Goals <ul style="list-style-type: none"> – Pain management contracts – Guidelines for pain referrals – Drug testing per policy and prn | <ul style="list-style-type: none"> • Prescribing Controls <ul style="list-style-type: none"> – Red Flags – internal and external – No signature stamps – Tamper-resistant prescription pads – E-Prescribe – Prescription Monitoring Programs |
|--|--|

2. Documentation Practices

Documentation Practices

- **Treatment plans:** Document in the medical chart reasons opioid prescription is clinically appropriate
 - Consider including discussion as to why non-opioid pain management options are inappropriate
- **Training programs:** Document and track medical staff participation in training programs; ensure all applicable staff attend mandatory trainings

Patient Counseling Practices

- Addiction and abuse counseling with each exam
- Re-evaluate and examine regularly
- Check the prescription profile of patients with each prescription renew
- Reasons for continuation of existing therapy in new patient

3. Training and Education

Training and Education

• **Controlled Substance Training**

- Prescribers
- Clinical staff
- Anesthesia
- Non-clinical staff
- Pharmacy
- Outpatient settings

Training and Education

• Prescribing practices training for physicians

- Reinforce understanding and importance of opioid policies

• Other training may include:

- How to appropriately respond to drug seeking patients
- How to recognize drug diversion and drug misuse among peers
- Risk of abuse and addiction to opioids
- Non-opioid alternatives

4. Data Analysis and Auditing Strategies

Auditing and Surveillance

- Data analysis
- Benchmarking
 - Identifies high prescribing physicians to focus auditing efforts
 - Provides documentation to protect healthcare entities and high-prescribing physicians who are appropriately prescribing opioids

Auditing and Surveillance

- Analytics reports and outliers
- Discrepancies and other considerations
- Pharmacy
- Anesthesia
- Nursing

Key Takeaways

Key Takeaways

- Opioid epidemic is currently viewed as a public health crisis.
 - Enforcement will naturally be focused on this issue
- Compliance Programs should consider whether to incorporate additional strategies to mitigate this risk.
- A formal program is essential.
- Consider ongoing assessments.
- “Trust but verify.”

Q&A
