

**AHLA**

# **X. Federal Enforcement of Fraud and Abuse Involving Opioid Abuse and Diversion**

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AHLA Fraud and Compliance Forum

## Federal Enforcement of Fraud and Abuse Involving Opioid Abuse and Diversion

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### Opioid Overdose Deaths in the U.S.

- In 2014, opioids were involved in 47,000 deaths in the U.S.
- Approximately 129 people die every day from drug poisoning, 61% of them are pharmaceutical opioids or heroin related.



SOURCE: Office of the Attorney General Memorandum, September 21, 2016.  
Subject: Department of Justice Strategy to Combat Opioid Epidemic

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## Economic Impact of the Opioid Epidemic

- \$55 billion in health and social costs related to prescription opioid abuse each year.
- \$20 billion in emergency department and inpatient care for opioid poisonings.

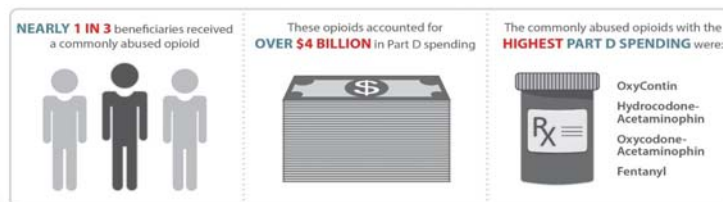


Source: Pain Med. 2011;12(4):657-67. 2013;14(10):1534-47.

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## Part D Drug Spending, 2015

- From 2006 to 2015, total spending for Part D drugs increased by 167%, growing from \$51.3 billion to \$137 billion.
- Part D spending for opioids was highest for OxyContin, hydrocodone-acetaminophen (Vicodin), oxycodone-acetaminophen (Percocet), and fentanyl.
- Part D spending for commonly abused opioids reached \$4.1 billion in 2015.



Source: HHS OIG Data Brief, June 2016, OEI-02-00290, "High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns."

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## **3 Pillars of Engagement Memo From the Office of Attorney General (9/2016)**

### Prevention

- Strengthen prescription drug monitoring programs (PDMPs).
- Ensure safe drug disposal.
- Prevent overdose deaths with naloxone.

### Enforcement

- Investigate & prosecute high-impact cases.
- Enhance regulatory enforcement.
- Encourage information sharing.
- Fund enforcement related research.

### Treatment

- Share best practices for early intervention.
- Support medication-assisted treatment.
- Promote treatment options throughout the criminal justice system.

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Source: OAG Memo distributed 9/21/2016 – Subject: Department of Justice Strategy to Combat Opioid Epidemic

## **Controlled Substances Act (CSA)** **21 U.S.C. § 801, et seq.**

- The CSA is the framework through which the federal government regulates the lawful production and distribution of controlled substances.
- The CSA places certain drugs and chemicals into one of five schedules.
- Schedule 1 has no accepted medical use.
- Schedules 2 through 5 include substances that have accepted medical uses and the schedules reflect substances that are progressively less dangerous and addictive.

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## **Controlled Substances Act** (continued)

- The CSA requires that any person or entity who handles a controlled substance must register with the Drug Enforcement Administration (DEA).
- The CSA requires registrants to maintain accurate records of all transactions involving controlled substances and accurate inventories.
- The CSA provides criminal sanctions for the illicit possession, manufacture, or distribution of controlled substances.
- The CSA also contains civil penalties for violations, including violations of the record keeping provisions.

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## **Controlled Substance Act Enforcement**

Schedule	Example	Prison Time	Fines
II	Oxycodone Fentanyl	Up to 20 Yrs.	Up to \$1M
III	Tylenol w/Codeine Ketamine	Up to 10 Yrs.	Up to \$500,000
IV	Valium Ambien Darvocet	Up to 5 Yrs.	Up to \$250,000

- Prison terms and fines double for distribution to persons under 21.
- Persons convicted can be subject to forfeiture of personal property and real estate

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## Opioid-Related Enforcement

### Massachusetts General Hospital (“MGH”)

- MGH discovered theft of almost 17,000 oxycodone pills by two nurses and reported to DEA
- DEA began an investigation and concluded that MGH failed to provide effective controls and procedures to guard against theft and diversion
- \$2.3 million civil penalty settlement

## **MGH** (continued)

- DEA findings:
  - Patient names remained active in ADMs for up to 72 hours after discharge
  - Two physician names remained active in ADMs although they were no longer employed by MGH
  - Nursing supervisors were not aware how often they were expected to review ADM reports for possible diversion
  - MGH did not discover one nurse's theft for over a year

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## ***U.S. ex rel. Denk v. PharMerica Corp.***

- PharMerica is a closed-door pharmacy that provides pharmaceuticals to long-term care facilities.
- A whistleblower initially reported to the DEA that the pharmacy was not obtaining prescriptions for controlled substances dispensed to nursing homes.
  - Staff contacted the pharmacy and asked that a drug be dispensed for the resident.
  - Pharmacy dispensed the drug and simultaneously created a document with some of the information necessary for a prescription and faxed it to the resident's physician.
- Sometimes pharmacy-generated Rx returned and, sometimes, not.

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## **PharMerica** (continued)

- CSA requires that Schedule II drugs (narcotics) be dispensed only after receiving an original written prescription. 21 C.F.R. § 1306.11(a).
- The CII written prescription requirement has two exceptions:
  - Prescriptions for nursing home residents can be faxed.
  - In an emergency situation, the practitioner may give an oral prescription to the pharmacy, followed within 7 days by a written prescription.
  - 21 C.F.R. § 1306.11(d) and (f)
- Schedule II prescriptions cannot be “refilled” – a new prescription must be given. 21 C.F.R. § 1306.12(a).
- \$31 million settlement ..

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## **Safeway Settlement**

- The CSA regulations require pharmacies to notify DEA of the theft or significant loss of a controlled substance within one business day of discovery. 21 C.F.R. § 1301.76(b).
- The DEA began investigating Safeway pharmacies in Seattle and Wasilla, Alaska for waiting to report thefts/losses to the DEA until after they completed internal investigations. The delay was, in some cases, months.
- Turned into a national investigation, where DEA sampled Safeway’s pharmacies.
- \$3 million settlement (July 2017) for failing to timely report.



## **2017 National Health Care Fraud Take-Down**

- Many opioid focused cases:
  - In Indiana, 5 defendants charged with health care fraud related to unlawful distribution and dispensing of controlled substances.
  - In California, 3 defendants charged for role in a drug diversion scheme and for paying or receiving kickbacks.
  - In Arkansas, 24 defendants charged for drug diversion schemes.

## **The Path to Preventing Opioid-Related Enforcement**

## **Centers for Disease Control** **Guidelines for Prescribing Opioids**

Encourage providers to implement leading practices for responsible prescribing which includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients.

1. Identify and treat the cause of the pain, use non-opioid therapies.
2. Start low and go slow.
3. Close follow-up.
4. Conduct a physical exam, pain history, past medical history, and family/social history.



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Source: CDC Guidelines for Prescribing Opioids for Chronic Pain, 2016

## **CDC Guidelines to Avoid Liability**

(continued)

5. Conduct urine drug test.
6. Consider all treatment options.
7. Implement pain treatment agreements.
8. Monitor progress with documentation.
9. Use safe and effective methods of discontinuing opioids.
10. Use PDMP data to identify past and present opioid prescriptions throughout treatment.



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Source: CDC Guidelines for Prescribing Opioids for Chronic Pain, 2016

## **Compliance Assessment - Diversion Prevention Program**

- Create Diversion Prevention Program
  - Overseen by multidisciplinary Steering Committee that includes Medical Staff, Pharmacy, Nursing, Loss Prevention/Security, Human Resources, Compliance, Patient Safety/Clinical Risk Management, Legal Services, Operations.
- Develop control standards
  - Include comprehensive background investigations of employment candidates & mandatory pre-employment and periodic drug testing.
- Solidify incident response and reporting processes.
- Ensure effective and consistent training for signs of diversion and drug-seeking behavior.
- Automated drug-dispensing machine/Pyxis – location – in sight of other professionals or camera.

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## **Compliance Assessment - Regular Auditing**

- Conduct risk assessment through Diversion Prevention Committee to prioritize audits, including scope and location/department.
- Review storage and security processes to ensure that controlled substances and prescription pads/paper are secured.
- Identify high risk areas where waste diversion may occur (i.e., surgical, anesthesia, procedural) and develop regular audit process to monitor these areas.
- Ensure effective investigation and reporting processes are in place to address suspected diversions.

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## **Compliance Assessment** **Using Analytics To Detect Diversion**

### **Opioid Data Mining Project**

- Identify prescribing time period (ex. April 11, 2016 - April 17, 2016).
- Develop filter protocol to identify common indicators of improper prescribing:
  - 10 or more prescriptions for opioids within a week,
  - prescriptions with a count of 60 or more pills,
  - immediate releasing, including 20-30 mg IR opioids and all medications with Oxycodone, Methadone and Fentanyl in title.
- Run opioid prescribing report out of Epic (or other system) and filter as described above.
- Based on results, work with leadership to review physician prescribing practices.
- Develop opioid prescribing tool kit and other materials to facilitate discussion.
- Coordinate with leadership and Human Resources to develop corrective action plan, as appropriate.