

# *Government Enforcement in the Opioid Era*

HCCA Houston Regional  
Healthcare Compliance Conference

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- Former 10-year Assistant U.S. Attorney
- Attorney with U.S. Office of Counsel to the Inspector General for HHS and U.S. Department of HHS, Office of General Counsel

## **Alethea M. Huyser**

- Senior Associate, Fredrikson & Byron P.A.
- Former State Assistant Solicitor General
- Led team that developed Minnesota's legal opioid enforcement strategy

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## Today's Agenda

- Recent enforcement trends in opioid over-prescribing cases
- Legal and regulatory changes affecting opioid prescribing
- Practical compliance efforts to identify and reduce risks associated with opioid prescribing

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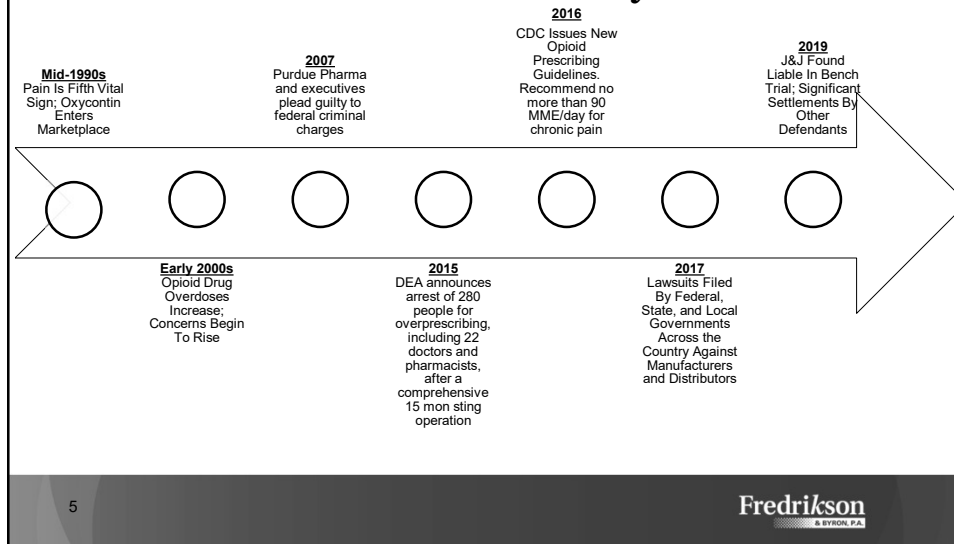
## Current Opioid Enforcement & Litigation

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# Opioid Prescribing A Brief History



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## Actors In Enforcement & Litigation



### Federal:

- Department of Justice (Civil and Criminal)
- Federal Bureau of Investigation
- Drug Enforcement Agency
- Health and Human Services
- Federal Drug Administration

### Tribes

### State, County, & Local:

- State Attorneys General/Prosecutors (Civil and Criminal)
- Regulatory Agencies
  - Departments of Health
  - State Boards

### Private Litigants

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# Prescribers and Pharmacies

## Active federal and local task forces pursuing these investigations

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, September 18, 2019

### Texas Health Care Fraud and Opioid Takedown Results in Charges Against 58 Individuals

The Justice Department announced today a coordinated health care fraud enforcement operation across the state of Texas, involving charges against a total of 58 individuals across all four federal districts in Texas for their alleged involvement in Medicare fraud schemes and networks of "pill mill" clinics resulting in \$66 million in losses and 6.2 million pills. Of those charged, 16 were doctors or medical professionals, and 20 were charged for their role in diverting opioids.

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# Prescribers and Pharmacies



Drug Enforcement Administration

Dallas  
Clyde E. Shelley, Jr., Special Agent in Charge  
@DEADallasDiv

May 10, 2019

Contact: SA Elaine Cesare

Phone Number: (571) 324-7520

FOR IMMEDIATE RELEASE

### Texas doctors are served temporary restraining orders from illegally prescribing highly addictive opioids

DALLAS – The United States Attorney's Office for the Northern District of Texas and the Department of Justice's Civil Division today announced an action to stop two Texas doctors from unlawfully prescribing powerful opioids linked to abuse and diversion. To protect the public, the United States sought and the court granted immediate relief through a temporary restraining order.

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## Primary Legal Vehicles

- Federal/State/Local Criminal Liability
- State Licensing Investigations
- Civil Litigation

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## Healthcare Providers



### “Pill Mills” – Common Factual Allegations

- Large Amounts of Opioids Prescribed
- Documentation, including use of PMPs
- Co-prescribing opioids with benzodiazepines and/or carisoprodols
- Patient medical history
- Distance traveled to clinic
- Location and physical status of clinic
- Age of patients
- Patient criminal history
- Cash payments

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## Healthcare Providers Common Sources for Complaints

- Family Members
- Pharmacists
- Other Treatment Providers
- Whistleblowers
- Newer Trend: Big Data
  - PMPs
  - Drug Manufacturer Data
  - Insurance Companies
  - State Databases

### Improve Monitoring and Surveillance of the Use and Health Effects of Prescription and Illicit Opioids Texas Health Data

The [Texas Health Data website](#) provides statistical information on public health topics. With funding from the Centers for Disease Control and Prevention (CDC), Texas Health Data is adding more opioid data and interactive maps to show the data at a local level. This data will help Texas target and evaluate prevention, intervention, and treatment efforts.

#### Texas Syndromic Surveillance

Syndromic surveillance uses health data in real time to look for early warning signs, so there is enough time to respond to a detected health crisis.

Thanks to funding from the CDC, DSHS is enhancing its syndromic surveillance system by collecting more data from hospitals, free-standing emergency centers, and urgent care providers. We are also including available data on opioids from EMS providers and poison control centers.

DSHS plans to hold a workshop to train staff in each of the eight public health regions on how to access and use opioid surveillance data from this system and from [Texas Health Data](#). Once scheduled, [you can register on the ASTHO website](#).

#### Controlled Substance Overdose Surveillance Enhancement

Texas law requires healthcare providers report overdoses involving controlled substances, including those due to opioids, opium derivatives, hallucinogenic substances, stimulants, depressants, and cannabimimetic agents. Funded by the Council of State and Territorial Epidemiologists, DSHS is improving how it collects these reports and uses surveillance data.

These enhancements will improve our ability to answer important questions about the distribution and causes of controlled substance overdoses in Texas. These answers will lead to strategies for drug overdose prevention and education.

Please note that patient's name, address, or details about patient identity should **not** be reported.

To report a controlled substance overdose case, visit the [Texas Penalty Group 1 Controlled Substance Overdose Report website](#).

For more information, email [epitox@dshs.texas.gov](mailto:epitox@dshs.texas.gov).

## Healthcare Providers Criminal Liability



### Typical Federal Criminal Charges:

- Unlawful distribution of controlled substance
- Conspiracy for unlawful distribution of controlled substances
- Healthcare Fraud
  - Combines typical street drug cases and HCF

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## Healthcare Providers Federal Consequences

- HHS has suspended approximately 650 providers from federal health care programs due to opioid prescribing and abuse concerns
- Corporate Integrity Agreements & Ongoing Monitoring

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## Healthcare Providers State Licensing Investigations

- State Licensing Boards Actively Pursuing Overprescribing Cases:
  - May follow a criminal charge
  - State also may open own investigations
  - Source of information for personal civil liability
- Example of Typical Legal Standard:
  - Care allegedly failed to meet minimum and prevailing standards

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## Pharmacy Liability Criminal Liability

- Under Controlled Substances Act:
  - Pharmacists have a “corresponding responsibility”
  - Must:
    - Verify DEA registration or licensure
    - Be attentive to “red flags” and verify questionable prescriptions
  - Pharmacist should ensure prescription being dispensed is for a legitimate medical reason

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## Pharmacy Liability, cont'd

- Criminal Actions
  - Distributors, pharmacists and pharmacy owners are being targeted with trafficking, conspiracy, and controlled substances charges
    - Cases involve alleged knowing and egregious behavior
    - Usually involve some outlier behavior compared to peers

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## Pharmacy Liability, cont'd

- Suspension of DEA Certificate of Registration
  - If alleged “threat of imminent harm” may do so immediately
  - DEA has issued 31 immediate suspensions and 129 orders to show cause in last two years
- State Licensing and Agency Boards

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## Providers and Pharmacies Civil False Claims Act

- New trend is Civil federal and State FCA Cases
- Allegations typically of ignored “red flags” of diversion and abuse, such as:
  - unusually high dosages of oxycodone and other opioids
  - dangerous combinations of opioid prescriptions other controlled substances
  - patients travelling extremely long distances to get and fill prescriptions
- Federal programs billed for prescriptions
  - AND upcoded office visits that were “med checks”

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## EKRA and Medical Labs

- Eliminating Kickbacks in Recovery Act of 2018
  - Creates new risk for certain providers (sober homes and labs) that pay commission to employees as no AKSesque safe harbor
  - Anticipated regulatory/statutory fix
- Prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for the referral of a patient
- Applies to services billed to private AND public health plans

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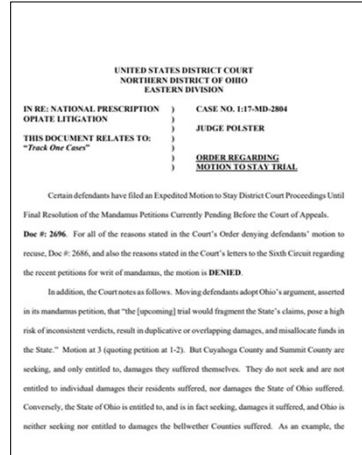
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## Civil Litigation Against Manufacturers, Distributors, Sellers

### The Ohio MDL Case

- Consolidated More Than 2,000 Federal Cases Brought Primarily By Tribes, Counties, & Cities
- Tension With State Attorneys General
- Significant Settlements



## Hospitals joining the cases ...on plaintiffs' side

- West Boca Medical Center is a Plaintiff in the Ohio MDL
- Seeking damages for cost of care related to opioid treatments
- Tuscan Medical Center is pursuing similar claims in Arizona state courts

Drug manufacturers challenging the legal viability of these claims

## Actions by State Attorneys General

### J&J Trial: *State of Oklahoma v. Johnson & Johnson et al.*, Case No. CJ-2017-816

- Bench Trial, Order August 26, 2019
- Court Found J&J Liable for Public Nuisance
- Awarded \$572 Million
- J&J Is Appealing Decision

### Settlements with States Under Consideration

- Purdue Pharma Bankruptcy
- INSYS Bankruptcy

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## Other Private Litigation Medical Malpractice/Negligence

Patients pursue private lawsuits alleging damages from addiction

According to Medical Professional Liability Association:

- Malpractice payouts for claims involving opioids (medication errors, failure to supervise or monitor case, failure to instruct or communicate with patient) up 32% from 2006 to 2016
- Defense costs for those claims increased 100% during the same period

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# Regulatory and Legislative Trends

## An Overview

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## Governments Are Acting.

- Scope of crisis and publicity are putting pressure on government actors to take active role
- Results in:
  - Increased State and federal oversight
  - More rules and regulations
  - Questioning of past medical decision-making by clinicians

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## Legislative Action

- In 2019, National Council of State Legislatures tracked 293 pieces of legislation from 46 states related to opioid prescribing
- Themes:
  - Laws requiring use of prescription monitoring databases
  - Increased CME/training requirements

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## Legislative Action, cont'd

- As of September 2019:
  - 36 states have set limits on the amount of opioids that can be prescribed by doctors
  - 5 of those only apply to Medicaid recipients
  - 2 states do not set specific amounts, but require the lowest effective dose
- Access to Naloxone
- Partnering with First Responders

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# An Ounce of Prevention Compliance Programs

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## Opioid Prescribing Compliance Programs

### Purposes:

- 1) Prevent and address harm to patients caused by overprescribing
- 2) Investigate Yourself So The Government Won't
- 3) Protect from perceived pattern or practice or lack of policies and procedures that could have prevented the occurrence, and which may trigger reports to state or federal agencies

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## Components of Opioid Compliance Program

- Education of changing medical standards
- Promote practices to prevent new addictions
- Identify alternative treatment options
- Track prescribing patterns that indicate a problem prescriber
- Chart reviews
- Treating legacy patients
- Stay abreast of medical and legal developments

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## Education and prevention programs:

- Clinic Supervisor/Trained Compliance Officer
- Written policies for organization
- Are prescribers:
  - Getting relevant CMEs and trained on CDC and state guidelines?
  - Implementing current State Medical Board standards?
  - Accessing Prescription Drug Management Program?
  - Monitoring & Documenting Expectations?
  - Implementing and enforcing pain contracts?

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## Monitoring for Problem Prescribing

- Put procedures in place to monitor for problem prescribers
- Consider using clinicians to review charts, look for outliers, patterns, etc.
- Address Red Flags
  - Prescribing for contraindicated use
  - Insufficient intake, documentation
  - Failure to check PMPs
  - Overall prescribing levels
  - Signs of patient diversion that are unaddressed

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## Monitoring, cont'd

- Have procedures in place to handle adverse events, problem prescribers
- Be mindful of obligations to report to state medical boards and/or DEA
- Make sure compliance program exists and work in substance as well as form

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## Monitoring, cont'd

- Legacy Patients pose unique difficulty
  - Identify opportunities for titrating down prescription levels
  - Document consideration of alternative treatment methods
  - Verify need/appropriate use of prescriptions
  - Careful monitoring with PMPs & criminal history
  - Enforcement of Pain Contract terms

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## Monitor Medical and Legal Development

- Ongoing medical and legal attention to opioid prescribing and management
- Important to take active role in monitoring changes to medical standards, regulatory requirements, and applicable laws
  - Designate an opioid compliance position?

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# Questions?

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