

HCCA Philadelphia Regional  
Healthcare Compliance Conference

# Government Enforcement in the Opioid Era

Sean McKenna, Spencer Fane, LLP

Alethea Huyser, Fredrikson & Byron, P.A.

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### Sean McKenna

- Partner at Spencer Fane, LLP
- 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

### Leah 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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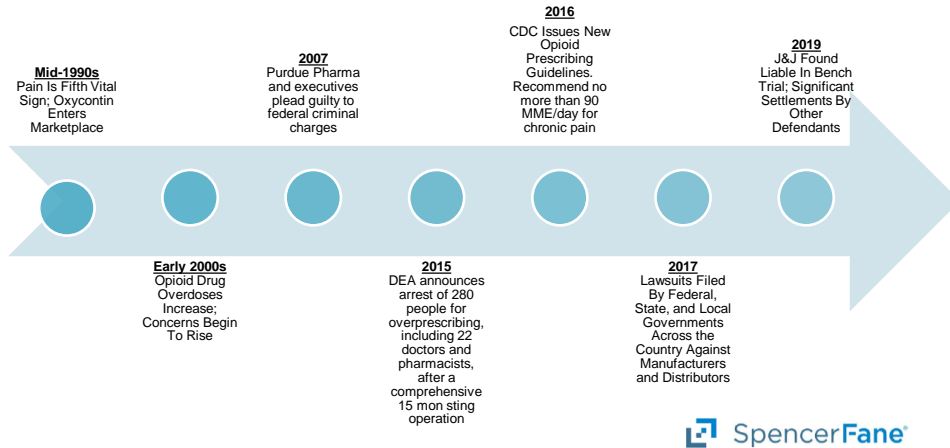
## Current Opioid Enforcement & Litigation

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# Opioid Prescribing

## A Brief History



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## Actors In Enforcement & Litigation



### Federal Gov't:

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

### Tribes

### State, County, & Local Gov't:

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

### Private Litigants

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## Prescribers and Pharmacies

Active federal and local task forces pursuing these investigations

- Federal enforcement priority across the country
- DOJ-involved Task Forces in Pennsylvania:
  - FBI Opioid Task Force
  - J-CODE (Joint Criminal Opioid DarkNet Enforcement Team)
  - Opioid Fraud and Abuse Detection Unit



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## Prescribers and Pharmacies

- In May, Omnicare Inc., a subsidiary of CVS, agreed to pay a \$15.3 million penalty and undergo additional auditing and monitoring
- Not all cases are big cases: some involve one prescriber and one or two patients



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## Primary Legal Vehicles

- Federal/State/Local civil and criminal liability
- State licensing investigations
- Civil litigation
- Class actions/shareholder derivative suits



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## Federal Guidance

Guidance abounds, a few examples:

- CDC Prescribing Guidelines, for prescribers
  - They have app for that!
- HHS advise on Safe Opioid Prescribing
- HHS Toolkits to assist payors assess prescribing levels and determine MME



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## Local Guidance: Pennsylvania

- State and local task forces
- State prescribing guidelines
- Pennsylvania Medical Society has links and resources on new requirements, such as:
  - CMEs for opioid prescribing
  - Advise on opioid treatment agreement laws
  - Additional prescribing guidelines



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## Healthcare Providers



### “Pill Mills” – Common Factual Allegations

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



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## 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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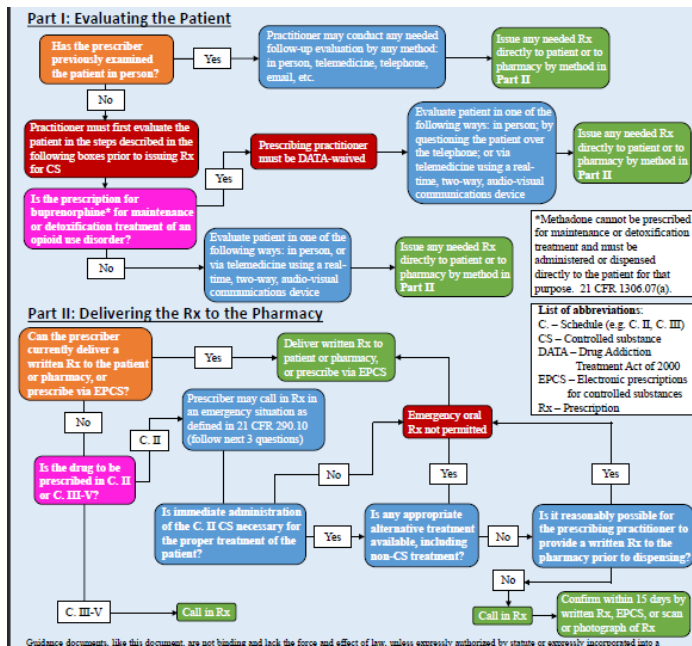
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# New Exemption: Telemedicine and Opioids

- Due to Covid 19, DEA announced an exception allowing prescribers and patients to connect remotely via telehealth for opioids and other controlled substances
- Need to make sure specific guidelines are followed





## 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 pursue overprescribing cases:
  - May follow a criminal charge
  - State also may open own parallel investigation
  - Source of information for 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



## 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



## 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
  
- Federal programs billed for prescriptions
  - AND upcoded office visits that were “med checks”



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## EKRA and Medical Labs

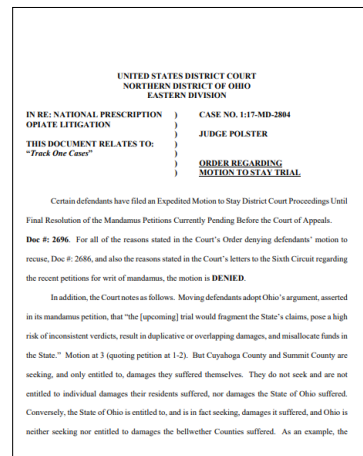
- Eliminating Kickbacks in Recovery Act of 2018
  - Creates new risk for certain providers (sober homes and labs) that pay commission to employees as no AKSesque safe harbor
  - Anticipated regulatory/statutory fix
- Prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration,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



## Civil Litigation Against Manufacturers, Distributors, Sellers

### The Ohio MDL Case

- Consolidated More Than 2,000 Federal Cases Brought Primarily By Tribes, Counties, & Cities
- Significant Settlements



## Aside: new discovery provides another reminder to *be thoughtful* with your email

**Subject:** Saw This And Had To Share It...

*To the Tune of The Beverly Hillbillies*

Come and listen to a story about a man named Jed  
A poor mountaineer, barely kept his habit fed,  
Then one day he was lookin at some tube,  
And saw that Florida had a lax attitude.  
About pills that is, Hillbilly Heroin, "OC,"

Well the first thing you know ol' Jed's a drivin South,  
Kinfolk said Jed don't put too many in your mouth,  
Said Sunny Florida is the place you ought to be  
So they loaded up the truck and drove speedily.  
South, that is.  
Pain Clinics, cash 'n carry.  
A Bevy of Pillbillies!

Well now its time to say Howdy to Jed and all his kin.  
And they would like to thank Rick Scott fer kindly invitin them.  
They're all invited back again to this locality  
To have a heapin helpin of Florida hospitality  
Pill Mills that is. Buy some pills. Take a load home. Y'all come back now, y'hear?

Thanks,

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## Constant Developments:

- New potential trials, in Cleveland, California, Ohio, among others
- Lots of interesting questions continue to arise:
  - Can clinics and hospitals sue as plaintiffs?
  - Can pharmacies bring in prescribers as part of their defense?
  - Disputes between local, state, and tribal governments

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## 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



## 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



# 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
- 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



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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



## 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?



# Questions?



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Presenters:



Sean McKenna  
Spencer Fane, LLP  
(214) 459-5890  
smckenna@spencerfane.com



Alethea M. Huyser  
Fredrikson & Byron, P.A.  
(612) 492-7103  
ahuyser@fredlaw.com

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