HCCA Philadelphia Regional
Healthcare Compliance Conference

Government Enforcement in the
Opioid Era

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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

Current Opioid Enforcement & Litigation
Opioid Prescribing
A Brief History

Mid-1990s
Pain Is Fifth Vital Sign; Oxycontin Enters Marketplace

2007
Purdue Pharma and executives plead guilty to federal criminal charges

Early 2000s
Opioid Drug Overdoses Increase; Concerns Begin To Rise

2015
DEA announces arrest of 280 people for overprescribing, including 22 doctors and pharmacists, after a comprehensive 15 month sting operation

2016
CDC Issues New Opioid Prescribing Guidelines, Recommend no more than 90 MME/day for chronic pain

2017
Lawsuits Filed By Federal, State, and Local Governments Across the Country Against Manufacturers and Distributors

2019
J&J Found Liable In Bench Trial; Significant Settlements By Other Defendants

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
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

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
Primary Legal Vehicles

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

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
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

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
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

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
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

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
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

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”
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 looking 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,
Kintfolk 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 speedilly.
South, that is,
Please, clinics, cash 'n carry.
A Bevy of Hillbillies!

Well now its time to say Howdy to Jed and all His kin,
And they would like to thank Rick Scott for 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
Actions by State Attorneys General

  - 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

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
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

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
An Ounce of Prevention
Compliance Programs

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
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

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?
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

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
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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