Navigating the Changing Regulatory Enforcement Landscape Relating to Opioids

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A Few Statistics

- HHS Secretary declared a public health emergency in response to the growing use and abuse of prescription opioids
  - 4x sales of prescription opioids and 2x opioid-related deaths in past 2 decades
  - Drug overdoses are the leading cause of accidental deaths
    - ~90 deaths from opioid overdoses/day; ½ involve prescription opioids
    - In 2016, ~64,000 drug overdose deaths; 42,000 opioid related
  - 75% of heroin users began their drug abuse by misusing prescription opioids

CDC: Prescriptions and Pain

Presentation Overview

- Recent Enforcement Actions
- Physician's Perspective on Opioids
- Legislative Changes
- Tips for Navigating the Changing Enforcement Minefield

Recent Enforcement Actions

- Increased Enforcement:
  - Professional licensing boards
  - Federal agencies
  - Local law enforcement
- Since July 2017:
  - 600 individuals excluded for opioid diversion and abuse
- Some investigation and enforcement tools:
  - Opioid Fraud and Abuse Unit
  - Prescription Interdiction & Litigation (PIL) Task Force
  - Data Analytics

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Federal Enforcement Actions: Recent Actions Against Healthcare Facilities

- University of Michigan Health System (August 2018)
  - $4.3 million settlement
    - Failed to obtain DEA registrations
    - Failed to maintain complete and accurate records
    - Failed to timely notify the DEA of theft or loss of controlled substances
- Effingham Health System (May 2018)
  - $4.1 million settlement
    - Failed to provide effective controls and procedures
    - Failed to timely notify the DEA of suspected diversion
- Nantucket Cottage Hospital (May 2018)
  - $50,000 settlement
    - Failed to properly maintain controlled substances records
    - Failed to maintain effective controls against diversion

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Federal Enforcement Actions: Recent Actions Against Individual Providers

- Physician and addiction treatment clinic entered into a $23,000 settlement agreement (August 2018)
  - Directed another physician to pre-sign hundreds of blank prescriptions
- DOJ announced the "largest ever health care fraud enforcement action" (June 2018)
  - Focused on allegations of billing for medically unnecessary opioid prescriptions
  - Charged 601 individuals across 58 federal districts for schemes involving over $2 billion
- Chiropractor entered into a $1.45 million settlement agreement (December 2017; January 2018)
  - Operated 4 pain clinics as "pill mills"
- 2 pharmacists paid $5 million in restitution for victims' assistance (October 2017)
  - Dispensed opioids to "pill mill" customers

Federal Enforcement Actions: Recent Actions Against Pharmacies

- Leo's Lakeside Pharmacy (June 2018)
  - $75,000 settlement
    - Failed to account for and keep accurate records of frequently abused opioids
- CVS
  - $1.5 million settlement
    - Failed to timely report the loss or theft of certain controlled substances

State Enforcement Actions

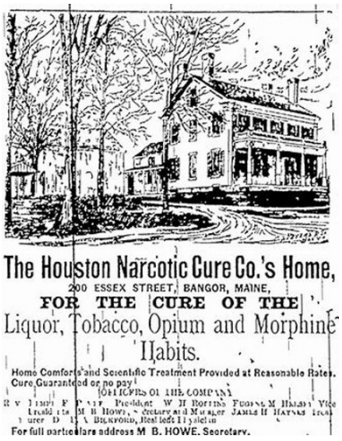
- Lawsuits by state Attorney Generals
  - Typical Allegations:
    - Overstating benefits
    - Downplaying risks
    - Failure to monitor
    - Failure to identify suspicious orders
  - Typical Defenses:
    - No private right of action under the CSA
    - Prescribers break the chain of causation
    - Free Public Service Doctrine
- Criminal prosecutions
- Lawsuits by family members

Enforcement Actions: Takeaways

- Increased investigations of healthcare professionals and entities
  - Targets throughout the distribution chain
- Wide range of settlement amounts
  - Less likely that small violations will fall through the cracks
- Penalties/settlements of millions of dollars even for individuals
- Civil state law claims

Civil War and Opioids

Opioids were used for pain management in the American Civil War. This photo is from Hospital at Fredericksburg, Va., May, 1864. (Courtesy of National Library of Medicine)



The Genesis of the Opioid Crisis?

"Addiction Rare in Patients Treated with Narcotics"

To the Editor

Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. **We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.**

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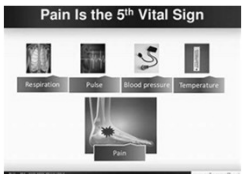
January 10, 1980
N Engl J Med 1980; 302:123

Contributing Factors

Three other factors have contributed to the opioid crisis.

1. In 2001, the Joint Commission issued its Pain Management Standards, which led to classifying pain as the "fifth vital sign."
2. The second factor is the government ordered patient satisfaction survey's. This caused physicians to issue unnecessary opioid prescriptions for pain relief in order to achieve better patient satisfaction scores.
3. Purdue Pharmaceuticals.



Purdue Pharma's Marketing Campaign

- Purdue bought more than $18 million worth of advertising in major medical journals that touted OxyContin. Some of the ads, federal officials said grossly overstated the drug's safety.
- Purdue aggressively pursued doctors and other health workers with literature and sales calls.
- OxyContin contains oxycodone, an opioid as potent as morphine and abusers learned they could crush the pills and snort or inject the dust.
- The company pleaded guilty in 2007 to felony charges of "misbranding" OxyContin "with the intent to defraud or mislead." The company paid $600 million in fines and other penalties. Among the deceptions it confessed to directing its salespeople to tell doctors the drug was less addictive than other opioids.

Federal Legislative Changes to Address Opioid Challenges

- **Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, H.R. 6, 115th Cong. (2018)**
  - Improves grants for treatment programs and expands Medicaid coverage for inpatient rehab
  - Requires USPS to screen international packages for fentanyl
  - Requires Medicaid programs to identify and flag at-risk beneficiaries
  - Instructs CMS to evaluate the use of telehealth services to treat substance use disorder
  - E-prescribing for coverage of Part D prescription controlled substances Requires prescription drug plan sponsors to establish drug management programs for at-risk beneficiaries
  - Creates an online portal for information sharing
  - Requires providers to screen for opioid use disorders during the initial Medicare physical

Federal Legislative Changes to Address Opioid Challenges

- Sharing Health Information
  - When certain health information can be disclosed without a patient's consent:
    - A provider can share information with a patient's family and close friends when sharing the information is in the best interests of an incapacitated or unconscious patient **and** the information is directly related to the family or friend's involvement in the patient's care or payment for the care
    - A provider can share information with individuals in a position to prevent or lessen a serious and imminent threat to the patient's health or safety

Federal Legislative Changes to Address Opioid Challenges

- **Sharing Health Information: Overdose Prevention and Patient Safety Act, H.R. 6082, 115th Cong. 2018**
  - Better aligns HIPAA with 42 C.F.R. Part 2
  - Allows more sharing of substance use disorder records
  - Increases penalties for unlawful disclosure of substance use treatment records
  - Prohibits discrimination based on data revealed in treatment records

Federal Legislative Changes to Address Opioid Challenges

- Medicare Drug Management Programs
  - 1 in 10 Part D beneficiaries regularly receive prescription opioids
  - CMS issued a Final Rule allowing Part D plan sponsors to establish drug management programs for at-risk beneficiaries
  - CMS proposed to permit Medicare Part D plans to limit at-risk beneficiaries' access to opioids
  - CMS announced creation of an Opioid Prescription Drug Monitoring Tool

Federal Legislative Changes to Address Opioid Challenges: Other Proposed Legislation

- **Preventing Overdoses While in Emergency Rooms Act of 2018, H.R. 5176, 115th Cong. (2018)**
  - Requires HHS to establish a grant program for hospitals to develop protocols for discharging patients treated for drug overdoses
  - Improves integration and coordination of post-discharge care of patients with substance use disorder

State Legislative Changes to Address Opioid Challenges

- Opioid Prescribing Limits
  - Limits on timing of prescriptions (e.g. MA, NC, FL, CT, LA, NJ, PA)
    - Often 3-7 days
  - Limits on amount of opioids prescribed (e.g. MD, AZ, CT, DE, MA, NJ, NY, PA, RI, VT)
    - Daily supply limits
    - Morphine milligram equivalents (MME)/day limits
  - Some pharmacies and payors are joining in (e.g. CVS, Blue Cross)

State Legislative Changes to Address Opioid Challenges

- **Prescription Drug Monitoring Programs (PDMPs)**
  - Allow providers to analyze patients' past prescription drug use before prescribing opioids
  - Correlated with decreases in opioid prescribing and in opioid-related deaths
- **PDMP Use by State Licensing Boards**
  - Alaska: BOP may give reports to prescribers on their opioid prescribing practices
  - North Carolina: Allows for notification to licensing board if prescriber's behavior increases risk of diversion
  - Maine: Allows release of data on opioid prescribing practices to hospital's chief medical officer
- **Mandatory PDMP Use**
  - California: prescribers will be required to consult PDMP before prescribing Schedule II-IV controlled substances
  - Georgia and Mississippi: tie PDMP registration to ability to secure/renew DEA registration
  - Georgia and South Carolina: penalize practitioners who fail to query the PDMP
  - Kentucky and North Carolina: penalize pharmacies for improper reporting

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State Legislative Changes to Address Opioid Challenges

- **Integrating PDMPs and EHR**
  - Ochsner Health System: first health system to implement an integrated system
    - Reduced the time it takes to search for prescription data
    - Increased providers' use of prescription data in their practices
    - Reduced the incidence of opioid abuse
  - Deaconess Health System: first Indiana hospital system to integrate prescription data with its EHR
- **Limitations of PDMPs**
  - Use isn't always mandatory
  - Many practitioners oppose change to a mandatory system
    - UC Davis survey: indicated most physicians and pharmacists think practitioners *should* check the PDMP before prescribing, but only about 23% of physicians and 39% of pharmacists think it should be required
  - Mandatory use may be restricted to certain contexts
  - No national system

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State Legislative Changes to Address Opioid Challenges

- **Redesigning Treatment and Discharge of Patients with Opioid Disorders**
  - Virginia: conduct H&P, review the PDMP, assess patient's risk for abuse, and document that all of these actions have been taken
  - New York: proposed requiring hospitals to develop policies and procedures to identify and refer patients with substance abuse disorders and assist patients in coordinating appropriate services after discharge
  - New Jersey: requires practitioners to discuss when prescribing opioids the risks of addiction and dependence and the availability of alternative treatment programs

State Legislative Changes to Address Opioid Challenges: Other Approaches

- Requiring wholesalers to report "suspicious" opioid orders (e.g. WV, OR)
- Revising drug formularies (e.g. TX)
- Requiring pain management facilities to be registered/certified (e.g. LA)
- Revising Certificate of Need (CON) statutes (e.g. KY)
- Expanding availability of telemedicine care (e.g. KY)

Navigating the Changing Enforcement Minefield

- CDC Guidelines: 3 Principles
  - Non-opioid therapy is preferred for chronic pain
  - Use the lowest effective dosage
  - Exercise caution when prescribing and carefully monitor patients

https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf

Navigating the Changing Enforcement Minefield

- Look out for red flags:
  - Multiple prescriptions from multiple physicians
  - Multiple prescriptions treating the same symptoms
  - Requests for early refills
  - Travelling long distances to see a physician/pharmacist
  - Paying for a high number of prescriptions in cash
  - Prescription refills denied by another pharmacist
  - No individualization in dosing
  - Disproportionate prescribing of controlled substances

Navigating the Changing Enforcement Minefield

- Don't:
  - Prescribe opioids unless medically necessary
  - Prescribe opioids as the first line of therapy
  - Provide ongoing pain treatment without a treatment plan
  - Prescribe drugs for long periods of time without reassessments
  - Rely solely on patients' subjective reports of pain

Navigating the Changing Enforcement Minefield

- Do:
  - Note inconsistencies in patients' symptoms
  - Note drug-seeking behavior
  - Consider alternative medical explanations for symptoms
  - Plan an endpoint for treatment
  - Avoid prescribing opioids as first-line treatment, except for active cancer, palliative care, or end-of-life care (consider using nonopioid therapies instead of or in addition to opioids)
  - Consider alternatives to opioid treatment
  - Establish goals for the patient's pain and function

Navigating the Changing Enforcement Minefield

- Do:
  - Discuss the risks and benefits of opioids and alternative treatments
  - Appropriately document informed consent discussion and consider controlled substances agreement
    - Potential risks and benefits of the opioid therapy.
    - Risks of OUD, overdose, and death even at prescribed doses.
    - Nonpharmacological and non opioid therapeutic options for pain management.
    - The likelihood that tolerance and physical dependence will develop.
    - Risks of impaired motor skills affecting driving, and operating machinery.
    - Risks when combining opioids with other CNS depressants, including benzodiazepines and alcohol.

(https://www.nhms.org/content/examples-opioid-informed-consent-agreement)

Navigating the Changing Enforcement Minefield

- Do:
  - Discuss the risks and benefits of opioids and alternative treatments
  - Prescribe immediate-release opioids, use lowest effective dosage, and prescribe for short durations
  - Avoid concurrent prescriptions of opioids and benzodiazepines whenever possible
  - Institute appropriate follow up and plan an endpoint for treatment
    - Consider urine drug testing
  - Clearly document the clinical rationale for each controlled substance prescription
  - Consider use of telemedicine as a tool to expand buprenorphine based MAT for opioid use disorder treatment (https://www.hhs.gov/opioids/)

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Navigating the Changing Enforcement Minefield

- Do:
  - Stay up to date on legislative developments, particularly state prescribing requirements
  - Provide periodic training for all opioid prescribers
  - Develop policy for screening, monitoring and testing patients receiving opioid prescriptions
    - Consider CDC Guidelines for Prescribing Opioids for Chronic Pain
  - Implement a protocol for patient intervention when patients are suspected of developing dependency or addiction
  - Review physician prescribing habits to proactively identify and address potential concerns

Navigating the Changing Enforcement Minefield

- Do:
  - Maintain complete and accurate records
  - Maintain effective controls to prevent diversion
  - Encourage safe storage and disposal of opioids and all medications
  - Promptly notify relevant agency of theft or loss of prescription opioids

Conclusions

- No one is immune from addiction including the educated, the affluent, and those who had no intention of acquiring a drug habit.
- Opioid medications do have a legitimate medical use to help alleviate pain and physicians are not blind to the dangers of opioid abuse.
- Clinicians today are more cautious when prescribing opioids and other prescription pain medications, closely observing their patients for signs of abuse and addiction.
- It is important for clinicians and their organizations to stay well informed of current laws, and any pending legislation regarding opioid prescribing.

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QUESTIONS?

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