Navigating the Changing Regulatory Enforcement Landscape Relating to Opioids

Anna M. Grizzle
Tizgel K.S. High
Jerry Williamson, M.D.

Presentation Overview

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

Perspective

More deaths caused by overdose than car accidents and gun violence
Additional impact

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
  - Various government task forces
  - Data Analytics
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

Federal Enforcement Actions: Recent Actions Against Pharmacies

U.S. v. Oakley Pharmacy, Inc., et al. (M.D. Tenn.)
- “First of its kind” lawsuit to stop two TN pharmacies for illegally dispensing opioids
- Allegation: Turned a blind eye to red flags when routinely dispensing controlled substances
  - Unusually high doses and dangerous combinations of prescriptions
  - Patients traveling long distances to fill prescriptions
  - Patients paying high cash prices
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

“The Genesis of the Opioid Crisis?

“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.

Jane Porter
Hershel Jick, M.D.
Boston Collaborative Drug Surveillance Program Boston University Medical Center, Waltham, MA 01880
January 10, 1980
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 surveys. 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)**

- Expanded Medicare and Medicaid coverage
- 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

### 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

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
Navigating the Changing Enforcement Minefield

**Compliance program → train → audit → review findings → act**

Maintain a comprehensive compliance program

- Consider guidelines for safe opioid prescribing for patients with chronic non-cancer pain (CDC)
  - What to do PRIOR to prescribing opioids
  - How to f/u & monitor patients on long term opioids
  - How to monitor opioid doses (MED)
  - What to do with concerns of addiction/diversion
  - When to consider a specialty referral

Ensure providers stay up to date on state law changes

- Use local resources (licensing boards, pharmacy boards, hospital associations) to maintain current on prescribing and opioid use requirements
- Designate a director or committee responsible for educating providers on changes and when rules are effective
- Patient education regarding risks of opioid usage
- Guide providers to continuing education on the topic or consider insourcing the education
Navigating the Changing Enforcement Minefield

Compliance program → train → audit → review findings → act!

- Review prescribing habits to proactively identify potential concerns
- Sufficiently demonstrate analysis of audit findings
- Demonstrate remediation of underlying misconduct

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

Other Tips

- 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

Other Tips

- 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
Responding to Regulatory Inquiries

- Develop regulatory response team
  - Include subject matter experts
  - Consider checklist of information to be reviewed
  - Develop response protocols and point person for response
- Understand nature of request and potential ramifications
  - Consider implications of potential criminal liability
  - Follow response protocols
- Conduct own investigation of issues
  - Consider need for privilege
  - Recognize evolution of law during treatment periods
  - Implement corrective action plan as needed

QUESTIONS?