Navigating the Changing Regulatory Enforcement Landscape Relating to Opioids

Panel

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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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Herschel Jick, M.D.
Boston Collaborative Drug Surveillance Program Boston University Medical Center, Waltham, MA 0
January 10, 1980
CONTRIBUTING FACTORS

1. In 2001, the Joint Commission issued its Pain Management Standards, which led to classifying pain as the "fifth vital sign."

2. Government ordered patient satisfaction survey's - physicians issue unnecessary opioid prescriptions for pain relief to achieve better patient satisfaction scores.

3. Purdue Pharmaceuticals.

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SURVEY

Table 2

<table>
<thead>
<tr>
<th>Questions</th>
<th>No pain</th>
<th>Mild</th>
<th>Moderate</th>
<th>Less than severe</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>What type of pain did you expect in the post-operative period?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>What type of pain did you experience in the post-operative period?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>When you were in pain, APMS responded</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>What was the quality of pain relief after APMS management?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How would you rate the attentiveness and sensitivity of APMS staff?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How was your overall experience with your pain management service?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

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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.

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

Perspective

The New York Times
The Upshot

Bleak New Estimates in Drug Epidemic:
A Record 72,000 Overdose Deaths in 2017

Aug. 15, 2018

Drug overdoses killed about 72,000 Americans last year, a record number that reflects a rise of around 10 percent, according to new preliminary estimates from the Centers for Disease Control. The death toll is higher than the peak yearly death totals from HIV, car crashes or gun deaths.

Peak deaths for:
Car crashes - 1972
53,000

HIV – 1993
46,000

Gun – 1993
39,000
Additional impact

Economic cost of the opioid crisis: $1 trillion and growing faster

- The economic toll of the opioid crisis is estimated to have topped $1 trillion from 2001 through 2017, a new report says.
- The economic fallout from the epidemic of heroin and prescription painkiller abuse is on track to cost $500 billion from 2018 to 2020 alone.
- More than 62,000 Americans are believed to have fatally overdosed from opioids in 2017.

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
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 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

Every Morning When You Arrive at Work There is A Line Waiting For The Doors to Open

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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

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

- Authorizes/improves grants for prevention and treatment
- Provides support for states to improve their PDMPs and promote data sharing
- Clarifies FDA’s authority to require manufacturers to package opioids as “blister packs”

- 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
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

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)

Potential Risks for Physicians and Other Providers and Facilities

+ Staffing
  ▶ It is estimated that by 2025, there will be a shortage of 250,000 substance abuse and mental health providers
  ▶ Some Federal Staffing Requirements
    • Medicare Conditions of Participation
      – Requires enough physicians on staff to handle complications from opioid overdoses
    • The Emergency Medical Treatment and Labor Act (EMTALA)
      – Requires hospitals to stabilize patients and treat emergency medical conditions
      – Requires that services provided to the public be available through on-call coverage
Potential Risks for Physicians and Other Providers and Facilities

- Urine drug testing
- Working with contractors
- Vicarious liability

Opioid Overdoses Nationwide
12-District Opioid Initiative

- On August 2, 2017, Attorney General Jeff Sessions announced the formation of the Opioid Fraud and Abuse Detection Unit.
- Dedicated opioid prosecutors were assigned to combat prescription opioid “pill mill” schemes.
- Joint effort by FBI, DEA, HHS-OIG and various state MFCUs.

KY Overdoses by County (2012-2015)
TN Opioid Deaths By County (2015)

Medicare Part D: Opioids per capita
Medicare Fraud Strike Forces

Appalachian Regional Prescription Opioid Strike Force
Navigating the Enforcement Minefield

Compliance program → 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 do to with concerns of addiction/diversion
  - When to consider a specialty referral

Navigating the Enforcement Minefield

Compliance program → 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 Enforcement Minefield: Auditing Red Flags – Provider

<table>
<thead>
<tr>
<th>Top 50 list – writing opioid Rx at rate far exceeding peers</th>
<th>Patient overdose/death within 60 days of opioid Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many of the provider’s patients are doctor shopping (3-5 providers)</td>
<td>Overutilization of ancillary services (referrals)</td>
</tr>
<tr>
<td>High patient volume</td>
<td>Inadequate/non-existent exams</td>
</tr>
<tr>
<td>High percentage of provider’s patients prescribed a CS</td>
<td>Lack of meaningful diagnostic testing OR medically unnecessary/excessive testing (UDS, x-ray)</td>
</tr>
<tr>
<td>Prescribing multiple CS at the same time (opioid &amp; benzodiazepine)</td>
<td>Failure to follow diversion prevention measures - UDS, check CSMD/PDMP</td>
</tr>
<tr>
<td>Morphine mg Equivalents (MME) &gt; 90-120 per patient per day</td>
<td>Out of state patients/group travel</td>
</tr>
</tbody>
</table>

## Navigating the Enforcement Minefield: Auditing Red Flags - Pharmacy

<table>
<thead>
<tr>
<th>High % of pharmacies’ CS patients from a single MD</th>
<th>High dosage CS/quantity compared to ailment</th>
</tr>
</thead>
<tbody>
<tr>
<td>High volumes of CS compared to peer pharmacies</td>
<td>Multiple patients present identical sets of Rx</td>
</tr>
<tr>
<td>Dispensing multiple CS at the same time (opioid &amp; benzodiazepine)</td>
<td>Out of state patients/group travel</td>
</tr>
<tr>
<td>Charging high cash prices</td>
<td>Failure to utilize PDMP</td>
</tr>
</tbody>
</table>
Responding to an Enforcement Action

Investigation of the Claims

59 patients
1878 visits & 430 narcotic logs

9 overdoses
7 patient deaths
Investigation of the Claims

<table>
<thead>
<tr>
<th>Patient</th>
<th>Diagnosis</th>
<th>Medication(s) Prescribed</th>
<th>MME</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe</td>
<td>C. DDD, M.D.</td>
<td>Percocet 10/325 mg 1 pc x 24 h</td>
<td>12</td>
</tr>
<tr>
<td>Jane Smith</td>
<td>C. DDD, M.D.</td>
<td>Percocet 10/325 mg 1 pc x 24 h</td>
<td>12</td>
</tr>
<tr>
<td>Mary Johnson</td>
<td>C. DDD, M.D.</td>
<td>Percocet 10/325 mg 1 pc x 24 h</td>
<td>12</td>
</tr>
<tr>
<td>Robert Brown</td>
<td>C. DDD, M.D.</td>
<td>Percocet 10/325 mg 1 pc x 24 h</td>
<td>12</td>
</tr>
</tbody>
</table>

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.
Questions?

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