Overdose and Opioids

- Opioid overdose has now surpassed motor vehicle crashes as a leading cause of preventable death
- Drug overdose deaths involving any opioid rose from 8,048 in 1999 to 47,600 in 2017
- Growing concerns about abuse of both prescription fentanyl and illicitly manufactured fentanyl

*Report: Americans Are Now More Likely To Die Of An Opioid Overdose Than On The Road, NPR, Research News, January 14, 2019
**National Institute of Drug Abuse, Overdose Death rates, National Drug Overdose Deaths Involving Any Opioid, number among all ages, by gender, 1999-2017
***HHS OIG Data Brief, Opioid Use in Medicare Part B: Beneﬁts Concerning (June 2018)
National Drug Overdose Deaths Involving Any Opioid, All Ages, by Gender, 1999-2017

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018

Opioid Crisis – Enforcement

- October of 2017: declared a public health emergency
- DOJ has made opioid crisis a high enforcement priority
- Issuance of warning letters
  - US Attorney in Massachusetts sent letters to opioid prescribers where data identified them as having prescribed opioids to a patient within 60 days of that patient’s death
  - Strike Forces
    - August 2019 – DOJ Health Care Fraud Section charged 41 individuals in nine indictments for alleged involvement in a network of “pill mill” clinics and pharmacies
    - Those charged include medical providers, clinic owners and managers, pharmacists, pharmacy owners and managers as well as drug dealers and traffickers
    - Charges allege participating doctors, medical professionals and pharmacies knew the prescriptions had no legitimate medical purpose and were outside the usual course of professional practice
Discussion Agenda

- Overview of regulation of controlled substances
- Recent developments in opioid prescribing and dispensing
- Practical tips for compliance reviews and risk mitigation

Baseline Legal Standards – Controlled Substances Act

- Numerous technical requirements
  - Prescriber must have DEA registration number
  - No refills permitted for Schedule 2
  - Must use tamper-resistant prescription pads
  - Patient ID verification requirements
  - Verbal orders (e.g., limited to emergency for Schedule 2)
  - Mandatory reporting to DEA of theft, loss or other events
  - Various DEA record-keeping regulatory requirements (e.g., DEA Form 222s)
Baseline Legal Standards – Controlled Substances Act

- “A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”

- “The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”

21 C.F.R. § 1306.04

Baseline Legal Standards – Controlled Substances Act

- “An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription ... and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. 21 C.F.R. § 1306.04
Baseline Legal Standards – Controlled Substances Act

What is the “usual course of professional practice” or “legitimate medical purpose”?

- “[I]n the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States.”


Recent Developments – Flashback to 2016

**CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016**

- Recommendations to primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care
- Treatment recommendations organized into three areas: (1) determining when to initiate or continue opioids for chronic pain, (2) opioid selection, dosage, duration, follow-up, and discontinuation, and (3) assessing risk and addressing harms of opioid use

![Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation](image)
Recent Developments – Push Back to CDC Guidelines

Health-care providers say CDC’s opioid guidelines are harming pain patients

By Lenny Bernstein
March 6, 2019

More than 200 health-care experts told the Centers for Disease Control and Prevention Wednesday that the agency’s landmark guidelines for the use of opioids against chronic pain are harming patients who suffer from long-term pain and benefit from the prescription narcotics.

Recent Developments – 90 MME “Limit” Discredited

FDA identifies harms reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering

Safety Announcement

4/23/2019: The U.S. Food and Drug Administration (FDA) has revised the labels of several brand names of opioid pain medicines to require that health care professionals should not abruptly discontinue opioid medicines in patients who are physically dependent. When you and your patient have agreed to taper the dose of opioid pain medicines, consider a variety of factors, including the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. No standard tapering schedule exists that is suitable for all patients.

Patients taking opioid pain medicines long-term should not suddenly stop taking your medicine without first discussing with your health care professional a plan for how to slowly decrease the dose of the opioid and continue to manage your pain. Even when the opioid dose is decreased gradually, you may experience symptoms of withdrawal (See Additional Information for Patients). Contact your health care professional if you experience increased pain, withdrawal symptoms, changes in mood, or thoughts of suicide.
Recent Developments – 90 MME “Limit” Discredited

The recommendation of high-dose prescribing focuses on initiation. The guideline also recommends that the plan be based on the patient’s goals and concerns and that tapering be slow enough to minimize opioid withdrawal. A 10% per week or per month for patients who have been on high-dose opioids for years.

Recent Developments – CDC Backtracks

No Shortcuts to Safer Opioid Prescribing

Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., and Roger Chou, M.D.

The guideline also recommends that the plan be based on the patient’s goals and concerns and that tapering be slow enough to minimize opioid withdrawal. A 10% per week or per month for patients who have been on high-dose opioids for years.
Recent Developments – Unintended Consequences

**USA TODAY**

Pain patients left in anguish by doctors ‘terrified’ of opioid addiction, despite CDC change

Last month, the CDC clarified its position, saying the response to the opioid crisis went too far. In a New England Journal of Medicine editorial, a panel of experts cited examples such as inflexible thresholds on dosages, abrupt tapering and misapplication of the guidelines for people with cancer, sickle cell disease or recovering from surgery.

Recent Developments – State Prescription Standards

- **As of October of 2018, at least 33 states have enacted legislation related to opioid prescription limits**

- **Colorado, SB 18-022:**
  - In general, the rules subject the prescribing of opioid analgesics for acute pain to strict parameters:
    - No more than a seven (7) day supply can be prescribed for adults (new patients);
    - One second fill of seven (7) day supply;
    - Excludes chronic pain, hospice, some surgical cases;
    - PDMP check required
  - *DORA, Guidelines for Prescribing and Dispensing Opioids* (3/14/2019)
Compliance Approach

- Treatment of pain is still good medicine

- Traditional compliance process can be applied to opioid and controlled substance issues

Compliance Approach

- Risk assessment
  - Majority of government focus on clinical setting and prescriptions
    - DEA is largely focused on prescribing decisions
    - Traditional hospital-based diversion still exists
  - Review where your organization touches on controlled drugs
    - Pharmacy, prescribing, administration, disposal
    - Clinics, off site departments, ASCs, hospital
  - Review types of controlled substances and volume
Compliance Approach

- Risk assessment, cont.
  - Optics of high level dosages (MME or otherwise)
  - Optics of concurrent prescribing/dispensing of opioids and benzodiazepines (among other “combinations”)
  - Elephant in the room:
    - Continuing treatment of long-term chronic pain patients?
    - Lack of SUD treatment options?
    - Lack of reimbursement for non-opioid treatment?

Compliance Approach

- Policy and procedure review
  - Review policy and procedures
  - Update to reflect changes in law or environment
  - Mock DEA inspection
Chronic Pain Policy

- Concise, practical and readable
  - Physician involvement is critical

- Significant discretion on standards
  - Record basis for potentially controversial standards

- Issues to address
  - New patient intake
    - Geographic limits; prior treatment; medical history
  - Criteria for use of treatment agreement

Issues to address

- Use of treatment plan, goals and schedule for re-evaluation
  - Including assessment of non-opioid options

- Monitoring safeguards (set your own)
  - PDMP review
  - Urine drug testing
  - Evidence of diversion or dependence
  - Documentation of expectations and support process

- Response to suspected diversion
Chronic Pain Policy

- Issues to address
  - Objective clinical standards, such as
    - Maximum dosages and combination of drugs
    - Use of short acting and long acting drugs
    - Heroin and illicit drug use
    - Evidence of injury or pain
  - Standards for referral to pain specialist
  - Standards for referral to substance abuse treatment
  - Process for lost prescriptions

Chronic Pain Policy

- Issues to address
  - Standards for tapering
    - Expected timelines
    - Standards for exceptions (if any)
  - Issues/cases to be addressed by informal peer review
  - Patient noncompliance and termination
    - Consistency is important
Compliance Approach

- **Data review**
  - Look for outliers or unexpected data
  - By prescriber; by location; by drug type
  - Use PDMP data, if possible, or other public data

- **Education**
  - Training of staff
  - Education available for prescribers
  - Consider a physician champion
  - Encouragement of prescribers
    - CME is likely necessary as standard of care is changing

Document plan to address any issues identified (i.e., corrective action)
- Many prescribing issues involve professional judgment
- Lack of bright lines makes substantive review difficult, but enforcement risk exists
- Engage experts if needed
- Document efforts and plans
  - Can be patient specific
Legal Risk Can Be Mitigated

- Physician/Pharmacist concerns about their personal exposure are real and appropriate
  - Encourage open dialogue
  - Recognize that professional opinions can differ

- Organizational support is essential
  - Assist physicians in providing quality care in a changing environment
  - Assist with documentation
  - Assist with difficult cases
  - Assist with education

Legal Risk Can Be Mitigated

- Key elements
  - Develop policy on use of opioid analgesics to treat chronic pain
  - Review and assess current patients with chronic pain and current prescription practices
  - Have a clear process to document basis for high dose prescriptions
  - Consider additional clinical education
## Legal Risk Can Be Mitigated

### Chronic Pain Patient

<table>
<thead>
<tr>
<th>Right Checks</th>
<th>Right Chart Note</th>
<th>Right Prescription</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient chart reviewed and contains:</td>
<td>Note from today's encounter contains:</td>
<td>Today's prescription reviewed:</td>
</tr>
<tr>
<td>☐ Current PDMP confirming no unknown prescriptions or other physician prescribing opioids</td>
<td>☐ Current 5As of pain management</td>
<td>☐ Today's prescription is no more morphine equivalents than prior prescription</td>
</tr>
<tr>
<td>☐ Urinalysis dated within ___ days confirming presence of prescribed opioids and lack of others or illicit drugs</td>
<td>☐ Risk of abuse, addiction or referral for substance abuse treatment</td>
<td>☐ Prescription for no more than 30 day period</td>
</tr>
<tr>
<td>☐ Treatment plan and informed consent</td>
<td>☐ Statement addressing risk of diversion</td>
<td>☐ No prescription for benzodiazepines or carisoprodol</td>
</tr>
<tr>
<td></td>
<td>☐ Statement addressing titration or discontinuation of opioid</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Statement addressing need for or compliance with pain contract</td>
<td></td>
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</tr>
</tbody>
</table>

### Resource Materials
Legal Risk Can Be Mitigated

- Systems and protocols that increase clinician efficiency
  - Patient evaluation: initially and periodically
    - Assessment of risk and function
    - Depression and anxiety screening
    - Screening for addiction
  - Treatment planning and risk mitigation
    - Patient agreements with periodic updating
    - PDMP checks: initially and at least every 3 months; establish delegates, as permitted
    - UDT: initially and at least annually (frequency commensurate with risk)
    - Naloxone (Narcan) prescribing/dispensing

Legal Risk Can Be Mitigated

- Systems and protocols that increase clinician efficiency (continued)
  - Patient education:
    - Expectations
    - Risks, benefits, alternatives
    - Safe use, storage and disposal
    - Titration to low dose may be necessary
  - Documentation
    - Means to easily document best practices in EMR
    - Cues to include clinical rationale, especially when prescribing/dispensing outside of guidelines
    - Pharmacist documentation of resolution of Rx “red flag(s)” when dispensing/documentation of refusal to dispense
Legal Risk Can Be Mitigated

- Foster an environment where clinical guidelines are seen and used as practice supports, not practice constraints
- Education: institution-wide
  - Clinicians:
    - Safe prescribing/dispensing, guidelines, rationale
    - Non-pharmacologic and non-opioid treatments
    - If possible, include situation-specific recommendations
  - Patients: appropriate expectations


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Compliance Concerns Related to the Opioid Crisis

Denver Regional HCCA Conference
October 18, 2019

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