Compliance Concerns Related to the Opioid Crisis
Kansas City Regional HCCA Conference
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Jeffrey Fitzgerald, Esq.
Polsinelli PC
jfitzgerald@polsinelli.com
303.583.8205

Overdose and Opioids

- Opioid overdose has now surpassed motor vehicle crashes as the 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

*Eric D. Hargan, Acting Secretary, U.S. Department of Health and Human Services, HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis, October 26, 2017
**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 D: Remain Concerning (June 2018)
Opioid Crisis – Enforcement

- October of 2017: declared a public health emergency in
- 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
  - April 2019 – Appalachian Regional Prescription Opioid Strike Force charged 60 individuals, including 53 medical professionals, across 11 federal districts, for their alleged participation in illegally prescribing and distributing opioids
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.”

  United States v. Moore, 432 U.S. 122 (1975)

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

<table>
<thead>
<tr>
<th>Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation</th>
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<tbody>
<tr>
<td>4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/opioid (ER/OA) opioids.</td>
</tr>
<tr>
<td>5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥150 MME/day or carefully justify a decision to titrate dosage to ≥150 MME/day.</td>
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</tbody>
</table>
Recent Developments – Push Back to CDC Guidelines

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

Lorray Barnholin
March 6, 2019

More than 300 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 harm reported from sudden discontinuation of opioid pain medications and requires label changes to guide prescribers on gradual, individualized tapering.

Satisfy Assessment

June 11, 2019. The U.S. Food and Drug Administration (FDA) has received reports of serious harm in patients who are physically dependent on opioid pain medications suddenly having their medications discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.

Health care professionals should not abruptly discontinue opioids in a patient who is physically dependent. When you and your patient have agreed to taper the dose of opioid analgesic, 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 opioid tapering schedule exists that is suitable for all patients.

Patients taking opioid pain medications long-term should not suddenly stop taking your medicine or not disclose that they are taking it to your healthcare provider. 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 your mood, or thoughts of suicide.
Recent Developments – 90 MME “Limit” Discredited

The Guideline does not endorse mandated or abrupt dose reduction or discontinuation, as these actions can result in patient harm. The guideline includes recommendations for clinicians to work with patients to taper or reduce dosage only when patient harm outweighs patient benefit of opioid therapy. The recommendation on high-dose prescribing focuses on initiation. The guideline offers different recommendations for patients already on opioid doses greater than or equal to 90 morphine milligram equivalents per day. The recommendations include reviewing the risks and benefits of combining high-dose therapy, and if a patient would like to taper, collaborating with the patient on an individual plan. 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, e.g., 10 percent a week or 10 percent a 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.

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Recent Developments – Unintended Consequences

USA TODAY

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

Kim Allaker and Jayne O'Donnell, USA TODAY Published 3:54 p.m. ET June 24, 2019; Updated 4:05 p.m. ET June 30, 2019

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 – HHS Pain MGMT Best Practices Inter-Agency Task Force

- The Task Force was convened by HHS in conjunction with US Dept. of Defense, Dept. of Veterans Affairs, and Office of Natl. Drug Control Policy to address acute and chronic pain in light of the ongoing opioid crisis.

- Various health insurance plans, retail pharmacies, and local and state governments are implementing the CDC Guideline as policy, limiting the number of days a patient can receive prescription opioids even when the seriousness of the injury or surgery may require opioids for adequate pain management for a longer period. A more even-handed approach would balance addressing opioid overuse with the need to protect the patient-provider relationship by preserving access to medically necessary drug regimens and reducing the potential for unintended consequences.
Recent Developments – State Prescription Standards

- As of October of 2018, at least 33 states have enacted legislation related to opioid prescription limits
- Ohio is an example of a rather aggressive state approach to the opioid crisis:
  - 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;
    • No more than a five (5) day supply can be prescribed for minors and only with the written consent of parent/guardian;
    • Providers may prescribe opioids in excess of the days’ supply limit only if they document the specific circumstances in the patients’ medical record;
    • Subject to various other exceptions in Ohio’s rules, the total MED or a Rx for the treatment of acute pain cannot exceed 30 MED per day.
  - O.A.C. 4731-11-13

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

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

Compliance Approach

- 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
Compliance Approach

- 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

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**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 carisporodol</td>
</tr>
</tbody>
</table>

- **Today’s prescription reviewed:**
  - □ Today’s prescription is no more morphine equivalents than prior prescription
  - □ Prescription for no more than 30 day period
  - □ No prescription for benzodiazepines or carisporodol
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

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
Chronic Pain Policy

- 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 expectations and support process
  - Response to suspected diversion

- 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
- Create policy and ensure it is followed

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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