Opioids Under Fire: Risks, Reporting Obligations, and Documentation

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THE EPIDEMIC

- Most people know opioid abuse is a big problem.
  - Covered regularly in the news.
  - Commission on Combating Drug Addiction created by President Trump.
  - Opioid crisis now a declared national emergency.
- The scary truth: the epidemic is much worse than the public understands.
The Statistics Are Staggering

- 142 Americans die per day from drug overdose and two-thirds of those overdoses are linked to opioids.
  - Equivalent to a 9/11 event every three weeks.
  - More than gun homicides and car crashes combined.
- Since 1999, the total number of prescription opioids in the US has quadrupled.
  - Opioid overdoses have also quadrupled in that time.
- Strangely, no increase in reported pain.

Overdose Deaths

Epidemic of Drug Overdose Deaths...

Overdose Deaths per 100,000

2003 2008 2014

Prescription Drug Deaths

Number of Deaths from Prescription Drugs

Source: National Center for Health Statistics, CDC Wonder

Opioid Deaths

Drug overdose deaths involving opioids, type of opioid, United States, 2000-2014
Sources of Abusers’ Opioids

- Theft from health care facilities.
- Drugs obtained from friend or relative.
  - Most common source for prescription opioid abusers (CDC).
- Opioids received through an excessive script from the abuser’s physician
  - Highest risk of overdose (CDC).

FEDERAL RESPONSES TO THE CRISIS
“In recent years some of the government officials in our country I think have mistakenly sent mixed messages about the harmfulness of drugs. So let me say: We cannot capitulate intellectually or morally unto this kind of rampant drug abuse. We must create a culture that’s hostile to drug abuse.”

- Attorney General Jeff Sessions, August 2, 2017

“To many trusted medical professionals like doctors, nurses, and pharmacists have chosen to violate their oaths and put greed ahead of their patients. . . . Their actions not only enrich themselves often at the expense of taxpayers but also feed addictions and cause addictions to start.”

- AG Sessions, July 13, 2017

Regulators Feeling Pressure

- Huge push for government agencies to actively fight the opioid crises.
  - Sessions: “You all are on the front lines of this fight.”
- Pressure to fight all forms of diversion of narcotics, but particularly over-prescribing.
  - Emphasis on the sheer number of opioid prescribed.
- Multiple agencies involved with this effort: DOJ, HHS, DEA, FDA, and others.
New Federal Enforcement Initiatives

- DOJ-HHS Medicare Fraud Strikeforce.
  - 120 charged for roles in prescribing and distributing narcotics.
  - The Kansas and Missouri MFCU listed as participants in the investigation.
- FDA: “Comprehensive action plan.”
- Opioid Fraud and Abuse Detection Units.

Opioid Fraud & Abuse Detection Unit

- Created by AG Sessions to “focus specifically on opioid-related health care fraud.”
- Deploy prosecutors to designated federal districts to use data to root out PROVIDERS who “are contributing to this epidemic.”
  - Reviewing prescription rates, patient death rates, patient demographics.
  - Looking for “regional hot spots for opioid use” to target.
  - Not deployed in Kansas or Missouri... yet.
Opioids in Kansas

In 2015, Kansas ranked 42nd in overdose death rate.
- MO was 21st
- OK was 20th

Opioid abuse is already relatively high in rural counties, particularly in western Kansas.

Urban areas in Kansas also seeing effects of crisis.
- Drug and alcohol abuse is now the leading cause of accidental death in Douglas County, over half related to opioids.

Statistics in Kansas
KS Pain Patient’s Quality of Care Act

- Legislature made several findings as part of the Act:
  - Pain is a significant health problem and may require use of controlled substances.
  - State has duty to restrict inappropriate use of controlled substances while support appropriate pain relief.
- Patients must be active participants in assessment, diagnosis and treatment of their own pain.
- Patients may accept or reject use of any therapies or treatments recommended.
- Nothing in act restricts, limits, or prevents prescribing, dispensing, or administering controlled substance for proper treatment of pain.
- Nothing in act requires prescribing, dispensing, or administering controlled substances if not clinically indicated or most appropriate treatment modality.

Joint Policy Statement on Use of Controlled Substances for Treatment of Chronic Pain

- Clinical decision not to treat chronic pain with opioid pain medication is an appropriate therapeutic decision and not inappropriate care.
- Reasonable suspicion of abuse or diversion constitutes grounds to refuse to prescribe opioids.
- Healthcare professionals not experienced in management of chronic pain may decline to treat patients if good faith attempts are made to refer to providers with more experience.
- Pain is always subjective, and providers rely heavily on self-reported data.
- Use of controlled substances to treat pain and improve function is legitimate medical purpose.
BOHA Controlled Substance Enforcement

- “Inappropriate prescribing” is one of nine “categories of misconduct” recognized by the BOHA.
  - “[S]hould be deemed serious because of its potential for public harm and its abuse of the unique privilege to prescribe drugs, including controlled substances.”
  - Kansas statutes: an inappropriate or unlawful prescription is “unprofessional conduct,” cause for revocation, suspension, or limitation of license.

- Breaks inappropriate prescribing into two categories:
  1. Willfully or negligently failing to follow requirements, but otherwise within lawful and ethical medical care.

- BOHA has established treatment of pain guidelines and position statements.

Example BOHA Investigation

- MD: family practice doctor in his early 60s in rural Kansas.
- BOHA complaint filed against MD.
  - Alleges over-prescription of pain meds, inappropriate combination of pain medications.
  - Subpoena of random patients MD has prescribed pain medications.
- BOHA asks for “narrative statement” from MD:
  - Philosophy for prescribing pain medications.
  - “Diagnostic reasoning” for treatment of each patient and analysis of whether MD followed BOHA guidelines.
  - Description of instances in which MD refuses to prescribe pain medications.
- MD carefully reviews charts and responds with a thorough letter, with the help of counsel.
OPIOIDS IN MISSOURI

Opioid crisis more severe in Missouri than Kansas.
- In 2015, Missouri ranked 21st in overdose death rate.
- Kansas was ranked 42nd.
- Missouri ranks No. 1 among Midwestern states for prescription opioids sold
  - Some attribute higher rate of prescription opioid sales to the lack of a state drug monitoring program (every other state has a program)
  - Like Kansas, opioid abuse is highest in rural counties, particularly in southern Missouri.

STATISTICS IN MISSOURI
THE INTRACTABLE PAIN ACT

Guidelines for treatment of chronic, intractable pain:
- Cause of pain cannot be removed or otherwise treated
- Usually, no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts
- Physician must document diagnosis and treatment of chronic pain in medical record
- Use of controlled substances must be therapeutic.
- Cannot prescribe controlled substances
  - to a patient for chemical dependency unrelated to the intractable pain, or
  - to a patient who the physician knows, or should know is using the medication in a non-therapeutic manner.

MO BOHA ENFORCEMENT

A physician may be subject to discipline if:
- The physician prescribes a controlled substance that is nontherapeutic in nature or manner;
- The physician fails to keep complete and accurate records of the diagnosis, treatment plan, and what has been prescribed;
- The physician prescribes any drug or other treatment without sufficient examination, including prescriptions not made in good faith to relieve pain and suffering or not to cure an ailment, physical infirmity or disease; and
- The physician violates any drug laws of Missouri, the federal government, or any other state.
PRACTICAL COMPLIANCE STEPS IN PRESCRIBING NARCOTICS AND TREATING POTENTIAL ABUSERS.

Delicate Balance: Care for Patients, Protect Providers

- Prescription opioids often are medically necessary and clinically appropriate.
- New studies suggest that standard of care may change (reduction of opioid usage or dosage).
- No one thinks narcotics are going away.
- KSBOHA: Too stiff of sanctions could curtail appropriate opioid use.
- How do we adequately treat patients with severe pain while limiting risk to providers?
Joint Policy Statement (KS), cont’d

- Principles for treating chronic pain:
  1. Assessment of Patient – assess and reassess
  2. Treatment Plan – factors to determine success
  3. Informed Consent and Agreement for Controlled Substance Treatment
  4. Periodic Review
  5. Consultation – psychiatric, addiction counselor, pain specialist, surgeon, or other specialists
  7. Compliance with Controlled Substance Laws and Regulations


Refer Patients to Specialists

- Regulators favor pain specialists or treatment facilities.
  - BOHA: concerned about docs “going it alone.”
  - Experts should handle delicate treatment problems.
- Esp. pain patients at high risk of misuse or diversion.
- Not always a perfect solution, sometimes impossible.
  - Limited availability of pain specialists, particularly in rural areas.
- Communication between PCP and specialist should be ongoing and uninterrupted.
- Document referral in medical record.
Controlled Substance Red Flags

1. Patient appears sedated, confused, intoxicated, or exhibits withdrawal symptoms
2. Patients travel in groups and/or have unusual common factors in their relationships with each other when requesting controlled substance prescriptions on same day
3. Patient repeatedly resists changes in therapy despite adverse effects
4. PDMP (Prescription Drug Monitoring Program) suggests "doctor shopping"
5. Patient pressures physician to prescribe by implying/making threats to prescriber/staff
6. Patient refuses to sign an opioid pain care agreement
7. Patient fails urine toxicology screen
8. Prescriber is aware that patient alters, forges or rewrites prescription
9. Patient requests specific drug combinations
10. Patient repeatedly seeks medications from ED
11. Patient suffers unintentional or intentional overdose

Prioritize Patient Communication

- The BOHA emphasizes patient communication, patient consent.
  - Clearly explain risks and obtain informed consent before treatment.
  - Discuss staggering statistics of opioid epidemic.
  - Explain treatment plan and anticipated length of controlled substance use.
  - Patient and family members should be involved in changes to treatment.
  - Obtaining consent is ultimately physician's responsibility.
- Written policies, treatment plans, and pain contracts may improve patient understanding.
Adopt Written Policies

- Implement and enforce policies and procedures regarding prescribing narcotics and drug diversion incidents.
  - Steps that must be taken before prescribing narcotics.
  - Policy for handling patients who show “red flags.”
  - Lost prescriptions policy.
  - Specific ED policy.
  - Policy for referrals to pain specialists or substance abuse facilities.
  - Policies for patient termination.
- Keep policies up-to-date and ensure all practitioners know and understand them.
- Do not allow any deviations from written policies, once established.

Treatment Plans

- Included in records of every patient prescribed opioids.
  - Institute treatment goals: plan to improve patient’s condition over time, objectives to determine success.
  - Avoid perpetual use of or dependence on opioids.
- Identify the problem: describe nature and severity of patient’s pain.
  - Consider the patient’s history of drug use.
- Consider use of non-narcotic pain management & treatment methods.
- Limit the number of days, dosage to be prescribed.
- Require periodic review.
  - Adjustments made throughout course of treatment, with patient’s informed consent.
  - If treatment goals are not being met, appropriateness of treatment must be reevaluated.
Patient Pain Contracts

- Identify conditions patients must follow in order to receive new prescriptions or refills.
  - Require adherence to the treatment plan.
  - No drugs from other providers.
  - Only use single, designated pharmacy.
  - May require no alcohol, other drugs.
  - May require urine testing.
- Important for "red flag" patients, patients with history of drug abuse.
- Important way to manage expectations.
- Must make consequences of breach very clear.
  - No additional prescriptions from provider (possible tapering).
  - Potential termination of patient relationship.

Urine Testing

- Test for drugs the patient is supposed to be using and drugs he/she is not supposed to be using.
  - Presence of too much of the prescribed drug or a different drug is a big concern.
  - Absence of the prescribed drug is also important (drug diversion concern).
- Unannounced, unscheduled urine testing could be part of pain contract.
- Providers should adopt policy establishing maximum number of days from last urinalysis that a script or refill may be provided.
- Consequences of failed urinalysis – breach of pain contract.
**Prescription Drug Monitoring Programs**

- Kansas has Statewide PDMP: K-TRACS.
  - "Dispensers" of controlled substances must report information to K-TRACS.
    - Date of script, date filled.
    - Quantity dispensed, refill number.
- Missouri
  - Previously, no statewide PDMP.
  - Many counties had PDMP - Jackson County partnered with St. Louis County PDMP.
  - Governor’s Executive Order on 7/17/17 established a PDMP.
    - Limits information doctors & pharmacists may access.
- Reference PDMP **before** prescribing.
  - Helps ID patients seeking same drugs from multiple physicians.
  - Review every time prescription for narcotic is written.
- Ensure that your personnel understand how to use PDMP.
- Document PDMP review in medical record.

**Documentation Is Essential**

- Document nature and intensity of patient’s pain, changes in pain over time.
- Record in writing all steps taken before prescribing narcotics (treatment plans, pain contracts, urinalysis, use of PDMPs).
- Note substance of patient communications.
  - Communications regarding treatment decisions, risks and benefits of treatment plans.
- No substitute for great documentation.
  - Difficult to get credit from regulators for precautions taken if not documented.
Don’t Forget Education and Training

- Important part of your compliance program.
- Physicians and other providers may benefit from intensive training on narcotics.
  - Internal education or outside programs.
- Medical education on related controlled substances is widely available.
  - Both state and federal regulators have made educating providers about the risks of opioid abuse a high priority.

No Better Way to Control Risks

- Refer to Pain Specialists (if possible).
- Establish policies.
- Follow all steps in those policies.
- Document every step, every time.