Legal Issues in Opioid Prescribing

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Conflict of Interest

• I have no relevant financial relationships to disclose

• I will not recommend off-label use of any medications
Objectives

- Identify legal risks associated with prescribing opioids to patients with chronic pain
- Identify current standards and guidelines
- Employ best practices to avoid liability and reduce risk of Corrective Action/Discipline by Medical Board
Legal Risks

• Malpractice- Civil Liability for breach of the standard of care causing harm.
  
  • Overdose or Death
  
  • Ineffective Pain Management
  
  • Failing to note substance history and “re-addiction”
Legal Risks

• Criminal Prosecution- patient death or drug trafficking
  • California MD sentenced to 30 years in prison after conviction for 2\textsuperscript{nd} degree murder in three overdose deaths
  • Prince’s death ruled an overdose from Fentanyl
    • Search warrant issued at physician’s practice after it was learned he had treated and prescribed for Prince twice in April 2016 preceding Prince’s death
Legal Risks

• Licensure risk
  • Investigation-complaints made by patients, family members, or other health care providers (pharmacists)
  • Corrective Action- Not formal discipline but may be published on physician profile
  • Discipline - Reprimand, Suspension, Revocation
    • Formal process
    • National Practitioners Data Bank report
Legal Risks

• Reciprocal Discipline
  • Loss or restriction of DEA prescribing authority
  • Licenses in other states subjected to “me too” discipline
  • Exclusion from Government programs
  • Loss of Provider status on Payer Panels
Reduce Risk with Published Guidelines

• CDC Guidelines for Prescribing Opioids for Chronic Pain- March 2016

• “Model Policy” from Federation of State Medical Boards

• DEA Practitioner’s Manual
CDC Guidelines

• Improving practice through clinical practice guidelines to treat pain while reducing misuse, abuse and overdose

• Not regulation or law (unless adopted by licensing boards or state legislation)

• Application
  • Rx opioid- Primary care patients < 18 yrs
  • chronic pain (< 3mths or past time of normal tissue healing)
  • Does not include cancer or end of life care
CDC Guidelines

Non-opioids preferred!

Document

- expected benefits for pain and function < risks.
- evaluation of risk factors for harm (abuse, addiction, drug seeking)
- treatment goals before starting and during treatment.
- clinically meaningful improvement.
CDC Guidelines

• **Document**
  
  • Review Prescription Monitoring Program **before** starting opioid therapy and during therapy (ranging from every prescription to every 3 months).
  
  • Urine drug testing **before** starting opioids-at least annually for all patients on long-term opioid therapy (assess for prescribed medications and controlled substances or illicit drugs).
CDC Guidelines

Document

- Evaluation of patients within 1 to 4 weeks of starting long-term opioid therapy or of dose escalation.
- Evaluation of patients receiving long-term opioid therapy every 3 months or more frequently.
CDC Guidelines

- Avoid prescribing opioid pain medication and benzodiazepines concurrently.
FSMB Guidelines

• **Document** physical exam, past pain and medical history, family and social history

• Consider all treatment options, risks/benefits of opioids, use when alternatives are ineffective

• Start patient on lowest effective dose

• Monitor and **document** pain and treatment

  Progress: Vigilance at higher doses

• **Use** Drug and Urine screens
FSMB Guidelines

• Use Pain Management Agreements

• Use safe and effective methods for discontinuing
  • Tapering
  • Referral to substance abuse specialists or other resources

• Use Prescription Monitoring Sites - to detect diversion, abuse and misuse of prescriptions
Prescription Monitoring Programs

• To be used by prescribers and pharmacists to assist in managing their patient’s care.

• Pharmacies/Dispensing Prescribers submit prescription data to the PMP system for Schedules II, II, IV and V controlled substances and butalbital containing products.

• Prescribers and pharmacists, and delegated staff may be authorized to access information from the PMP database.
Informed Consent and Pain Management Agreements

• Achieved and documented via pain management agreement

• Guidelines state PMA’s recommended but Boards now treat as mandatory
  • PMA should be placed in chart
Processes to Minimize Abuse

• Physicians are expected to incorporate safeguards into their practice to minimize the potential for abuse and diversion of controlled substances
  • FSMB Model Policy
  • DEA Practitioners Manual

• Consider separate record/log to track all prescriptions
Dear Doctor

“The Board has received a report regarding your practice of medicine.

It is alleged you improperly prescribed controlled substances to a patient and improperly monitored her use of drugs. She died of mixed drug toxicity including marijuana, methamphetamine, benzodiazepines, oxycodone and hydrocodone.”

Investigator

Medical Practice Board
Dear Investigator,

- I was the PCP for 2 years.
- Rx controlled substances for chronic pain
- Dx low back pain and osteoarthritis of knees
- Obesity
- Goal was pain control to increase exercise for weight loss
- She made functional improvement and weaned herself from her walker
Dear Investigator, (continued)

• No pain management contract. We had a verbal agreement

• I am enrolled in PMP and use it periodically to monitor patients.

• Used PMP for this patient a few times, one instance of Rx for hydrocodone from urgent care center and discussed with patient.
Dear Health Center

Enclosed is a Subpoena for:

• Medical records of deceased patient described in the complaint.

• Medical records of 5 other patients from pharmacy database by Doctor’s prescriber number
Dear Doctor,

“Enclosed is a Notice of Conference from the Office of Attorney General requesting your appearance before the Complaint Review Committee to discuss the issues outlined in the Notice. ……

You have the right to be represented by counsel.”

Executive Director

Board of Medical Practice
Investigation By Medical Practice Board

Medical Records showed:

• Patient presents to Doctor in early December

• Prior history – November, Patient presented at the same clinic for low back pain. Reported having an Rx for ________ with a pain contract but her doctor moved.
  • Provider 1 reviewed record and noted discrepancies in her story and the amount of medication taken and wrote Rx for Gabapentin 300mg, 90 tablets 2 refills
• Patient wants __________ and reports “unpleasant visit with Provider 1”
• Doctor notes “uncomfortable, no acute distress”
• “we discussed a pain medication contract”
• Initiates Hydrocodone, 2 t.i.d. #90 and diazepam 2 mg, b.i.d #30 tablets “for spasms”

Based on CDC and Federation of State Medical Board Guidelines, is anything wrong?
Mistakes

• Provider 1 did not Rx opioids— Is pt dr shopping? Evaluation of risk factors?
• No documented evaluation or diagnosis
• No documented risks, benefits, goals, treatment plan.
• No PMA (oral discussion would have been ok if documented)
• No urine test
• No PMP check
MISTAKE

• Doctor missed his first and best opportunity to take another direction with this patient!
• 2 wks later: “modest relief with __________”
  • Stopped Gabapentin due to “side effects”
  • “taking diazepam t.i.d”
  • Rx for Amiltriptyline 25mg, Hydrocodone/APAP/325mg #180, and diazepam 2mg #60
• 6 wks after first visit: switched to Hydrocodone/APAP 10/500 max 4/day
  • Explained “the equivalent dose of eight of the previous 5/325 tablets and increased doses of diazepam to 5mg.
  • “waiting on appointment with the pain clinic”
• Late January

• Doctor is on vacation for a month. This patient shows up on your panel in a 15 minute return visit time slot. She reports “worse pain over the last few weeks…had a fall and injured left hand with some bruising” but she did not have evaluated at the time. She’s out of pain medications.

• What do you do?
Doctor

- authorized 180 Hydrocodone/APAP 2 q. 4 hours
- February – “ramping up on the Lortab 10/325 taking the maximum dose at 12 per day…taking ________ with that up to 8 mg daily” “long discussion about pain medication options” : d/c’d _________ and substituted tizanidine 2mg, t.i.d for muscle spasms” and authorized 140 Hydrocodone 10/325.
- Pt continues with follow up, sometimes twice a month
- April-Pt requests diazepam again due to “anxiety issues”
What would you do?

In late April, Doctor is on vacation again. Patient calls in requesting Diazepam refill. What do you do?

A. Authorize the refill
B. Check the PMP
C. Review record for last prescription and refuse because it's too soon
D. Discuss the patient with Doctor on his return
Rest of the story

• In May, switched pt to Oxycodone and documented “patient is going to dispose of the Vicodin” d/c __________

• Late May pt returns because of pain. Oxycodone dose increased to 15mg q 4hrs. “bring medications in so we can do a pill count”

• June “switched back to Hydrocodone/APAP” but no mention of a pill count.

• Pattern continues through July

• August “we will look at a pain contract upcoming”
Rest of Story

• Dec 2013 Medical examiner autopsy stated patient had been at home with her husband when she complained of difficulty breathing. Transported to hospital and pronounced dead.

• Report listed final diagnosis of mixed drug toxicity, morbid obesity, history of tobacco use, no significant injury or trauma
Findings By Medical Board

- Doctor failed to:
  - assess patients for risk of chemical dependency, toxicity, diversion or suicide
  - **document** a treatment plan and medical basis for increases in daily dosages
  - monitor efficacy
  - use controlled substance contracts or enforce the termination provisions of the contracts when patients violated the terms of the agreement
  - conduct pill counts or routine biological fluid screens to monitor compliance
Findings By Medical Board

- Doctor failed to:
  - explore non-narcotic treatment options
  - recognize drug seeking behavior
  - provide referrals to specialists or pain clinic programs
  - review the Prescription Monitoring Program (PMP) before prescribing controlled substances

- Frequently authorized controlled substances based upon patient’s claims of pain… but failed to document objective clinical findings to support the need for initiating or renewing medications
All Findings Resulted in License Suspension

Practices viewed as inappropriate in such a way to require Board action:

1) Unethical conduct
2) Failed to conform to the minimum standard of care
3) Failed to maintain adequate medical records
4) Inappropriate prescribing practices
Documentation

- Documentation is essential to defending a Board investigation or malpractice case
- “The Board will judge the validity of treatment based on available documentation.”
  - FSMB Model Policy
- “Inadequate documentation is a feature of nearly all complaint reviews which lead to investigations or discipline.”
  - MN Board of Medical Practice
Patient Abandonment: Ethical Considerations

- Physician may withdraw from care, but cannot do so without giving notice to the patient sufficiently in advance to permit another medical attendant to be secured.
  - AMA Code of Medical Ethics E-8.115

- Physician may not discontinue treatment without giving reasonable assistance and sufficient opportunity to make alternative arrangements for care.
  - AMA Code of Medical Ethics E-10.01
Termination of Care

- Establish ground rules via pain management agreement
- If patient violates agreement, attempt to educate/rehabilitate
  - Absent egregious circumstances, allow more than one strike
- Document non-compliance and attempts to rehabilitate patient
- Taper and Refer to PM or addiction specialist
Termination of Care

- Send letter of termination
  - Confirm valid address and send letter via hand or certified and first-class mail
  - Describe reasons for termination
  - Provide 30-day notice and provide interim treatment and medication
- Risk of liability for withdrawal/under-treatment is remote
- Risk of complaint to Medical Board is likely but defensible --documentation is critical!
Seek Legal Advice

• If you receive any communication from the Medical Board indicating a complaint.

• If your medical records on a patient are requested by the Medical Board or State AG’s office

• If you are contacted by:
  • Law Enforcement
  • DEA
  • Private attorney representing patient or patient’s family
Questions & Discussion