LEGAL ISSUES IN OPIOID PRESCRIBING

Joanne L. Martin, JD
Mayo Clinic
Rochester, MN

Pain Management is important and integral to the practice of medicine. The use of opioids may be necessary for pain relief of moderate to severe pain. However, the use of opioids for other than a legitimate medical purpose, such as drug abuse and/or diversion poses a threat to the individual and society.

Physicians have a responsibility to minimize the potential for abuse and diversion.

The validity of prescribing will be judged on the physician's management of the patient

Federation of State Medical Boards Policy Preamble 2011

Existing guidelines vary in recommendations, and primary care providers say they receive insufficient training in prescribing opioid pain relievers. It is important that patients receive appropriate pain treatment, and that the benefits and risks of treatment options are carefully considered.

Centers for Disease Control

Legal Risks Associated with Inappropriate Opioid Prescribing

1) Medical Licensing Board Review

a) Investigation- Medical Boards have a process for investigating all complaints filed by patients, family members, or other health care providers. The ***Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain*** ("Model Policy") by the Federation of State Medical Boards has been adopted in whole or in part by many state licensing boards. If there is a complaint and investigation arising out of licensee's prescribing practices, the Model Policy may serve as the standard against which a licensee's practice will be evaluated. In most instances, if after investigation a complaint is dismissed, the complaint and investigation remain confidential. However when a complaint results in a finding that there is probable cause to believe that a violation of the medical practice act has occurred, the Board process may become available to the public. Probable cause may be found when there is:

1. Failure to document-
    i. "*The Board will judge the validity of treatment based on available documentation"* (Model Policy -Federation of State Medical Boards)
    ii. *"Inadequate documentation is a feature of nearly all complaint reviews which lead to investigations or discipline."* MN Board of Medical Practice
2. Failure to conform to the standard of care

b) Corrective Action and Discipline (process and terminology will vary by state)

1. Medical Boards may impose remedial or corrective action which does not constitute formal discipline against a licensee through corrective action agreements. Corrective action agreements require the licensee to complete certain remedial steps: additional education; submitting records for audit; reporting to a monitor; writing a paper; or, some combination thereof. Because these are agreements with the Board and not formal disciplinary actions taken by a Board, corrective action agreements are not reported to the National Practitioners Data Bank. However, state licensing boards publish the information on their Corrective action agreements are reserved for less serious violations.
2. Formal Discipline by a Medical Board is reported to the National Practitioners Data Bank and possibly, to the DEA, if a physician failed to employ safeguards in prescribing.

(1) Suspension of license may occur only after formal administrative action by the Board. Suspension of a license is for a period of time (6 months-2 years, but could be indefinite) and may be effective immediately upon issuance of an order from the board or stayed (meaning that a physician may continue to practice). Suspensions may impose conditions, such as proctoring, additional training etc., as determined by the Board. When the conditions have been completed the physician may apply for reinstatement.

(2) Revocation or removal of a license is the most serious discipline and is reserved for egregious malpractice or misconduct. Revocation occurs after a formal administrative complaint and hearing before an administrative judge. The proceedings are similar to a trial but occur without a jury.

c) Tips for Responding to Medical Board Complaints

1. Boards generally notify the licensee of a complaint made against their license by mail. Be sure that the Medical Board has your correct mailing address. Be certain that office staff is trained to notify you immediately of any correspondence from your licensing board. Do not ignore correspondence from the Board as responses are time sensitive.
2. Review the allegations made by the complaining individual and your medical record carefully. Most of the time, the licensing board will want a written response and explanation of your care, along with copies of the relevant medical records. In some instances, there may be an interview. Consider retaining legal counsel and notifying your insurance carrier. (some professional liability insurance carriers provide legal counsel to assist with Board matters) Most complaints are dismissed after the reviewing committee for the Board receives an explanation of the care that was given, provided that the care met standards and is supported by the documentation in the medical record.
3. If the complaint is not dismissed after providing a written or verbal explanation, a formal Notice to attend a conference before a panel or committee of board members may be sent to the physician. If legal counsel has not already been retained, do so at this point. While some complaints are dismissed after a conference or meeting with the panel, often this may be an indication that some form of corrective action and possibly discipline is being considered. Legal counsel can be effective in negotiating the terms of the corrective action, or, if suspension is being considered, persuade the panel that corrective action is a more appropriate course of action.
4. Visit your licensing board's website often to look for updates in regulations, review disciplinary actions, review your profile, and to understand your licensing board's processes.

2) **Civil liability-medical malpractice:** negligent prescribing or breach of the standard of care as it relates to prescribing practices which causes damage or harm to the patient.

a) Types of malpractice cases have included:

1. Overdose or death
2. Overprescribing resulting in injury or accident.
3. Ineffective pain management
4. Failing to note prior substance abuse and "re-addiction"

b) Malpractice cases may be on the increase due to:

1. Public awareness resulting in less social stigma for patients who become addicted;
2. Attorney advertising – there are attorney websites devoted to prescription malpractice;
3. Emphasis on prescribing guidelines by Centers for Disease Control and the Federation of State Medical Boards.

3) **Criminal prosecution:** Infrequent, but increasing risk. To be valid, a prescription for a controlled substance must be issued for a <u>legitimate medical purpose</u> by a practitioner acting in the usual course of professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances.

a) Recent prosecution in California resulting in conviction.

1. In 2015, California doctor, Lisa Tseng, was convicted of second degree murder in connection with three deaths from prescription drug overdoses. All patients were in their 20's and died between March and December 2009.

2. Dr. Tseng averaged writing 25 prescriptions/day and over 27,000 prescriptions in a three year period
3. Dr. Tseng was found guilty of 23 counts, including 19 counts of unlawful controlled substance prescription and one count of obtaining a controlled substance by fraud. In February, 2016 she was sentenced to 30 years to life in prison.

b) Physician who treated Prince prior to his overdose is under investigation.
c) Prosecution in Georgia in 2016 (United States of America vs. Edd Colbert Jones III) for unlawful dispensing. Controlled substances were not prescribed for a legitimate medical purpose where: inadequate verification of patient's medical complaint; cursory medical examinations; inadequate medical history and no follow up verification; insufficient dialogue with patients regarding treatment options, risks and benefits; failure to refer to specialists; lack of diagnostic testing; failure to assess risk of abuse; and failure to monitor. The foregoing findings also form the basis of licensing board disciplinary action.

4) Loss of DEA registration and prescribing authority [See: (https://www.deadiversion.usdoj.gov/crim_admin_actions/index.html)]

a) In the event a state board revokes or suspends a license or otherwise recommends that a DEA registration be surrendered, the DEA will take action and request a voluntary surrender of the practitioner's DEA registration. If the practitioner refuses to voluntarily surrender the registration, the DEA will pursue administrative action to revoke the registration.
b) DEA regulations require that all registrants provide effective controls and procedures to guard against theft and diversion of controlled substances.
   1. Practitioners should not employ as an agent or employee who has access to controlled substances any person who:
      (1) Has been convicted of a felony related to controlled substances
      (2) Had been denied a DEA registration, had a DEA registration revoked, or had surrendered a DEA registration.
   2. Practitioners must notify the DEA, upon discovery, of any thefts or significant losses of controlled substances.

Risk Management Strategies- Published Guidelines and Model Policy

1) DEA Practitioners Manual (http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section3.html)
   a) Safeguards for Prescribers-in addition to the required security controls, practitioners should:
      i) Keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use.
      ii) Write out the actual amount prescribed in addition to giving a number to discourage alteration of the prescription
      iii) Use prescription blanks only for writing a prescription order and not for notes.
      iv) Never sign prescription blanks in advance
      v) Assist the pharmacist when they phone to verify information about a prescription order; a corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure accuracy
      vi) Contact the nearest DEA filed office to obtain or to furnish information regarding suspicious prescription activities
      vii) Use tamper-resistant prescription pads.

2) Federation of State Medical Boards Model Policy (http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf) As of 2012, 57 of 70 State Medical Boards have policy, rules, regulations or statutes reflecting the Federation's 1997 or 2004 Model Guidelines for the use of Controlled Substances for the Treatment of Pain. Use of the following recommendations should be documented in the medical record.
   a) Conduct a physical exam, past pain and medical history, family and social history
   b) Consider all treatment options, risks/benefits of opioids, use when alternatives are ineffective
   c) Start patient on lowest effective dose

d) Monitor and document pain and treatment Progress: Vigilance at higher doses
e) Use of Drug and Urine screens
f) Use Pain Management Agreements
g) Use safe and effective methods for discontinuing
h) Tapering
i) Referral to substance abuse specialists or other resources
j) Use Prescription Monitoring Sites- to detect diversion, abuse and misuse of prescriptions

3) The Centers for Disease Control and Prevention (CDC) released the **CDC Guideline for Prescribing Opioids for Chronic Pain** in March 2016. The Guideline and additional information is published on the CDC website. (https://www.cdc.gov/drugoverdose/prescribing/guideline.html)

a) The Guideline provides recommendations regarding initiation or continuation of opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessment of risk and addressing harms of opioid use. The Guideline is intended:

i) To be used by primary care providers (e.g., family physicians or internists) who are treating patients with chronic pain (i.e., pain lasting longer than 3 months or past the time of normal tissue healing) in outpatient settings.

ii) To apply to patients aged 18 years of age or older with chronic pain outside of palliative and end-of-life care.

b) The Guideline is not intended to apply to patients in treatment for active cancer.

c) The Guideline is not a federal regulation; adherence to the Guideline will be voluntary.

d) Key elements addressed in the CDC Guideline include:

i) Non-opioid therapy is preferred for chronic pain.
ii) Consider opioid therapy if expected benefits for both pain and function outweigh risks.
iii) Establish treatment goals, risks and benefits and continue only if there is clinically meaningful improvement.
iv) When initiating, prescribe short-acting opioids instead of extended-release/long acting opioids at lowest effective dose.
v) Before starting and during opioid therapy, evaluate risk factors for harm.
vi) Incorporate strategies to mitigate risk, including offering naloxone when factors that increase risk for opioid-related harms are present.
vii) Review Prescription Drug Monitoring Program data base before starting opioid therapy and periodically during therapy (ranging from every prescription to every 3 months).
viii) Implement additional precautions when increasing dosage to 50 or greater milligrams per day in morphine equivalents and avoid increasing dosages to 90 or greater.
ix) Three or fewer days will usually be sufficient for non-traumatic pain not related to major surgery.
x) Evaluate patients within 1 to 4 weeks of starting long-term opioid therapy or of dose escalation. Evaluate patients receiving long-term opioid therapy every 3 months or more frequently.
xi) Use urine drug testing before starting opioids and at least annually for all patients on long-term opioid therapy to assess for prescribed medications as well as other controlled substances and illicit drugs.
xii) Avoid prescribing opioid pain medication and benzodiazepines concurrently.

4) Additional resources:

a) The Canadian Guideline For Safe and Effective Use of Opioids: (http://www.cpso.on.ca/cpso-members/resources-for-physicians/national-opioid-guideline "*The guideline is not intended to be used as a policy or standard of practice, but as a practical resource to provide Canadian physicians with the best available information, research and consensus of opinion on this topic*" - College of Physicians and Surgeons of Ontario

b) National Conference of State Legislatures –Prevention of Prescription Drug Overdose and Abuse (http://www.ncsl.org/research/health/prevention-of-prescription-drug-overdose-and-abuse.aspx)

c) CMS –***The Role of a Prescription Monitoring Program in Reducing Prescription Drug Diversion, Misuse and Abuse*** (https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/medicaid-integrity-education/downloads/prescriptiondrug-monitoring-factsheet.pdf)

d) **Pain Management Agreement** (sample attached). Pain Management agreements are strongly recommended by the Model Policy, CDC Guidelines and State Licensing Boards. Agreements typically referred to marijuana as an "illegal" substance. The use of medical marijuana may be legal in some states and practitioners will need to determine whether to prohibit or incorporate its use into the pain management agreement.

e) **Material Risk Notice**- an informed consent required by the Oregon Medical Board in order to prescribe pain medications. Check your state licensing board website for similar requirements for informed consent that may apply in your state. Absent a state requirement, you may wish to incorporate some or all of the elements of the Material Risk Notice into your Pain Management Agreements as evidence of having obtained informed consent.

Sample Pain Management Agreement

The purpose of this Agreement is to prevent misunderstandings about certain medicines you will be taking for pain management. This is to help both you and your doctor (or health care provider) to comply with the law regarding controlled medicines.

I understand that this Agreement is essential to the trust and confidence necessary in a doctor/patient relationship and that my doctor undertakes to treat me based on this Agreement.

I understand that if I break this Agreement, my doctor will stop prescribing these pain control medicines and may terminate the patient/physician relationship. In this case, my doctor will taper off the medicine over a period of several days as necessary to avoid or minimize withdrawal symptoms. Also, a drug-dependence treatment program may be recommended.

I will communicate fully with my doctor about the character and intensity of my pain, the effect of the pain on my daily life, and how well the medicine is helping to relieve the pain.

I will not use any illegal controlled substances, cocaine, etc. or other substances that have not been acquired through legitimate means.

I will not share, sell or trade my medication with anyone.

I will not attempt to obtain any controlled medicines, including opioid pain medicines, controlled stimulants, or antianxiety medicines from any other person, including other health care providers. If unanticipated circumstances require that I obtain any of these types of medications from another doctor, I will promptly inform my doctor that this has occurred.

I understand that I must attend regular appointments as required by my doctor. If I am unable to attend a scheduled appointment, I must cancel at least twenty-four hours in advance and reschedule another appointment at the time of cancellation. Frequent cancellations will not be permitted.

I understand that I must treat my doctor and my doctor's staff with respect. Rude, disrespectful, or abusive behavior will not be permitted.

I will safeguard my pain medicine from loss or theft and will keep them away from children. Lost or stolen medicines will not be replaced.

I agree that refills of my prescriptions for pain medicine will be made only at the time of an office visit or during regular office hours. No refills will be available during evenings or on weekends.

I agree to use _____Pharmacy,
located at _____,
telephone number _____, for filling prescriptions for all of my pain medicine.

I authorize the doctor and my pharmacy to cooperate fully with any city, state or federal law enforcement agency, including this state's Board of Pharmacy, in the investigation of any possible misuse, sale, or other diversion of my pain medicine. I authorize my doctor to provide a copy of this Agreement to my pharmacy. I agree to waive any applicable privilege or right of privacy or confidentiality with respect to these authorizations.

I agree that I will submit to a blood or urine test if requested by my doctor to determine my compliance with my program of pain control medicine.

I will bring all unused pain medicine to every office visit.

I agree that I will use my medicine at a rate no greater than the prescribed rate and that use of my medicine at a greater rate will result in my being without medication for a period of time.

My doctor has explained to me the risks associated with taking controlled medicines, including the risks of physical dependence. My doctor has also explained that taking these medicines in a manner that violates this agreement, (such as taking them with illegal drugs or at a rate greater than the prescribed rate) may cause serious injury or even death.

I agree to follow these guidelines that have been fully explained to me. All of my questions and concerns regarding treatment have been adequately answered. A copy of this document has been given to me.

This Agreement is entered into on this _____ day of _____ , _____.

Patient signature: _____

Physician signature: _____

Oregon Medical Board

Material Risk Notice

When prescribing opioids for chronic pain, the law requires health care professionals to provide careful assessment and documentation of the medical condition causing pain as well as co-morbid medical and mental health conditions. Goals for treatment should be established with the patient before prescribing opioids. Patients must be informed of the risks and sign a Material Risk Notice.

A **Material Risk Notice (MRN)** is a written record documenting the provider-patient discussion on long-term controlled substance therapy for intractable pain. Similar to obtaining informed consent for a procedure, the health care professional first explains the intended opioid therapy and provides the MRN document, which the patient signs to acknowledge understanding.

At a minimum, the MRN should include:

- the diagnosis
- the controlled substance(s) to be used
- the anticipated results
- alternative therapies
- any additional therapies that may be necessary
- warning regarding potential for
- side effects
- allergies
- medication interactions
- impairment of judgment or motor skills
- dependence and addiction and withdrawal precautions

The health care professional is required to keep the MRN, documentation of follow-up and repeated assessment of the therapy in the patient's permanent medical record. Further, the health care professional must maintain a dispensing record in the patient's chart showing the amount, dosage and timing of prescribed or administered controlled substances.

The MRN supplied here was created and approved by the Oregon Medical Board. Health care professionals may use their own customized MRN if it includes the minimum information required.

Material Risk Notice

Form created by the Oregon Medical Board for use by healthcare professionals to be retained as part of the patient's permanent medical record.

This will confirm that you, _____, have been **diagnosed** with the following condition(s) causing you chronic intractable pain:

I have recommended treating your condition with the following **controlled substances**:

In addition to significant **reduction in your pain**, your personal **goals** from therapy are:

Alternatives to this therapy are:

Additional therapies that may be necessary to assist you in reaching your goals are:

Notice of Risk: The use of controlled substances may be associated with certain risks such as, but not limited to:

1. **Central Nervous System**: Sleepiness, decreased mental ability, and confusion. Avoid alcohol while taking these medications and use care when driving and operating machinery. Your ability to make decisions may be impaired.
2. **Cardiovascular**: Irregular heart rhythm from mild to severe.
3. **Respiratory**: Slowing of respiration and the possibility of inducing wheezing, causing difficulty in catching your breath or shortness of breath in susceptible individuals.
4. **Gastrointestinal**: Constipation is common and may be severe. Nausea and vomiting may occur as well.
5. **Dermatological**: Itching and rash.
6. **Endocrine**: Decreased testosterone (male) and other sex hormones (females); dysfunctional sexual activity.
7. **Urinary**: Urinary retention (difficulty urinating).
8. **Pregnancy**: Newborn may be dependent on opioids and suffer withdrawal symptoms after birth.
9. **Drug Interactions** with or altering the effect of other medications cannot be reliably predicted.
10. **Tolerance**: Increasing doses of drug may be needed over time to achieve the same pain relieving effect.
11. **Physical dependence and withdrawal**: Physical dependence develops within 3-4 weeks in most patients receiving daily doses of these drugs. If your medications are abruptly stopped, symptoms of withdrawal may occur. These include nausea, vomiting, sweating, generalized flu-like symptoms, abdominal cramps, abnormal heartbeats. All controlled substances need to be slowly tapered off under the direction of your physician.
12. **Addiction (Abuse)**: This refers to abnormal behavior directed towards acquiring or using drugs in a non-medically supervised manner. Patients with a history of alcohol and/or drug abuse are at increased risk for developing addiction.
13. **Allergic reactions**: Are possible with any medication. This usually occurs early after initiation of the medication. Most side effects are transient and can be controlled by continued therapy or the use of other medications.
14. **Accidental Overdose**: In some instances, controlled substances may accumulate, leading to respiratory difficulty, coma, or death. This risk is increased by certain medical conditions, higher dose opioid treatment, other medications including tranquilizers, CNS depressants, alcohol, marijuana or other illicit drugs.

This confirms that we discussed and you understand the above. I asked you if you wanted a more detailed explanation of the proposed treatment, the alternatives and the material risks, and you (initial one):

_____Are satisfied with the explanation and desired no further information.
_____Requested and received, in sufficient detail, further explanation of treatment, alternatives, and material risks.

Patient Signature _____ Date:_____

Explained by me and signed in my presence.

Provider Signature _____ Date:_____