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RISK MANAGEMENT

The Pain Game

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Mrs. L. was referred to you by her PCP for evaluation and treatment following concerns raised by her family about her increasing work absence, frequent requests for pain medication due to unrelenting pain following knee replacement surgery last year, and a history of depression. At the beginning of the evaluation, Mrs. L. asks you if you will be able to help with her pain. What should you do?

Patients similar to Mrs. L. may be problematic for a psychiatrist. Physicians who prescribe opioid analgesics to patients complaining of chronic non-cancer pain may become increasingly vulnerable to medical malpractice litigation and licensing board actions. Physicians may also face increased scrutiny as they treat the expanding population of opioid-dependent patients.

Most physicians believe that their prescribing practices will not be investigated. However, a recent article published in the *Annals of Internal Medicine* highlights consideration of the evolving landscape of pain management with opioid analgesics by practitioners both treating and following patients complaining of chronic non-cancer pain.[1] Taken in conjunction with the recently revised Federation of State Medical Boards (FSMB) Model Policy, physicians who treat patients with analgesic opioids may be more vulnerable than ever to medical malpractice litigation and licensing board actions.[2]

Liability Exposure

Traditionally, medical malpractice defense attorneys handled both malpractice claims and licensing board actions in matters where opioid prescriptions were alleged to have led to adverse incidents such as accidental overdose, suicide, and motor vehicle accidents. Instances of this type have remained relatively rare. However, the increased availability of opioid medications and resultant complications from their use, may lead to an increase in such cases.

These cases typically have commonalities such as the identification of an original source of severe pain (post-surgical, post injury), the acceptance of the validity of the patient's representation and history of continued unrelenting pain, and a hesitation to discontinue the pain medication based upon an under-appreciation of alternative pain treatment regimens. The patients, who often have a history of reliance on pain medications, report that opioid analgesics are the only treatment that "work," and have access to multiple providers who concurrently prescribe narcotics.

Lack of documentation may arguably be most consequential to the practitioner when faced with a disciplinary action from a state licensing board.

In pursuing medical malpractice actions, plaintiffs' attorneys often rely upon document deficiencies in a physician's patient records, such as lack of a treatment plan for the continuation of opioid analgesics, a lack of written informed consent, a failure to identify concurrent treaters (who are often prescribing the same or similar dosages of opioids), and a lack of a cumulative summation of the prescriptions, refills and dosages. These will be problematic issues should a case be brought against a physician.

Lack of documentation may arguably be most consequential to the practitioner when faced with a disciplinary action from a state licensing board. State licensing boards are taking notice of the changes in the understanding and consequences of long-term pain management and have been increasingly investigating practitioners. As most state board disciplinary actions do not require a causal linkage between the questionable conduct and damages, insufficient record keeping may make it easier for a licensing board to make an adverse determination. Thus, it is important that physicians self-audit current clinical pain management protocols and augment office policies and procedures while following both acute and chronic pain patients.

The Lack of Scientific Support for Long-Term Opioid Treatment

The National Institutes of Health Office of Disease Prevention (NIH ODP) recently convened an independent panel to conduct an unbiased review of the scientific literature on the safety of long-term prescription opioid use, and the impact of such use on a patient's pain, function, and quality of life. The seven-member panel concluded that chronic non-cancer pain spans a multitude of conditions, presents in different ways, and requires an individualized, evidence-based management approach. The Annals of Internal Medicine published, *"The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systemic Review for a National Institutes of Health Pathways to Prevention Workshop."*[3] The article identified that chronic pain affects an estimated 100 million Americans, and despite many alternative treatments for chronic pain, 5 to 8 million Americans use opioids for long-term pain management. The article indicated that opioid prescriptions and use have increased over the past 20 years from 76 million in 1991, to 219 million in 2011. The Centers for Disease Control and Prevention have classified prescription drug abuse as an "epidemic" and a leading cause of death second only to motor vehicle accidents. Nonetheless, despite the long-known and evolving crisis, the investigators concluded that there was a notable lack of evidence to support the use of long-term use of opioids for chronic pain. In fact, the study revealed a "paucity of research" of the effectiveness of opioid treatment for chronic pain.[4]

Proposed National Standards?

In 2013, the FSMB revised their "Model Policy" for care and treatment of patients with opioid analgesics.[5] Since its publication, the Model Policy has been widely distributed to state medical boards, medical professional organizations, patient advocacy groups, state and federal regulatory agencies, and practicing physicians. The American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities have all endorsed the Model Policy. Many states have adopted all or part of the Model Policy. Please note, however, that every state continues to regulate its own prescribing practices. As such, it is important to understand your individual state's prescribing laws.

The Model Policy emphasizes the professional and ethical responsibility of physicians to assess and manage patients' pain, assess the relative level of risk for misuse and addiction, monitor for aberrant behaviors and intervene as appropriate. It also includes references and the definitions of key terms used in pain management.

The Model Policy indicates that the prescribing physician should corroborate the patient's self-reports. These corroboration efforts may include obtaining the medical records of prior and concurrent treating physicians, and checking a state's online database of prescription medications. However, such efforts may not be commonplace even amongst pain-management centric practices.

The hallmark of the FSMB Model Policy is a recommendation for an individualized treatment plan. The FSMB proposes that the treatment plan and goals "should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies." The FSMB proposes that the treatment plan should, "contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and non-pharmacologic." They recommend that it also should, "specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function." The Model Policy also indicates that the plan should document any further diagnostic evaluations, consultations, or referrals that have been considered and why those have been employed or been deemed unnecessary.[6]

Treating Chronic Pain

The lack of medical evidence to support long-term opioid use, together with a colorable national standard of care for assessment and treatment of chronic pain, and no requirement of a catastrophic outcome, is driving an increase in medical malpractice claims which are being brought by plaintiffs' attorneys. These claims are being brought on the basis of an addiction; that a physician failed to properly treat a chronic pain condition or failure to refer to a pain-management specialist and emotional and physical distress. Likewise, state licensing agencies may also pursue actions based upon the failure to obtain corroboration of the complaints and/or lack of a treatment plan. This broadening of the potential scope of liability may open the door to a continued increase in possible future claims, and investigations by state licensing boards.

So where does this leave the psychiatrist who follows or originally prescribes opioid pain medication, and is subsequently confronted with an individual who continues

to complain of chronic unrelenting pain? First and foremost, the psychiatrist must consider if he/she has the sufficient education, training and experience to treat the patient's chronic pain condition. If not, it is important to consider whether additional training or education is needed or if the patient should be followed by another provider.

If the psychiatrist does treat the patient's chronic pain, the patient records should reflect a detailed pain evaluation, at least one recognized medical indication for the original opioid prescription and for continued treatment with opioids. When prescribing opioid medications, the psychiatrist should have an early detailed treatment plan which identifies a timetable of treatment, non-opioid medication options, and office visits with constant investigation into the severity of a patient's pain, medication dosages and other sources of prescriptions. The records should also memorialize an informed consent discussion and include a signed consent explaining the medication options and a plan to alter the initial treatment plan at pre-designated times. The consent should also reflect the patient's appreciation of the consequences of both short-term and long-term treatment with opioids and an agreement to alter the treatment regimen instead of turning to an increase in medication. Finally, the office staff should record efforts to monitor all refills and obtain concurrent treatment records.

When prescribing opioids, psychiatrists should also consider side effects or possible adverse reactions with other medications. In addition, they should consider the potential impact on the patient's psychiatric treatment and if the patient has other comorbidities. These issues should be discussed with the patient and documented in the medical record.

Moreover, consideration must be undertaken in situations of patients complaining of chronic non-cancer pain who also have a psychiatric comorbidity. There are well established positive associations between psychiatric comorbidity and the severity of substance abuse.[7] Hence the practitioner should consider the risk of abuse/misuse with each chronic pain patient. Frequent contact with the patient is essential.

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Treating Minors/Teens

Special consideration should be paid when treating minors for chronic pain. Psychiatrists should clearly and objectively document the thought process undertaken when determining the clinical necessity of prescribing opioids to children and adolescents. It is important to be aware of your state's regulations on age of consent for treatment. If indicated, involve the minor patient's parents/guardians in care and treatment. Consider whether a referral to another provider such as a pediatric pain specialist or the patient's primary care physician should be part of the patient's treatment plan.

Conclusion

The potential pitfalls of opioid prescribing should not deter physicians from providing optimal care to patients complaining of severe pain. With compliant record keeping, early management of the expectations of the patient, and transparency between the patient's needs and the physician's obligations, the quagmire of opioid management may be successfully navigated. Should you have questions, contact your local attorney or risk management professional.

About our Author

Brian L. Hoffman is a Partner in the Los Angeles office of Wood, Smith, Henning & Berman, a national law firm with 17 offices in ten states. Mr. Hoffman's practice spans 25 years focusing solely on the defense of the healthcare industry and healthcare providers. He is licensed to practice in all the courts throughout California, and has been named a Super Lawyer in the Healthcare field for the past six consecutive years. He is a frequent speaker on medical malpractice issues affecting the healthcare industry.