Treating chronic pain can be risky for physicians

Opioids are the most-prescribed class of prescription medications in the United States. Physicians are the legal gatekeepers for prescription medications to treat chronic pain. Over the last 10 years,

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prescriptions for opioid analgesics have exploded, as have emergency-room visits related to opioid overdose and death.

As physicians prescribe more opioids, there are corresponding increases in the diversion or misuse of such drugs, along with increases in adverse patient outcomes from misuse and overuse. At the same time, the costs to State Medicaid programs are accelerating with payments to physicians who prescribe, and to pharmacies who supply the medications to patients. State licensing boards and prosecutors have noticed. They take seriously complaints from patients and pharmacies about unusual physician prescribing practices, and they have developed techniques to investigate outlier physician prescribers.

Medical Board Expectations

Pain management is an important part of many medical practices. It is also a common occurrence at the meetings of the Arizona Medical Board and the Arizona Board of Osteopathic Examiners to find physicians being regularly disciplined for inappropriately prescribing controlled substances. A brief review of recent board minutes and disciplinary orders reveals the following common findings from chart audits of prescribing practices:

- Inadequate history and physical examinations;
- Failed to perform a proper diagnostic work-up;
- Failed to obtain and review prior medical records;
- Failed to obtain specialist consultations;
- Failed to order or perform drug screens;
- Failed to respond to positive drug screens;
- Relied only on the patient's self-reports of pain levels;
- Failed to access functional status;
- Failed to have any goals for short and long term functionality;
- Failed to discuss possible side-effects, complications or alternative treatments;
- Failed to re-evaluate the patient after initiating treatment with controlled substances;
- Failed to order a trial of anti-inflammatory or non-controlled substances;
- Failed to obtain a controlled substance agreement or if it was obtained failed to enforce it;
- Failed to obtain a pharmacy board audit;
- Provided "early" refills or replacement prescriptions based on flimsy reasons;
- Failing to recognize drug seeking behavior and other red flags in patients;
- Prescribed high levels of short acting pain medication to patients with a high risk for addiction and/or potential for diversion or abuse.

In a recent medical license revocation order, the Arizona Medical Board noted that the standard of care requires:

With respect to chronic pain and patients on chronic opioid therapy, standard of care involves a balanced or comprehensive approach with adjuvant medications and an alternative therapeutic treatment plan in order to potentially minimize known side effects of opioid therapy, including tolerance, physiologic and mental dependency, and to evaluate for diversion, abuse, and addiction. Known risk stratification regarding chronic opioid use for chronic pain patients recommends a higher level of screening for patients who have had a history of illicit drug abuse and for those patients under 35 years of age.[1]

In the same order, the Board also stated that for good medical care:

- The initial evaluation of a chronic pain patient shall include a pain history, a

directed physical examination, review of diagnostic studies, previous interventions, drug history and assessment of coexisting diseases or conditions.

- Treatment plan should be tailored to the individual. The treatment objective should be clearly stated. The use of high-dose opioids carries substantial risk: habituation, potential for misuse and diversion, deterioration of mental and physical functioning and overdose. Therefore, consideration should be given to different treatment modalities including rehabilitation behavioral strategies, noninvasive techniques and the use of non-opioid medications. An opioid trial should not be initiated in absence of a complete assessment of the chonic pain patient.
- Informed consent should be obtained including a discussion between the physician and the patient with regard to the risks and benefits of the use of controlled substances.
- There should be a periodic review of the treatment efficacy and reassessment of the etiology of the patient's pain, as well as the patient's state of health, their functional status, adequacy of analgesia, opioid side effects, quality of life and indications of medication misuse.
- Attention should be given to the possibility of a decrease in functioning, or quality of life, because of opioid usage.
- The physician should consider consulting a pain specialist or psychologist depending on the expertise of the practitioner and the complexity of the presenting problem.
- The medical record should be accurate, legible and provide sufficient information for another practitioner to assume continuity of the patient's care. These records should contain documentation in the areas listed in the bullet points above.[2]

The Arizona Medical Board and the Arizona Board of Osteopathic Examiners each publishes on their website Guidelines for the Prescribing of Controlled Substances for Treatment of Chronic Pain.[3] The Arizona Medical Board also publishes Guidelines for Treatment of Chronic Pain. Together these guidelines are designed to improve appropriate prescribing for effective pain management while preventing drug

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diversion and abuse. More importantly, they provide a clear, concise statement of the standard of care for the appropriate treatment of chronic pain and the use of controlled substances. These are well-established guidelines and prescribing physicians are held accountable to them by the Medical Boards. There is no reason not to follow them; yet, many physicians do not.

Medical Malpractice Actions

Physicians prescribing opioids who are not knowledgeable about the pharmacology of drugs, current pain management guidelines, and new research in pain medicine are at high risk for medical malpractice actions brought by patients and their families for the adverse outcomes and the collateral impacts of overdoses and deaths. Whether the patient is Michael Jackson or someone who is not famous, such malpractice cases are difficult to defend when opioids have not been prescribed and monitored in accordance with the Medical Board guidelines for use and treatment. Plaintiffs' attorneys will add up the prescriptions and compare the defendant physician's chart against the published guidelines to create a compelling case for failure to meet the standard of care in prescribing and treating such patients. Moreover, these cases may be more difficult because they are brought in conjunction with or shortly after medical board disciplinary actions for the same conduct.

Juries are not sympathetic to physicians who do not stay within the boundaries of prescribing when treating patients with such potent medications. Failing to properly prescribe and monitor opioids has both civil and administrative exposure and in some instances even criminal exposure.

Prescribing controlled substances requires careful detailed-oriented management.

Illegal Prescribing

The U.S. Department of Justice Drug Enforcement Administration (DEA) Office of Diversion Control publishes an annual list of DEA involved cases against physicians that resulted in arrest and prosecution of the physician. It also provides a list of the administrative actions against physicians to revoke their DEA registration. The DEA uses law enforcement techniques, often in combination with state and federal agencies, against prescribing physicians that include undercover agents posing as patients who videotape encounters, pharmacy surveys, surveillance, data mining, search warrants, and interviews with employees, patients, and vendors. Typical criminal prosecutions against physicians include charges for:

- Possession with intent to distribute;
- Prescribing or dispensing with no legitimate medical purpose;
- Illegal sale of prescription drug samples;
- Conspiracy to distribute and conspiracy to launder money;
- Murder in second degree;
- Involuntary manslaughter;
- Negligent homicide;
- Felony murder;
- Health care fraud.

Some recent representative cases include the following:

- New York physician prescribed hundreds of prescriptions for controlled substances, particularly OxyContin and Dilaudid, to new "patients" for conditions he made no attempt to verify, without making bona fide inquiries into whether the patients had previously experience with these drugs or other opiates, and without determining whether the dosages prescribed would be safe to take alone or in combination with other substances the patient might be ingesting. Physician was sentenced to 3 years in prison, followed by 5 years supervised parole.
- Georgia physician dispensed a quantity of controlled substances for other than a legitimate medical purpose. Physician admitted that he knowingly violated federal law by illegally writing prescriptions for 19 patients. Physician was sentenced to 10 years in prison, followed by 3 years supervised release and 250 hours community service. He was also ordered to pay a special assessment of $17,500.
- Pennsylvania physician operated a medical clinic that was in actuality a "pill mill" at which patients could obtain medical prescriptions for controlled substances without any medical necessity for the prescriptions. Physician was sentenced to prison for a term of 15 months followed by supervised release of two years, and ordered to pay a special assessment of $400, a fine of $7,500, and restitution in the amount of $59,684 to the Social Security Administration. He was also ordered to forfeit over $1 million in cash and properties that were alleged as the proceeds of his sales of fraudulent prescriptions.

- Florida physician prescribed controlled substances to patients without determining a sufficient medical necessity for the prescriptions. Physician also committed health care fraud in that he caused patients to fill such prescriptions at various pharmacies, allowing the pharmacies to file claims and obtain reimbursement from Medicaid, Blue Cross, and other health care programs. He also prescribed controlled substances to patients that resulted in the overdose deaths of patients from the use of the prescriptions. Physician was sentenced to prison for a term of 24 years followed by three years supervised release, fined $250,000 and he forfeited property of $835,000.
- Arizona physician operated pain clinic 1-day/week seeing 50 to 188 patients per day and giving as many as 40 injections per day. He signed prescriptions, performed brief exams and created false electronic records for patients. He averaged 210 prescriptions per day. He also upcoded and billed Medicaid. Physician pled guilty to 3 felonies, paid $700,000 restitution, forfeited $2,000,000 in seized property and was sentenced to 2-1/2 years in prison.
- Arizona physician indicted on 130 counts for conspiracy to illegally distribute controlled substances, health care fraud, and money laundering for signing thousands of prescriptions for controlled substances that were paid by Medicaid in the amount of $4.5 million.

Conclusion

Prescribing controlled substances requires careful detailed-oriented management. Most physicians who get into trouble begin as caring physicians who slowly evolve into physicians who cannot say "no" to their patients, and become too busy to monitor, document and challenge their patients' continued use of controlled substances. Physicians who do not maintain and follow the current standards of practice place themselves, their licenses, and their patients at risk. Some physicians may even be at risk for criminal prosecution, particularly those who find that being an easy prescriber, will quickly lead to a word of mouth mushrooming of patients with chronic pain. The risks in prescribing outside of established guidelines are high, and getting higher. **AM**

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