How to Avoid Liability When Prescribing Opioids

Are you prepared to deal with this ongoing crisis?

BY ANDREA LINNE

There's no escaping the opioid crisis. It's a nationwide epidemic that's rampant in cities, suburbs and rural areas, with weekly if not daily reports in local news of people—rich and poor, young and old—who overdosed and died. Both the causes and cures of the epidemic are complicated and multifaceted, but over-prescribing opioids has contributed to the crisis. Today, there are federal and state guidelines—including guidelines from state boards of podiatry—for the prescribing of opioids for acute and chronic pain.

In addition, most states and the District of Columbia have a prescription drug monitoring program (PDMP), a statewide electronic database that collects designated data from a pharmacy on controlled substances dispensed in the state; it tracks which controlled substances were dispensed, how much, to whom, and by whom. Missouri is the only state without a PDMP, though lawmakers might pass prescription drug tracking legislation this year. A doctor can check to see what controlled substances a patient is taking or may have been on in the past. The goal, according to the Centers for Disease Control and Prevention (CDC), is to identify "patient behaviors that contribute to the epidemic and facilitate a nimble and targeted response." However, the CDC says that pharmacies submit this data to state PDMPs at varying intervals—ranging from monthly to daily. The NABP PMP InterConnect allows participating state PMPs to be linked, providing a more effective means of combating drug diversion and drug abuse nationwide.

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Some podiatrists welcome these regulations while others feel they're under a microscope and think their medical judgment is being usurped by bureaucrats, says J. Kevin West, a senior healthcare attorney in the

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Idaho office of Parsons Behle & Latimer. "There are two sides," West says. "Some doctors prescribe opioids for good reasons, and they feel state boards, the U.S. Food and Drug Administration, and the U.S. Drug Enforcement Administration (DEA) are looking over their shoulder every time they prescribe. But too many drugs are circulating. Instead of prescribing 10 pills, doctors prescribe 30 or 40." A recent *PM News* online poll found that 44 percent of respondents have either decreased or discontinued prescriptions for opioids, while nearly 50 percent of respondents report that their prescriptions for opioids are unchanged.

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"In this environment, healthcare providers are being subjected to much higher scrutiny and procedural requirements on opioid prescriptions, and any irregularity can trigger a requirement that the doctor report to the DEA and in some states to licensing boards or other state regulatory authorities," says June Laird, a partner in the Colorado law firm McElroy, Deutsch, Mulvaney & Carpenter. "We have found that DPMs are not thinking about these reporting requirements when they should. One thing that will bring a DPM practice to an abrupt halt is when a DEA order or licensing board lifts their prescriptive authority pending investigation on a matter that should have been self-reported to the DEA or licensing board."

"There are a lot of policies and procedures that practices should have but may not," says Linda McSmith, manager of risk management for the Podiatry Insurance Company of America (PICA). "This is important for both employees and patients." There is a lot of oversight, she says, but still some podiatrists fail to stop and check the PDMP because it slows down their workflow.

It's All About Charting

Whether using paper or electronic medical records, documenting patient care completely and legibly is a basic rule. But some medical professionals, including podiatrists, fall short when it comes to good charting, often because they don't do it immediately after treatment when details are still fresh in their minds or they don't explain why they provided a particular service or prescription. The latter is especially important in the age of the opioid epidemic.

Dr. Kobak

Podiatrists who perform surgery and prescribe opioids for post-operative acute pain must document it, says Lawrence Kobak, DPM, JD, senior counsel in Frier Levitt's healthcare department, in New York, and general counsel to The New York State Pain Society and The Pennsylvania Pain Society. "That includes documenting that you checked your state's PDMP," Kobak says. "When you check a PDMP, there's a log, a record, of who checked and on what day. Have a printout of the record or scan it into the medical record. Some software can capture the log and put it in your records."

But checking a PDMP is not enough, Kobak says. "You also have to chart your findings," he says. "Indicate, for example, that you did not find any drugs that could interact with opioids and cause death. Copy and paste can help with bad handwriting but it's not enough. Your chart is about quality, not quantity."

Charting is also important when you renew a prescription for opioids. "It's not enough to just say 'post-op pain,'" Kobak says. "You have to chart whether the patient is feeling better and walking better. You have to chart what the post-op x-ray shows. You have to chart what else you are doing other than prescribing medicine to mask symptoms.

"Charting shows what you did and why and what you didn't do and why," Kobak says. "Guidelines are guidelines. If you go against federal or state guidelines, you better have a very good reason. Your chart is Exhibit A if there's ever an investigation into your prescribing practice. It's to protect yourself. And sometimes that could be from a patient who reports you because you did not renew their opioid prescription."

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How the Dominos Fall

The monitoring programs on opioid prescriptions filled vary from state to state. "These monitoring programs have created liability for podiatrists," Laird says. When a problem is detected within the monitoring system—either a patient is filling too many opioid prescriptions including prescriptions from a DPM, or a DPM is writing too many opioid prescriptions in general—the DPM is notified under most circumstances and sometimes so is his or her licensing board, which launches an investigation. Also, when a licensing board is investigating a complaint against a DPM—even when it's completely unrelated to opioid prescriptions—a report on all of the opioid prescriptions filled for the DPM's patient or for all patients during a specific time can be obtained by the board from the monitoring program, which can lead to disciplinary action for not adhering to

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opioid prescription guidelines.

"I've had to defend a number of DPMs in lawsuits and before Colorado's DPM Board, typically for one of two reasons," Laird says. In one scenario, a DPM asks a patient if he or she is taking any opioids. The patient says "no," and the doctor does not adhere to established guidelines by checking the opioid prescription drug monitoring database to confirm that the patient is not getting other opioid prescriptions filled and writes the patient an opioid prescription(s). "The usual claim in a lawsuit by the patient or their family when the patient has drug complications or injures himself while under the influence of the opioid is that the DPM failed to follow guidelines, failed to recognize the drug abuse tendency in the patient, and should have saved the patient from himself," she says.

The other scenario involves treating a patient with chronic pain, and it is not a question of a doctor not checking the monitoring program database, Laird says. "Many podiatrists treat elderly patients who aren't candidates for surgery but suffer with pain," she says. "So, the doctor prescribes a low dose of a Schedule II or even III narcotic for several months. Just helping several patients, say five to ten in this manner, could trigger a response from the monitoring program that can lead to the licensing board's involvement."

In either case, when an investigation is launched, the DEA and/or licensing board can suspend the podiatrist from practicing or limit the types of opioids he or she can prescribe. "I represented a podiatrist who couldn't do surgery because he couldn't prescribe pain medicine at the Schedule II level, and even though his only limitation was for Schedule II drugs, it brought his surgical practice to an abrupt halt until we were able to get the limitation lifted," Laird says. "Depending on the circumstances, getting a limitation lifted can take weeks and even months. Once you have a Schedule II or even III prescription privilege revoked, you're required to report it to the surgical facilities and/or hospitals where you practice, and if the DEA was not the agency that imposed the limitation, you need to report to that agency immediately. Also, insurance companies can pull you off their panel and alert their insureds that you're no longer approved to provide services."

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Dr. Borreggine

"It can take a year to resolve all these issues," Laird says. "It's a practice nightmare and, under worst circumstances, can shove a podiatrist into bankruptcy."

Podiatrists are in a tough position when it comes to treating patients with chronic pain, Laird says. "They have to tell their patients that they can't write prescriptions over the long term anymore and refer them to a pain-management doctor or group for that service. But there are limited numbers of those specialists and a lot of them don't accept Medicaid or military insurance or new patients. Then, when your patient says 'I can't find anyone,' you have to say, 'I'm sorry, I can't help you with that.'"

Privacy Concerns

Some podiatrists have expressed concern regarding whether checking a patient's drug history on a PDMP violates the Health Insurance Portability and Accountability Act (HIPAA), designed to safeguard personal medical information. "Checking a PDMP is not a violation of HIPAA," Kobak says. However, he adds, "The doctor should only check on people who are current patients. The PDMP is not for checking out a neighbor. If you designate someone in your office to check the PDMP, you must review HIPAA regulations with that person. The designated employee must understand that the PDMP is only to check on patients, not for their own curiosity. There is a record that someone logged on at a specific time and date and looked at a specific patient. The podiatrist would be responsible for any violation."

Last year, Joseph Borreggine, DPM, podiatric physician and surgeon with The Family Foot Care Center of East Central Illinois, posted this question on *Podiatry Management Online:* "I was wondering how appropriate it is, with the current HIPAA laws, if a medical provider can investigate a patient's opioid prescription history prior to them coming into the office as a new patient or even if a prescription opioid is not being written?" Dr. Borreggine explained his concern: "If a patient has an extensive opioid history that is unknown even in light of a pending prescription opioid Schedule II drug being written, then the care of this patient may become

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difficult in the future with respect to pain management. Unfortunately, most patients do not honestly reveal this information in their medical history and usually do not want physicians to know about this information."

While it's a legitimate concern, the answer is clear.

Podiatrists must be vigilant on all of their prescriptions, but especially opioids.—Laird

"One can access the prescribing data once the person has become a patient, not before," Kobak says.

Just as a podiatrist is responsible for an employee who violates PDMP guidelines, a podiatrist is responsible for an employee who forges their signature on any prescription. But additional duties arise for the DPM if the employee forges an opioid prescription, Laird says. "This has happened with at least two dozen clients of mine over the years," she says. "Employees do it for their own use, or for a friend or family member who is drug-dependent, or to sell as a money-making proposition. And sometimes, an employee just gets talked into it by a patient after the DPM refuses to write the prescription."

Podiatrists must be vigilant on all of their prescriptions, but especially opioids, Laird says. "If you discover that an employee has forged your signature on an opioid prescription, you must report it to the DEA immediately and in some states to your licensing board," she says, "and you need to fire the employee immediately because he or she can never be trusted again." Of course, it's best to take steps to prevent this from happening. "Run a tight ship when it comes to prescriptions," Laird says. "Have talks with staff members at least quarterly. Make it clear that only you write prescriptions for any drug, and take the time to educate them on the societal opioid crisis and the heightened scrutiny all prescribing healthcare providers are under when prescribing opioids. Explain that because of the network between doctors, pharmacies, and the monitoring programs, any opioid prescription forgeries will be tracked back to the employee, they will be caught, they will lose their job, and they will be liable for criminal charges."

"Most states require physicians to have education in opioid management, one or two hours, for the renewal of their license," PICA's McSmith says. In 2016, for example, New York State began requiring all podiatrists who have a DEA registration number and all residents prescribing with a facility DEA registration number to take three hours of training approved by the Department of Health in pain management, palliative care, and addiction. The American Podiatric Medical Association also provides education and supplemental materials to assist members in both addressing this epidemic and ensuring compliance with any federal or state requirements and/or guidelines.

Podiatrists need to make time to evaluate patients and look at their intake form, which should be updated yearly, says McSmith, who is also a registered nurse. "A patient who has sleep apnea and takes opioids could stop breathing," she says. "Older patients who take narcotics may lay around and not eat or drink, which puts them at risk of getting pneumonia and dehydration." It's also important to consider whether the patient seems depressed or might be postponing surgery to stay on pain medication. Keep in mind, she says, that patients with a drug history may not be as truthful on their intake form.

"When you do prescribe opioids," McSmith says, "it's important to take the time to review the benefits and risks with the patient." Some podiatrists rely on an opioid treatment agreement or contract, which is not legally binding, but critics say they are not effective and some patients will sign anything to get pain relief. "A narcotic contract is a good tool for some, not all, patients," she says. "It can be helpful if it provides a full list of expectations, including how they're going to need physical therapy and what they can do post-operatively to help themselves, instead of relying on more drugs." **PM**

Andrea Linne is a freelance writer living in New York City.