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INSIDE

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Strict Rules Addressing Opioid Crisis Create Risks for Physicians

The opioid crisis has led regulators and law enforcement at both state and federal levels to implement strict limitations on prescribing that can create substantial risks for individual physicians and the organizations that employ them or credential them. Staying out of trouble requires a clear understanding of the rules.

In August 2017, the Department of Justice formed the Opioid Fraud and Abuse Detection Unit, which uses prescribing data to prosecute healthcare professionals engaged in opioid-related healthcare fraud. In the unit's search for pill mills, any physician or organization prescribing a high volume of opioids can come under scrutiny.

DATA FROM PRESCRIPTION DRUG MONITORING PROGRAMS SERVE AS A PRIMARY SOURCE FOR FEDERAL PROSECUTORS ENFORCING OPIOID STANDARDS.

The Drug Enforcement Administration (DEA) also is fighting opioid abuse by revoking controlled substance registrations for those who prescribe excessively. The DEA demonstrated its power to do so in February and March of 2018 by arresting 29 people and revoking 147 controlled substance registrations. *(More information on the DEA fraud unit is available online at: https://bit.ly/2VTw75S.)*

Losing a controlled substance registration means the physician or organization can no longer prescribe or dispense controlled substances. For most, that means they cannot continue operating in healthcare. Healthcare organizations are responding to the increased oversight.

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A survey by healthcare performance improvement company Vizient in Irving, TX, found that 64% of hospitals have increased their investment in opioid medication management over the previous year, with 78% implementing more prescriber education. Fifty-six percent introduced new technology to monitor prescribing, 54% added new options for acute pain management, and 44% limited dosage and quantities for prescribers.

In assessing the interventions they have introduced, survey respondents were most happy with dosage guidelines for acute care patients upon discharge, with 74% saying they were extremely or very effective. The next two most effective strategies were adding new staff to monitor opioid use and introducing new technologies to monitor opioid prescribing.

Opioids Come With Danger

Federal prosecutors have started issuing letters directly to medical prescribers, warning them that their opioid prescribing is a "source of concern," says **Sarah Hall**, JD, a former federal white-collar crime prosecutor and now senior counsel with the Thompson Hine law firm in Washington, DC. She has extensive experience in prosecuting criminal healthcare fraud.

She calls the letters especially concerning for healthcare providers. There is little precedence for warning letters, so it is unclear what the reaction should be, Hall says.

The closest precedent is the "target letter" that federal prosecutors sometimes send to a target of an investigation. Hall explains that the federal *Justice Manual* describes a target as "a person as to whom the prosecutor or the grand jury has substantial evidence linking him or her to the commission of a crime and who, in the judgment of the prosecutor, is a putative defendant."

That signals that prosecutors are taking the issue quite seriously, Hall says.

"The world of opioids is a very dangerous place these days for doctors, patients, and society in general," Hall says.

Data from prescription drug monitoring programs serve as a primary source for federal prosecutors enforcing opioid standards, she says.

"Healthcare organizations should have a good understanding of their

EXECUTIVE SUMMARY

Opioid prescribing is under intense scrutiny from federal and state prosecutors, creating significant risk for both individual clinicians and healthcare organizations. Any high volume of prescribing or other anomaly can trigger an investigation.

- Failure to comply with prescribing guidelines may result in revocation of a controlled substance registration.
- Hospitals in certain geographic areas of high opioid use are already under scrutiny.
- Hospitals must closely monitor their physicians' prescribing practices.

physicians' prescribing practices. The feds look for outliers in billing, so with opioids that can be high volumes of opioids overall, or high volumes in relation to the size of the practice or hospital," she says. "They are looking at geographic areas where opioid prescribing is high, so if a hospital is operating in that area, it may automatically get attention from federal prosecutors. If you are in south Florida, Houston, Dallas, Baton Rouge, Detroit, and other areas mostly clustered on the East Coast, you're already under greater scrutiny than most healthcare organizations across the country."

Risk Greatly Increased

The risk level related to opioids has increased significantly in recent years, says **Harry Nelson**, JD, chairman of Nelson Hardiman law firm in Los Angeles and founding board chair of the Behavioral Health Association of Providers, which consults with addiction treatment facilities.

"Not only are state and federal prosecutors becoming more aggressive, but state medical boards are taking a much more in-depth approach of comparing hospital records, physician records, and coroner reports in cases in which patients have died," Nelson says. "They are asking questions about whether the immediate cause of death had any connection to opioid prescribing."

Also, any opioid prescription over 150 morphine milligram equivalents (MME) is now scrutinized closely, Nelson says.

"Any prescribing at that level is being viewed with intense suspicion. State medical boards are generally identifying anything over 80 to 90 MME as questionable, and after that, it is definitely going to be suspicious," he says "They will look for a reason to excuse it, and they are more lenient with palliative care like for cancer patients and with patients with a history of trouble tapering off. But they are going to look at it very closely, and that was not always the case."

Nelson says there also is an uptick in medical malpractice cases related to opioid prescribing.

"We are in a very high-risk environment where we've seen the pendulum shift from a focus on the risk of undertreatment of pain a decade ago to now this intense focus on overprescribing," Nelson says. "We're missing some pieces of the puzzle that doctors and hospitals need to have in place to have confidence in prescribing. We're missing a whole set of protocols that are condition- and setting-specific for appropriate use of opioids because now we have a one-size-fits-all guidance document from the CDC."

Nelson expects those more specific guidelines to come out within a few years, and in the meantime, he suggests risk managers develop internal guidance for physicians.

"The biggest problem I see is that the level of fear is keeping doctors from prescribing and leading to an enormous amount of suffering. I hear about cases in which doctors and nurses are emotionally wrought at their inability to treat serious pain, apologizing to patients who are genuinely suffering," Nelson says. "Organizations shouldn't wait for better national guidance. Work internally to articulate more specific guidance so that doctors will know they are safe in using particular dosages and duration in specific settings."

Many Regulations to Cover

Hospitals and individual physicians can find it difficult to keep up with all the new regulations regarding opioids, says **Joanna Starrels**, MD, attending physician at Montefiore Health System and associate professor at Albert Einstein College of Medicine in New York City. She focuses on the safety and effectiveness of opioids.

"Clinicians are increasingly aware of the opioid crisis, and they know that they should be taking more precautions and implementing these processes, but they may not have the time or resources to do that in a thoughtful and nuanced way," Starrels says. "There are multiple new regulations, CDC guidelines, and Joint Commission requirements for a pain management committee, that patients be screened for addiction, monitoring pain in a standardized way, monitoring opioid prescribing, and training employees in opioid management. There can be a lot for healthcare professionals to keep up with and implement."

Opioid tapering can be particularly difficult for some healthcare providers, Starrels says. The CDC recommendations include guidance on how to reduce the prescriptions of some patients receiving high dosages of opioids, but Starrels says that often is misinterpreted.

"Many providers and health systems feel they need to use blunt measures to reduce everyone who is on these higher-dose opioids to these thresholds stated by the CDC or below. That seems to be causing the most problems," she says. "For risk managers, there are two sides to the coin. On one side, careless

opioid prescribing can lead to serious consequences like addiction or overdose, but underprescribing opioids also can bring negative consequences. So patients and families are coming forward with complaints from both sides."

Some strategies that can help clinicians manage the increased regulation of opioids include increased staff support, team-based care, adding clinical decision support tools to the electronic health record, data monitoring of opioids to identify outlier providers, and better patient education, Starrels says. Good patient education is required now, she notes, and most physicians do not have the time to do it adequately. Hospitals and health systems can step in to provide more extensive education to patients.

"It sounds like a lot, and it is," Starrels says. "That's why the best model for this is a team-based approach."

Starrels believes the regulation of opioids, while well intentioned, is moving faster than the research used to support it. There already is evidence that patients are being harmed by underprescribing, and she suspects there could be more backlash coming.

"Some of the recommendations are not yet ready for prime time, in that we don't fully understand the consequences of implementing them across the board," she says. "In the past year or so, I've seen some hints of correction or slowing of this train that I think is appropriate."

Starrels does expect more health systems to continue implementing a comprehensive approach to data monitoring and opioid stewardship programs. She acknowledges that healthcare organizations can be left in a difficult position when the risks of noncompliance are so severe but says it is important to keep in mind the effect on patients.

"I do have some hesitation that being too aggressive in overcorrecting the problem of overprescribing opioids can have negative consequences for patients that are poorly understood. I caution health systems about implementing these changes — which are mostly recommendations and often based on data that is not proven — too aggressively."

Hospitals Can Be Liable

Criminal charges will fall on the individual prescribing the opioids unless prosecutors can prove the involvement of the employer, such as a hospital, Hall says. But broader civil liabilities and sanctions can be brought against the healthcare organization, she says, and those can bring extensive damage to its reputation along with substantial fines and other expenses.

"Hospitals definitely need to be involved with the prescribing practices of their physicians because the liability can come back on them in various ways," Hall says. "The more the hospital has a handle on medical professionals' prescribing practices, the better it will be able to avoid any potential investigations."

Hospitals and health systems are increasingly worried about consequences from opioid investigations, says **Dianne K. Pledgie**, JD, partner and compliance counsel with the law firm of Feldesman Tucker Leifer Fidell in Washington, DC.

"From the provider side, we are fielding concerns about ensuring appropriate opioid prescription practices are in place and followed, especially because of increased enforcement from the Office of Inspector General [OIG] and other authorities," she explains. "From a compliance and risk management perspective, we are working with providers to develop clear processes for treating chronic pain, including requiring providers to query the Prescription Drug Monitoring Program, having patients sign pain contracts, and conducting regular chart audits and peer review to ensure prescribing is appropriate."

At the same time, Pledgie says, many healthcare organizations are expanding their substance use disorder offerings. The compliance concerns for these new offerings include meeting licensing requirements for facilities and staffing. The federal government, as well as state governments, have supported the development of these services through grant funding, which requires compliance with a host of grant management rules, she says.

"In this area, too, the OIG has announced audits of the Substance Abuse and Mental Health Services Administration ranging from how grants are awarded to state-level controls over opioid treatment programs," she says. "Our clients are also partnering with other organizations to provide additional support to those with substance use disorders. These partnerships often create compliance challenges related to sharing patient information as a variety of state and federal laws come into play, including 42 CFR Part 2, the federal regulations which heighten the privacy protections for certain substance use disorder records."

Patients must consent in writing to the sharing of their records protected by Part 2 for purposes

of treatment or care coordination, unless one of a very few exceptions applies, Pledgie explains. Under HIPAA, such written consent is not required to disclose protected health information for treatment or care coordination. The Part 2 regulations affect the disclosure of patient records through health information exchanges, to law enforcement, to auditors, and more, she says.

Risks Extend Across Industry

The risk management challenges related to opioids extend throughout the entire healthcare industry, says **Alicia Marsiglia**, vice president and head of Allied Healthcare at the New York City office of Hiscox, an insurance underwriter.

"It's clear that states, cities, and counties are adopting the perspective that the whole health system should be held accountable for creating the opioid crisis. We see insureds or potential insureds in the treatment and distribution space — pharmacies, clinics, counseling, wholesale distributors — at a high risk of claims and regulatory scrutiny related to opioids," Marsiglia says. "I don't think we can say that it's only a physician's problem. Litigation can really be targeted at any provider in the continuum of care."

Managing compliance upfront is much easier than managing claims and license actions after the fact, Marsiglia says.

"The best way to defend against claims and regulatory scrutiny in most scenarios is to manage expectations with patients and be clear and upfront with patients about the available options," she says. "Prescribe and fill prescriptions like someone else is watching because at this point, it's likely the case. The level of oversight has necessarily increased to meet the challenges facing this industry."

Opioid compliance is one more burden for clinicians and risk managers already dealing with a variety of challenges, notes **Carla M. DewBerry**, JD, partner with the K&L Gates law firm in Seattle.

RISK MANAGERS SHOULD HELP THEIR ORGANIZATIONS DEVELOP A WORK PLAN TO STAY ABREAST OF DEVELOPMENTS IN OPIOID COMPLIANCE AND TO AVOID PITFALLS.

"Both practitioners and hospitals will be held accountable. Hospitals may have an easier time defining expected patterns and practices because this is standard work in a hospital," DewBerry says. "Some of the intensity of the new requirements may be a more challenging issue for clinicians. But doctors should anticipate that their home states may have adopted a stance similar to that in Washington, where the regulations now state that appropriate pain management is the treating physician's responsibility."

Risk management is similar for both individuals and institutions, DewBerry says. Both hospitals and clinicians have licenses to protect and they are possible defendants in cases that can come from many corners, DewBerry notes.

They both are required to produce and keep records of their actions, and therefore, their own files can be evidentiary; they rely on information from others such as patients, referral sources, and staff; and they have reputations to protect.

"You are seeing some of these risks being played out already in lawsuits which examine prescriptive practices, in new best practice guidelines and in the adoption of new regulations which clinicians must follow," DewBerry says.

"For example, many states have adopted rules for prescribing and monitoring opioids. These rules initially impact clinicians, and they can vary depending on factors such as the age of the patient, nature of the pain, the site of service, and impact of recent treatment received by the patient."

Outline for Risk Management

Risk managers should help their organizations develop a work plan to stay abreast of developments in opioid compliance and to avoid pitfalls, DewBerry says. The work plan would vary based on the size of the organization and its role in the delivery of care, but she offers this general outline:

- provider education on drug abuse and addiction;
- internal treatment protocols;
- grading patient pain levels;
- required assessments of the benefits and harm of opioid therapy for specific patients;
- required reassessments at a

specific time or based on identified factors;

• prioritizing nonopioid treatment, as appropriate;

• tapering the use of opioids;

• protocols for an assessment of the potential for misuse of medications by a patient;

• defining appropriate laboratory testing for drugs of abuse to identify the misuse (or nonuse) of prescribed medications.

Pursue Compliance in Usual Ways

Opioid compliance should follow the same general steps as any other compliance effort, says **Samuel J. Louis**, JD, an attorney with the Clark Hill law firm in Houston. Know what the regulations are, who the regulators are, and any guidance issued. Use that information to develop a compliance plan and train your employees, he says.

Louis recently worked with a hospital client to address opioid compliance, bringing in a DEA official to meet with hospital leaders. He notes that hospitals should be motivated to educate prescribing clinicians because of the potential risk of liability to the institution.

"Make sure that whatever your treatment regimen is, you can justify it through documentation of your patient over time. Documentation is key if you're trying to show that the amount of drugs you've prescribed is within the range of what is acceptable in the specialty and for that patient," Louis says. "Understand the sea change with respect to these prescriptions and ensure that you are in step with what regulators are expecting now with respect to determining need, dosage, and length of the prescription. On the administrative side, risk managers need to ensure those policies are not just in place but are actually being followed."

Hospitals and physicians are making a strong effort to curb the prescription of opioids, says **Scott Olson**, CEO of the addiction treatment center Pathway Healthcare in Birmingham, AL, which works closely with several hospitals.

"Most people are trying to determine, from a clinical diagnosis standpoint, when you should and shouldn't have an opioid prescription, and that is a change from how it was done in the past," Olson says.

"The thinking used to be that any pain is bad and you shouldn't have it, opioids work on the pain and insurance covered it, and doctors were incentivized to reduce your pain to zero. Now, there is more of a closer look at whether an opioid is what you really need, and if so, how long you need it." ■

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