MEDICAL RISK RESOURCE **Advisor**

ProAssurance Treated Fairly

PROMOTING PATIENT SAFETY • PROVIDING SOUND ADVICE • PLEDGING TREATED FAIRLY VOLUME 26 • SUMMER 2020

Understanding Your Risk

Controlled Substances and Your Practice

Author: William Ashley, JD
Senior Risk Resource Advisor

If you have questions on this topic, please contact Mallory Earley at 888-877-4498, extension 4789, or email MalloryEarley@ProAssurance.com.

The opioid crisis continues to grip American communities of all sizes. Licensing bodies and public health agencies spend much energy trying to reduce the number of opioid prescriptions clinicians write and encourage greater responsibility in controlled substance prescribing practices. This increased public scrutiny has borne results. The Centers for Disease Control and Prevention acknowledge that in 2018, the age-adjusted rate of drug overdose deaths in the United States decreased for the first time in a generation.[1]

Prescriber Risks

Physicians as gatekeepers

Many controlled substances are essential in treating patients with a vast array of ailments; however, physicians must approach their role as gatekeepers of controlled substances with great care. Efforts to reduce the overprescription of controlled substances have taken many forms, including criminal prosecutions, regulatory enforcement actions, civil lawsuits seeking damages, and improved medical education. These efforts place physician medication management under intense scrutiny. While much national attention focuses on physician prescribing behavior as it relates to opioids, physicians risk potential civil and criminal liability when prescribing any controlled substance.

Restrictions on prescribers

The Controlled Substances Act classifies certain drugs into one of five schedules. How a drug fits within this classification system depends on certain factors like its usefulness in treating certain illnesses, the drug's risk of abuse, and any risk the drug poses to public health.[2] Only drugs with a potential for abuse may be scheduled.[3] The Drug Enforcement Administration (DEA) reserves the highest classification, Schedule I, for drugs with a high potential for abuse and no currently accepted medical use.[4] Examples of Schedule I drugs include heroin, GHB, and LSD.[5] A physician may not issue a prescription order to dispense a Schedule I drug. The lowest classification, Schedule V, includes drugs with a currently accepted medical purpose and a low potential for abuse relative to other schedules. An example of a Schedule V drug is cough medicine with codeine.[6]

The Controlled Substances Act restricts licensed healthcare providers in their ability to prescribe controlled substances. For a prescription order to comply with the Controlled Substance Act, it must be issued: (1) for a "legitimate medical purpose"; (2) in the usual course of professional practice; and (3) based upon a qualifying medical relationship with a physician holding a DEA license.[7]

Continued on page 2

Continued from page 1

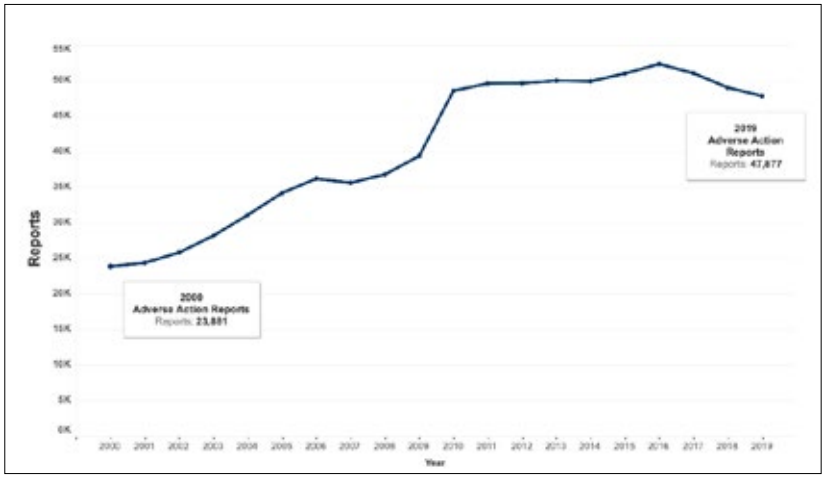
Controlled Substances and Your Practice

DEA enforcement actions against prescribers

From the years 2000 to 2019, adverse actions taken by the federal government against DEA license holders have nearly doubled, with 47,877 adverse actions reported in 2019 (figure 1).[8]

One such enforcement action involved a Missouri physician who the DEA alleged did not have a qualifying medical relationship with the patients to whom he was prescribing scheduled drugs. After a DEA investigation resulted in charges for violations under the Controlled Substances Act, a U.S. District Court for the Eastern District of Missouri sentenced Dr. Brij R. Vaid of Ladue, Missouri to 24 months of imprisonment and ordered him to pay $176,912 in restitution.[9] Dr. Vaid, an internal medicine physician, would provide his staff with pre-signed prescriptions for controlled substances, including oxycodone, hydrocodone, and XANAX®, without first examining the patients.[10] In sentencing Dr. Vaid, the District Judge concluded that Dr. Vaid "created a reckless risk of bodily injury to his patients, given the powerful prescription opioid drugs that he repeatedly provided to his patients."[11]

Figure 1



While DEA enforcement actions are on the rise, physicians also face potential criminal liability under state law for improper controlled substance prescribing. Because controlled substances pose a potential risk of harm to individuals, state prosecutors may seek to hold clinicians accountable for prescribing behavior that causes injury or death. Prosecutors charged one California physician with multiple counts of murder when four of his patients died as a result of his overprescription of opioids and narcotics.[12] Thomas McNeese Keller, a neurologist and pain management physician from Santa Rosa, California, is alleged to have prescribed controlled substances including Vicodin®, oxycodone, OxyContin®, Percocet®, and morphine, at "dangerously high levels."[13] Dr. Keller continued to drastically increase his patients' opioid prescriptions even after learning that some of his patients overdosed.

Legal Remedies

State and local governments sue drug companies

Criminal penalties are not the only means of addressing the overabundance of harmful controlled substances available nationwide. States, counties, and municipalities have begun using civil remedies to force a change of behavior in pharmaceutical manufacturers and distributors. By seeking awards of damages, local governments aim to recoup the cost of the opioid epidemic, which includes the cost of screening, treatment, rehabilitation, housing, and continuing medical education.[14]

Oklahoma uses public nuisance strategy

The State of Oklahoma used a civil cause of action known as public nuisance to hold pharmaceutical maker Johnson & Johnson to account for the cost it incurred in treating opioid-dependent Oklahomans.[15] Public nuisance is a legal theory of liability that targets an offending activity that affects an entire community, though the extent of the annoyance or damage inflicted may be unequal among individual members of the community.[16] The Attorney General's office was able to prove that due to its marketing practices, Johnson & Johnson had an outsized impact on the state's epidemic, though its sales were only approximately one percent of the Oklahoma opioid market.[17] After the trial concluded, the trial judge found in favor of the state and assessed damages at $572 million, later reduced to $465 million as the result of a math error.[18] Given the success of this tactic, many other governmental entities are following Oklahoma's lead.

Multidistrict litigation process continues

Likewise, counties and municipalities are using civil litigation to change how pharmaceutical companies market and distribute controlled substances in the United States. Over 2,400 suits filed by local governments against defendants in every phase of the opioid manufacturing and supply chain in the United

Continued on page 3

Continued from page 2

Controlled Substances and Your Practice

States have been consolidated into one federal district court in Ohio as part of the multidistrict litigation process (MDL).[19] While some individual cases within the MDL have settled, the parties continue to work toward a global settlement to address the opioid-related social costs incurred by the local government plaintiffs. Although recouping nuisance abatement costs is one motivation for suing opioid manufacturers, many believe the high cost of defending these suits and paying the resulting judgments will improve patient safety by altering corporate behavior.

Malpractice litigation

While governments are using civil law to remedy some of the large-scale effects of overprescription of opioids, malpractice litigation is an available remedy for families of patients who suffer a fatal overdose. One such patient was Jennifer Goodridge, who died after ingesting a mixture of opioids, muscle relaxants, and barbiturates prescribed by her primary care physician.[20]

Goodridge's behavior fit a familiar, if unfortunate pattern over the two years she treated with her doctor: she repeatedly asked for early refills of her prescriptions, and she took other controlled substances obtained from other sources. Goodridge's attorneys alleged that her treating physician failed to heed warning signs of her addiction, and neglected to monitor the medications he was providing her. In his defense, Goodridge's doctor claimed he counseled her on the risks of drug addiction and provided her with treatment alternatives. Unfortunately, these actions were not enough to insulate the physician from liability. After trying the case, and while the jury deliberated, Goodridge's doctor settled the case for an undisclosed sum.

Risk Management

Establish and document legitimate medical purpose

Fortunately, clinicians can effectively defend malpractice suits alleging the over-prescription of controlled substances with the implementation of sound risk management principles. A prescriber's main concerns should be two-fold: establishing that there is a "legitimate medical purpose" for the prescription, and demonstrating the prescriber's medical reasoning in the patient's chart.

One of the easiest ways to demonstrate the patient's suitability for treatment with a controlled substance is to gather as much useful data about the patient as possible. One way to accumulate this data and allow it to inform the prescriber's medical decision-making is to use a continuity of care tool. ProAssurance collaborates with Sure Med Compliance to offer its Care Continuity Program® to insureds at a discounted rate.[21] Patients use this tool to input data needed to document evidence of "legitimate medical purpose" for a prescription if the clinician decides to treat with a controlled substance.

Ensure treatment efficacy

Another area where clinicians can better mitigate prescribing risks is in setting a clear baseline and benchmark goals to measure treatment efficacy. Before treating any patient with controlled substances, clinicians should take a thorough history and physical that describes the nature and intensity of the patient's pain and the ways it interferes with the patient's activities of daily living. If available, the prescriber should incorporate the results of any diagnostic studies into the patient's chart.

A prescriber's main concerns should be two-fold: establishing that there is a "legitimate medical purpose" for the prescription, and demonstrating the prescriber's medical reasoning in the patient's chart.

At this point, it is also helpful to discuss with the patient what the patient hopes the treatment will accomplish. Clinicians should allow patients with chronic pain to set activity of daily living goals as a benchmark of the success or failure of a treatment regimen. For example, if the patient wishes to be able to participate in light exercise for thirty minutes, three days a week, the prescriber can determine whether a certain medication is effective in achieving the patient's goals. If the patient is unable to reach their goal, another treatment modality may be more appropriate.

Monitoring

Malpractice claims frequently involve allegations that physicians prescribed controlled substances they knew or should have known would have a negative interaction with other substances used by their patients. For example, a patient may claim that a physician violated the standard of care by prescribing benzodiazepines and opioids together. To this end, it is important to obtain a detailed baseline toxicology result to better understand the nature of the patient's pharmacological profile.

Continued on page 4

Continued from page 3

Controlled Substances and Your Practice

Likewise, prescribers should always query their state's controlled substance prescription monitoring program to identify the name and dosages of any drugs given to the patient by other clinicians. During the treatment relationship, the prescriber should also subject the patient to regular toxicology screening to ensure that the patient's pharmacological profile does not change. Positive test results can indicate whether the patient is taking other substances that may interact harmfully with the prescribed medication. Negative toxicology results may indicate that the patient is diverting medications.

Controlled substance agreements

Prescribers potentially risk their professional licenses when writing prescriptions for a controlled substance. Thus, clinicians should write prescriptions only on terms with which they are comfortable. The prescriber should communicate these terms and expectations to the patient and memorialize this conversation in a controlled substance agreement. The National Institute on Drug Abuse has sample controlled substance agreements which practitioners can modify to fit their specific practice requirements.[22] A controlled substance agreement is also useful in outlining the consequences of the patient's failure to meet the prescriber's expectations, which may include termination of the professional relationship. If a prescriber establishes firm boundaries before writing a first controlled substance prescription for a patient, it is easier to hold the patient accountable for aberrant behavior.

If a prescriber establishes firm boundaries before writing a first controlled substance prescription for a patient, it is easier to hold the patient accountable for aberrant behavior.

Cultural Changes and Progress

Medical education

While the decrease in overdose deaths is in some measure attributable to heightened regulatory scrutiny, public health officials have made concerted efforts to change clinical culture of controlled substance prescribing to staunch the opioid epidemic. Medical educators are beginning to reevaluate the way they teach new students on the appropriate treatment of pain. At the outset of the opioid epidemic, medical schools did not dedicate much time to the teaching of pain management, giving most medical students no more than nine hours of formalized pain education.[23] Now, medical educators incorporate pain management instruction into the entire curriculum.

At Johns Hopkins University School of Medicine, a mandatory four-day course in pain management is now required. Instructors teach students that pain is a physical and emotional experience, and can be affected by cultural sensitivities and mood.[24] The course challenges entrenched beliefs about pain and empowers students to understand that there is not a one-size-fits-all treatment for chronic pain. The intention of programs like the one at Johns Hopkins is to shift the culture of medicine away from seeing pain as a condition that clinicians can merely prescribe away.

Pain management in rural areas

Outside of formal medical education settings, the opioid epidemic is causing a similar culture shift in clinics across the country. Rural areas have shouldered a disproportionate share of the effects of the opioid crisis. One reason for this disparity is that rural populations tend to skew older, with greater need for chronic pain treatment.[25] These communities also tend to have fewer resources available to assist patients who are struggling with chronic pain and drug addiction.

After a patient came to her with a toxicology screen positive for opioids, heroin, and morphine, Dr. Angela Gatzke-Plamann, an internal medicine physician in Necedah, Wisconsin, decided to change the way she interacted with her chronic pain patients. Dr. Gatzke-Plamann began reducing the quantities of pain medications she would prescribe for routine procedures like cesarean sections. While evidence shows that physical therapy, exercise, psychotherapy, and other alternative treatments are effective at addressing chronic pain, access to these modalities of treatment is often limited in rural communities.

Dr. Gatzke-Plamann recognized the need for more specialized treatment in her community and obtained the requisite training to prescribe the addiction medication buprenorphine.[26] Before she will prescribe buprenorphine, Dr. Gatzke-Plamann requires her patients to sign a controlled substance agreement, which sets conditions on her willingness to prescribe the drug. Dr. Gatzke-Plamann will only prescribe controlled substances such as buprenorphine if the patient submits to random pill counts, toxicology screens, and participates in a treatment program that includes counseling. For Dr. Gatzke-Plamann, the contracts serve as a communication tool rather than a means of punishment.

Continued on page 5

Continued from page 4

Controlled Substances and Your Practice

Progress

Evidence suggests that the culture shift like the one demonstrated by Dr. Gatzke-Plamann is taking place across the country. One study found that between 2012 and 2017, there was more than a 50-percent drop in monthly opioid prescriptions for new patients.[27] This reduction is promising, since researchers cite high dosages and long durations of opioid prescriptions, particularly for the opioid-naive as a significant risk factor in creating opioid dependence.

These developments show that most clinicians better understand their responsibilities in managing patient access to controlled substances. Prescribers should understand the ways professional oversight agencies and patients are using the tools provided by criminal and civil law to fight the opioid crisis. By following sound risk management practices, prescribers can effectively treat pain, while also promoting patient safety, and reducing the risk of litigation.

Endnotes

1 Hedegaard H, Miniño AM, Warner M. Drug overdose deaths in the United States, 1999–2018. NCHS Data Brief, no 356. Hyattsville, MD: National Center for Health Statistics, 2020, https://www.cdc.gov/nchs/products/databriefs/db356.htm#section_1 accessed March 18, 2020.

2 Authority and criteria for classification of substances, 21 U.S.C. § 811(c) (2018), https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section811&num=0&edition=prelim accessed June 1, 2020.

3 Drug Enforcement Administration (DEA), US Department of Justice, Drugs of Abuse: A DEA Resource Guide, 2020 Edition, p. 8, https://www.dea.gov/sites/default/files/2020-04/Drugs%20of%20Abuse%202020-Web%20Version-508%20compliant-4-24-20_0.pdf accessed June 1, 2020.

4 Ibid, p. 9.

5 Ibid.

6 Ibid.

7 Op cit., 21 U.S.C. § 841(B)(i).

8 Singh H. National Practitioner Data Bank (2019): Adverse Action and Medical Malpractice Reports (1990-December 31, 2019). Statistic generated using the Data Analysis Tool at https://www.npdb.hrsa.gov/analysistool accessed July 29, 2020.

9 Martinez M, St. Louis County doctor sentenced for prescribing drugs without examining patients, KSDK.com, February 27, 2020, https://www.ksdk.com/article/news/local/st-louis-county-doctor-sentenced-for-prescribing-drugs-without-examining-patients/63-09830484-1bd9-4f1f-bd14-83a2374d1d9c accessed March 18, 2020.

10 Ibid.

11 Ibid.

12 Allen K. California doctor charged with murder in several opioid-related deaths, ABC News, August 15, 2019, https://abcnews.go.com/US/california-doctor-charged-murder-opioid-related-deaths/story?id=65004516 accessed March 18, 2020.

13 Ibid.

14 https://law.stanford.edu/2019/08/28/stanford-legal-experts-on-the-oklahoma-opioids-verdict-and-ongoing-litigation/ accessed March 18, 2020.

15 Hoffman J. Johnson & Johnson Ordered to Pay $572 Million in Landmark Opioid Trial, The New York Times, August 30, 2019, https://www.nytimes.com/2019/08/26/health/oklahoma-opioids-johnson-and-johnson.html accessed March 18, 2020.

16 Public Nuisance, Okahoma Statutes, OKLA. STAT. ANN. tit. 50 § 2 (2019) http://www.oklegislature.gov/osstatuestitle.html accessed June 8, 2020.

17 Hoffman, op. cit.

18 Raymond N, Stemple, J. Oklahoma judge reduces Johnson & Johnson opioid payout to $465 million, Reuters, November 15, 2019, https://www.reuters.com/article/us-usa-opioids-litigation-oklahoma/oklahoma-judge-reduces-johnson-johnson-opioid-payout-to-465-million-idUSKBN1XP27F accessed May 1, 2020.

19 Shen, W. Overview of the Opioid Litigation and Related Settlements and Settlement Proposals, CRS Legal Sidebar, LSB10365, Library of Congress, Congressional Report Service, November 25, 2019, https://www.hsdl.org/?view&did=831978 accessed March 18, 2020.

20 Schmelzer, E. Denver doctor settles opioid wrongful death lawsuit as statewide attention to painkiller addiction increases, The Denver Post, September 6, 2019, https://www.denverpost.com/2019/09/06/denver-doctor-opioid-wrongful-death-lawsuit-settlement/ accessed March 18, 2020.

21 Sure Med Continuity Care Program, ProAssurance, https://www.ProAssurance.com/SureMedCompliance accessed March 18, 2020.

22 National Institutes of Health, National Institute on Drug Abuse, Sample Patient Agreement Forms, https://www.drugabuse.gov/sites/default/files/files/SamplePatientAgreementForms.pdf accessed March 18, 2020.

23 GreenfieldBoyce, N. How to teach future doctors about pain in the midst of the opioid crisis, NPR Health Shots, September 11, 2019, https://www.npr.org/sections/health-shots/2019/09/11/756090847/how-to-teach-future-doctors-about-pain-in-the-midst-of-the-opioid-crisis accessed March 18, 2020.

24 Ibid.

25 Sable-Smith, B. Family doctors in rural America tackle crisis of addiction and pain, Kaiser Health News, January 10, 2020, https://khn.org/news/family-doctors-in-rural-america-tackle-crisis-of-addiction-and-pain/ accessed June 8, 2020.

26 Ibid.

27 Miller, J. Dramatic shift in opioid prescribing, Harvard Medical School News & Research, March 13, 2019, https://hms.harvard.edu/news/dramatic-shift-opioid-prescribing accessed March 18, 2020.

Medical Risk Resource Advisor is published by ProAssurance's Risk Resource Department.

Phone: **844-223-9648**
Email: **RiskAdvisor@ProAssurance.com**

Policyholders may find Risk Resource articles and information archived on our website: ProAssurance.com/Newsletters.

ProAssurance
Treated Fairly