

Defense of Opioid Malpractice and Board Discipline Complaints

By

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Introduction

This paper addresses the state of the art in the defense of opioid-related board discipline and professional negligence (i.e., malpractice) claims against prescribing physicians. It does not address the product-related fraud and other litigation affecting the opioid manufacturing industry alleging that manufacturers of prescription opioid medications overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed them to physicians, and that distributors failed to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.¹

Opioids produce euphoria. They also have an important role in relieving human suffering. At the same time it is important to respect their potential to cause harm in vulnerable individuals. To use opioids effectively and safely physicians must understand pharmacologic and clinical issues related to opioids and carefully structure treatment with respect to particular benefits and risks for individual patients. Seddon R. Savage, *Opioid Therapy of Pain*, Amer. Soc. of Addiction Med. 1500, 1524 (5th ed. 2014).² Long-term opioid therapy of chronic pain poses a spectrum of risks, including both risks for the individual patient, and with diversion of the medications. *Opioid Therapy of Pain*, at 1519. Thus great care is required in patient selection and management of opioids in chronic pain patients. *Id.*

As a result of the beneficial effect opioids have on pain mitigation, and the euphoric effect use also produces, opioid use and misuse have increased in parallel in recent years. As opioids have been increasingly prescribed for pain, opioid medications sold through prescription channels intended for therapeutic use quadrupled between 1999 and 2010, as did opioid overdose deaths. Sources of diversion of opioids to non-prescribed use include thefts from pharmacies, manufacturers and trucks, and from friends, relatives, and doctors. To effectively treat pain, it is critical that

¹ See, e.g., *In re: National Prescription Opiate Litig.*, MDL No. 2804, 290 F. Supp. 3d 1375 (U.S. Jud. Panel Mult. Litig. 2017).

² The ASAM *Principles* treatise is an invaluable resource for understanding opioid medicine, and its content informs standard of care and related duties in opioid prescription litigation and disciplinary proceedings. Its citations herein will rely upon its chapter titles.

prescribing physicians understand and employ clinical strategies to reduce diversion of these medications and that patients secure all supplies of opioids. *Opioid Therapy of Pain*, at 1501.

The scope of the problem is not limited to the individual patient's plight. Active substance abuse is associated not only with physical and psychological problems but also with social problems such as driving under the influence, domestic violence, gun violence, child abuse or neglect, prescription drug diversion, drug dealing, drug trafficking, prostitution, human trafficking, workplace accidents, bad debts, and other negative or criminal acts. H. Westley Clark, *Ethical Issues in Addiction Practice*, ASAM, at 1685.

The field of pain management has generated controversy because of its reliance on opiate-based pain medications (opioids) for the treatment of addiction, which are also a target of the government's war on drugs. See Diane E. Hoffmann & Anita J. Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards*, 31 J.L. Med. & Ethics 21, 22-23 (2003).

What are opioids? Opioids,

“are a class of prescription pain relievers derived from synthetic versions of opium. All opioids have a similar effect on the brain. Opioids work by binding receptors in the brain that control the perception of pain. They do so generally in the same way that heroine does and produce the same euphoric effects. There are serious risks associated with opioids, including tolerance, dependency, addiction, life-threatening respiratory depression, overdose and death. As patients take opioids, they develop tolerance and need more and more medication over time in order to achieve the same level of pain relief. Opioids change a person's brain to make the body physically and psychologically dependent on the medication. All patients who use opioids long enough will become tolerant and dependent, and some will become addicted. Addiction is a disease characterized by habituation, craving and preoccupation with obtaining and taking the drug.

Opioids are dangerous, and most are categorized as Schedule II drugs by the Drug Enforcement Administration, the class for the most potent legal drugs and the ones that have the potential to do the most harm. Opioids should only be prescribed for severe enough pain that it is not adequately relieved by alternative non-narcotic treatment. Opioid therapy should begin at the lowest effective dose of immediate-release opioids and go up slowly if needed. Opioids should be stopped as soon as possible.”

Koon v. Walden, 539 S.W.3d 752, 755 (Mo. App. 2017) (adding that patients addicted to opioids “cannot themselves articulate the effect the increased doses of medication are having on their lives and will continue taking medicine despite those adverse effects”).

Once addicted, a physician must treat a drug-addicted patient with an equivalent form of what they are taking illegally, otherwise they will go into withdrawal.

Clinically used opioids are prescribed for pain control and as maintenance medications for opioid addiction. In both contexts careful management is necessary to avoid risks of addiction, respiratory depression, and also diversion to the street for illegal drug acquisition. Lisa Borg, *et al.*, *The Pharmacology of Opioids*, ASAM, at 137. In the latter context when there is addiction to opioids, opioid pharmacotherapies support detoxification and maintenance having a well-proven long-term beneficial effect on patient health. *Id.* Hence the tension: the doctor is substituting one opioid for another in seeking to wean the patient from opioid dependence.

Prescription drug overdose, predominantly involving opioids, is the leading cause of accidental death in adults aged 25 to 64. Wesley Prickett, *et al.*, *Legal and Regulatory Considerations in Opioid Prescribing*, ASAM, at 1544. Data from 2009 showed that the number (416,458) of emergency room visits related to nonmedical use of prescription opioids more than doubled from 2005. In 2010 as many people abused OxyContin in the past month as used heroin, and 5.1 million abused some type of pain reliever (primarily hydrocodone and oxycodone) in a month. Andrew J. Saxon, *Special Issues in Office-Based Opioid Treatment*, ASAM, at 778.

The clinician treating pain and addiction patients must juggle multiple roles and obligations not only to the patient but also to the surrounding community. Critical to success is ensuring that both pain and addiction are addressed. Too often pain specialists ignore addiction (or worse, abandon the patient), while addiction specialists may fail to ensure that pain is evaluated and treated. The obligation to the community may best be met by meticulous efforts to prevent diversion. Edward C. Covington & Margaret M. Kotz, *Comorbid Pain and Addiction*, ASAM, at 1540.

Opioid Science

Opioids have been used for medicinal purposes for millennia. One of the first documentations of the use of opioid comes in the Sumerian ideogram of hul gil, the “plant of joy,” inscribed 5,000 years ago. Greek philosopher Theophrastus provided the first written account of the use of opium to relieve pain in 30 BC. Morphine was purified from opium in 1805 but its use did not become widespread until the hypodermic syringe was invented in 1853. Heroin was introduced as an over-the-counter drug by the Bayer Company in 1895 and widely marketed as a panacea for numerous medical conditions. *Opioid Therapy of Pain*, at 1500. With their incredible capacity to ease the suffering of pain, opioids strongly impact the reward systems in the brain that play a key role in the activation and perpetuation of addiction. Thus, the two together – chronic pain and addiction – present a “perfect storm” of complexity and challenge. Rollin M. Gallagher, *et al.*, *The Pathophysiology of Chronic Pain and Clinical Interfaces with Addiction*, ASAM, at 1435.

Opioid addiction and opioid analgesia are dependent upon opioid agonist activity at the body’s opioid receptors. Agonist activity at the opioid receptors provides a robust and reliable analgesia, making opioids the most effective treatment for pain known to science.³ *The Pathophysiology of*

³ An agonist is a substance that activates the receptor in the brain that it binds to producing a chemical reaction and resulting in feelings of euphoria and well-being. On the other hand, an antagonist is a substance that binds to an opioid receptor in the nervous system and blocks the receptor’s activation. Thus it produces no “high” and can lead to overdose if the patient skips a prescribed dose.

Chronic Pain and Clinical Interfaces with Addiction, at 1446. At the same time, opioid addicted patients are known to have low pain tolerance, so perception of pain is one of the main triggers of relapse to addiction in these patients. *Id.*, at 1447.

Opioids increase dopamine concentration in the limbic regions of the brain. The reinforcing effects of these drugs of abuse are due to their ability to surpass the magnitude and duration of the fast dopamine increase that occurs when triggered by natural reinforcers such as food and sex. Nora D. Volkow, & Kenneth R. Warren, *Drug Addiction: The Neurobiology of Behavior Gone Awry*, ASAM, at 3. The acute surge of dopamine from the ventral tegmental and nucleus accumbens regions of the brain to the prefrontal cortex, produce brain reward and euphoria. James W. Finch, *et al.*, *Clinical, Ethical, and Legal Considerations in Prescribing Drugs with Abuse Potential*, ASAM, at 1703.

Opioid Formulations/Products

The term “opioids” refers to all compounds, natural and synthetic, functionally related to opium derived from poppies and endogenous (i.e., within the body) opioid neuropeptides. Exogenous (i.e., outside the body) opioids that are significant in opioid addiction and its treatment include heroin, morphine, oxycodone, codeine, hydromorphone, hydrocodone, methadone, and buprenorphine. Lisa Borg, *et al.*, *The Pharmacology of Opioids*, ASAM at 135. Oxycodone is an immediate-release drug; OxyContin is a long-acting version of oxycodone (“contin” meaning “continuous”). *Koon v. Walden*, 539 S.W.3d 752 (Mo. App. 2017). Percocet, Percodan or Tylox are oxycodones. Vicodin and Lortab are hydrocodones. Dilaudid is a hydromorphone. Tylenol #3 is codeine. MSContin is morphine. Opana is an oxymorphone. Methadose and Dolophine are methadones. Ultram and Ultracet are tramadol. Subutex, Suboxone, and Butrans are buprenorphine. (Suboxone is a synthetic opioid that contains buprenorphine and is used to treat opioid dependence.) Duragesic is fentanyl.

A Duragesic patch causes the gradual release of fentanyl, which is absorbed through the skin over a seventy-two hour period. It suppresses respiratory function when too much is taken. *Komlodi v. Picciano*, 2012 WL 2377805 (N.J. App. June 26, 2012) (allowing retrial on causation following patient’s anoxic brain injury after chewing a prescribed patch and having a history of drug and alcohol abuse). Fentanyl can produce, for example, decreased respiratory rate, hallucinations, depression or anxiety, drowsiness, nausea, and itching. *Love v. Waring*, 560 S.W.3d 614 (Mo. App. 2018).

Naxolone, sold under the trade name Narcan, is used to reverse the effects of an opioid such as morphine. *Love v. Waring*, 560 S.W.3d 614 (Mo. App. 2018). Naloxone, if timely administered, will almost always reverse even severe physiological effects of a narcotics overdose. *Lane v. Provo Rehabilitation and Nursing*, 414 P.3d 991, 995 (Utah App. 2018). An opioid antagonist such as naloxone should be used in emergency situations with awareness that it may precipitate an acute abstinence syndrome in persons with physical dependence. *Opioid Therapy of Pain*, at 1512.

“Narcan is used as an ‘antidote’ for opiate and opioid overdoses. Narcan, like opiates and opioids, attaches to the opioid receptors located in the body’s central nervous system. Narcan, however, does not cause any of the effects that opiates

and opioids produce, such as pain relief, a ‘high’ feeling, and respiratory depression. Instead, because opioid receptors have a ‘stronger affinity for the Narcan molecule than [they do] for [opiates and opioids] Narcan just knocks out and takes residency in the receptor(s). . . .’ ‘[Once] [t]he Narcan displaces the opiate [or opioid] from the receptor[s] . . . the person’s opiate effects evaporate . . . the person wakes up and [he or she is] breathing and . . . alert...’ In other words ‘intravenous administration of Narcan . . . produce[s] a near-instantaneous reversal of the narcotic effect . . . with a minute or two at the most ...’”

Procaccini v. Lawrence and Mem. Hosp., 168 A.3d 538, 543 (Conn. App. 2017) (adding that Narcan wears off much faster than heroin or methadone, and thus overdose symptoms can recur following Narcan administration).

The terms opioid agonist and opioid antagonist require closer scrutiny.

Opioid Agonist Treatment

Medications found to be useful in treating opioid addiction include naltrexone (antagonist), methadone (agonist), and buprenorphine (partial agonist). Buprenorphine is a partial agonist used to treat withdrawal from opioids. Eric J. Nestler, *From Neurobiology to Treatment: Progress Against Addiction*, ASAM, at 49. Clonidine, an adrenergic agonist, produces cellular effect similar to opioid receptor activation, and dampens many of the signs and symptoms of opioid withdrawal in humans. *Id.*

For methadone care, after the initial dose the induction phase of care allows for subsequent careful adjustments of the dose to achieve elimination of drug craving and prevention of withdrawal symptoms while avoiding the risk of intoxication or overdose associated with the accumulation of methadone. Once a stable dose is established, based on the desired clinical effects, elimination of craving, and prevention of withdrawal, the maintenance dose begins. That dose continues for years potentially until there is a reason to change course. Judith Martin, et al., *Opioid Maintenance Treatment*, ASAM, at 762.

Methadone maintenance treatment provides a stable background dose of opioids that blocks craving, blocks the “high” of other opioids, and provides physiologic homeostasis. *Opioid Therapy of Pain*, at 1523. Being an opioid, methadone can be abused and can lead to overdose and death when it is diverted to nonmedical uses not intended for pain treatment. *Opioid Maintenance Treatment*, at 764. Methadone differs from other agonists in several ways that make its lethality if misprescribed or misused greater than other opioids, and thus it requires careful titration. *Opioid Therapy of Pain*, at 1509.

Methadone is often considered when a patient with active addiction or in recovery is thought to require protracted opioid analgesia. However, methadone is probably the most hazardous prescription opioid in common use because its prolongation of cardiac repolarization may lead to arrhythmic death. Even though hydrocodone and oxycodone are prescribed and diverted approximately 10 times more than methadone, unintentional overdose deaths associated with methadone exceed those associated with both. *Comorbid Pain and Addiction*, ASAM, at 1538. Methadone clinics provide a higher level of supervision because “[t]here’s a greater level of control

than for office-based opioid therapy because the client, the individual has to go to the clinic basically every day to receive one dose of methadone which will cut cravings for approximately 24 hours or longer." *Commonwealth v. Radecki*, 180 A.3d 441, 462 (Pa. Super. Ct. 2018). Patients maintained on methadone dealing with acute episodes of pain from surgery, trauma or dental work require careful titration in individual doses of pain medication to achieve the desired analgesic effect. *Opioid Maintenance Treatment*, at 767.

Opioid agonist treatment is usually conducted in outpatient treatment settings, such as methadone treatment programs or the physician's office. These programs use a long-acting synthetic opioid medication, usually methadone or buprenorphine, administered orally for a sustained period at a dose sufficient to prevent opioid withdrawal, block the effects of illicit opioid use and decrease opioid craving. Buprenorphine is available in two formulations that are taken sublingually: (a) a pure form of the drug and (b) a more commonly prescribed formulation called Suboxone, which combines buprenorphine with naloxone, an antagonist (blocker) at opioid receptors. Naloxone has no effect when Suboxone is taken as prescribed, but if an addicted person attempts to inject Suboxone, the naloxone will produce severe withdrawal symptoms. Thus this formulation lessens the likelihood the drug will be abused or diverted to others. Buprenorphine administration requires a waiver from the Drug Enforcement Administration allowing the physician to prescribe it. Andrea G. Barthwell & Lawrence S. Brown, Jr., *The Treatment of Drug Addiction: An Overview*, ASAM, at 399. An advantage of buprenorphine treatment is that it has a maximum dose effect ceiling that is well below significant respiratory depression for most patients. *Opioid Maintenance Treatment*, ASAM, at 765. The choice between use of methadone versus buprenorphine may be guided by site of care and level of care, local availability, or cost. *Opioid Maintenance Treatment*, at 766.

Buprenorphine is a synthetic opioid that is used to treat opioid dependence. Buprenorphine is a partial agonist at the opioid receptor that is available to detoxify addicts in maintenance treatment. It can be used in an office-based setting to provide opioid dependence care, and thus has reduced the disparity between the number of opioid dependent individuals and the number of in-patient treatment slots available to them. It is as effective as methadone in ameliorating withdrawal symptoms, treatment retention and treatment completion. Jeanette M. Tetrault & Patrick G. O'Connor, *Management of Opioid Intoxication and Withdrawal*, ASAM, at 675-676. Buprenorphine also has unique features helpful in maintenance and detoxification. Its ceiling on agonist activity reduces the danger of overdose, may limit abuse liability, and has low toxicity even at high doses. Its slow disassociation from opioid receptors results in a long duration of action (ideal for a maintenance medication) and also diminishes withdrawal signs and symptoms. It is as effective as methadone in tapering doses for the treatment of opioid withdrawal. *Id.* at 676. Sublingual buprenorphine is an excellent analgesic and can therefore be used to treat pain and addiction simultaneously. It is also less likely than full agonists to produce respiratory depression. *Comorbid Pain and Addiction*, at 1538.

For buprenorphine care, the preferred formulation is a combination of buprenorphine and naloxone (the opioid antagonist) that is designed to discourage injected diversion and misuse. Dose is carefully monitored during withdrawal to provide relief. *Opioid Maintenance Treatment*, at 765. Because it can be provided in an office-based setting, buprenorphine/naloxone may provide a timely treatment for patients who might not otherwise seek treatment at a methadone clinic. *Id.* Its efficacy at managing withdrawal can result in diversion by patients who save it for another time

or giving the dose to someone else. *Id.*, at 766. Advantages in the use of buprenorphine taken sublingually over methadone are lower withdrawal signs and symptoms, and reduced potential for overdose given its partial agonist properties. *The Pharmacology of Opioids*, at 142.

Partial agonists such as buprenorphine or tramadol provide analgesia via opioid receptors but they produce less receptor activation, and are viewed as having less, but still significant, risk for diversion. Tramadol doses are limited by seizure risk at higher doses and appears to have less abuse potential than pure opioid analgesics. *Opioid Therapy of Pain*, at 1509-1510.

Patients under opioid maintenance treatment often present with co-occurring psychiatric disorders. Low severity patients have been found to benefit from also from drug abuse counseling (focused on current life problems) and psychotherapy. High severity patients with co-occurring psychiatric conditions present special problems in management; but psychotherapy has been found to maximize their improvement. Access to professionally trained therapists is important to their recovery. *Opioid Maintenance Treatment*, at 769.

Patients stabilized on adequate sustained doses of methadone or buprenorphine can function normally. They can hold jobs, avoid the crime and violence of the drug culture, and reduce their exposure to HIV by stopping or decreasing injection drug use and drug-related high-risk sexual behaviors. Patients stabilized on opioid agonists can engage more readily in counseling and other behavioral interventions that are essential to recovery and rehabilitation. *The Treatment of Drug Addiction: An Overview*, at 399.

Opioid Antagonist Treatment

Antagonist therapies are used to block or counteract the physiologic or subjective reinforcing effects of substances. The drugs of choice here are naloxone and naltrexone, long-acting synthetic opioid antagonists with few side effects. They completely block the effects of self-administered opioids, including euphoria, and avoid respiratory depression risk. The theory behind this treatment is that the repeated lack of the desired opioid effects as well as the perceived futility of using the opioid, will gradually extinguish the habit of opioid addiction. These drugs have no subjective effects or potential for abuse and are not addicting. They often produce rapid onset of withdrawal symptoms, so patient non-compliance is a common problem. A favorable treatment outcome therefore requires that there also be a positive therapeutic relationship, effective counseling or therapy, and careful monitoring of patient compliance. Like methadone or buprenorphine, patients stabilized on naloxone or naltrexone can function normally. They can hold jobs, avoid the crime and violence of the street culture, and reduce their exposure to HIV by stopping injection drug use and drug-related high risk sexual behaviors. *The Treatment of Drug Addiction: An Overview*, at 400; Susan M. Stine & Thomas R. Kosten, *Pharmacologic Interventions for Opioid Dependence*, ASAM, at 735.

Statutory Prescription Law

Pursuant to federal law, opioid agonist treatment medications may be "administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs. . . ." 42 CFR 8.12(h)(1). Further, to "dispense" means "to deliver a controlled substance to an ultimate user . . . including the

prescribing and administering of a controlled substance. . . ." 21 USC § 802(10). Practitioners who dispense narcotic drugs "for maintenance treatment or detoxification treatment" are required to have a separate DEA registration. 21 U.S.C. § 823(g)(1).

Federal law provides that "[n]o medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use." 42 CFR 8.12(i)(4).

Maintenance treatment is defined as "the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs." 21 U.S.C. § 802(29). Detoxification treatment is defined as "the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses⁴ to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period." 21 U.S.C. § 802(30).

The Controlled Substances Act (the primary set of laws and regulations that govern medical use of controlled substances in the United States) drugs include morphine, fentanyl, methadone, and oxycodone. Their physical dependence, psychological dependence, and potential for abuse are rated "high." The Schedule III drugs include hydrocodone with acetaminophen, buprenorphine, ketamine and Marinol are rated moderate to low on physical dependence, high on psychological dependence, and moderate for abuse potential. *Legal and Regulatory Considerations in Opioid Prescribing*, ASAM, at 1545. As noted above, health care providers who wish to prescribe controlled substances must be registered and obtain a provider number from the Drug Enforcement Administration. It will investigate practitioners who do not comply with the laws regarding distribution of controlled substances. Common behaviors that result in investigation include issuing prescriptions without a bonafide physician-patient relationship, issuing prescriptions in exchange for sex, charging fees commensurate with drug dealing rather than providing medical services, issuing prescriptions using fraudulent names, and self-abuse by practitioners. *Legal and Regulatory Considerations in Opioid Prescribing*, at 1546. Federal regulations regarding controlled substances and the CSA are summarized in the Practitioners Manual found at www.deadiversion.usdoj.gov. *Id.*

Readers are urged to consider the effect of state regulations relating to opioid maintenance programs as well. For example, the Michigan Administrative Code also provided that patients prescribed take-home methadone during methadone maintenance treatment may only be dispensed methadone "in an oral, liquid form so as to minimize its potential for abuse." Mich. Admin. Code R. 324.14416(1).

⁴ The concept of "decreasing doses" trigger use of the terminology "titrate" or "titration" and "tapering" to describe the process of weaning a patient off the opioid. Technically, titration refers to the process of determining the dosage of medication that reduces the patient's symptoms to the greatest degree with the least amount of side effects. The more correct term for gradually ceasing use of a drug altogether is tapering. *Bazzle v. State*, 434 P.3d 1090, 1094 n.1 (Wyo. 2019).

Addiction Therapy and Withdrawal Mitigation

Drug addiction manifests as a compulsive drive to take a drug despite serious adverse consequences. *Drug Addiction: The Neurobiology of Behavior Gone Awry*, at 3. The adaptations in the brain that result from chronic drug exposure are long-lasting; this is why long-term treatment will be required for most addiction cases, just as it is for other chronic diseases such as hypertension, diabetes or asthma. *Id.* at 10. Discontinuation of treatment likely will result in relapse. A multimodal approach involving both behavioral therapy and pharmacological intervention is preferred.

Approaches to addiction treatment include blockage of drug targets and mimicry of drug action. Eric J. Nestler, *From Neurobiology to Treatment: Progress Against Addiction*, ASAM, at 50. The most straightforward strategy is to block the drug from getting to its target. The best example of this approach is naltrexone. It blocks the ability of opioids to produce their many effects, including addiction. *Id.* But its use blocks the body's endogenous opioid peptides (e.g., endorphin) leading to depressed mood, which lessens compliance. *Id.* Hence its use is mostly confined to highly motivated patients. *Id.* Another complication is that it leaves the brain in its addicted state and does not address intense drug craving. *Id.* at 51.

Prescribing methadone is the best example of employment of drug mimicry to activate drug targets and thus alleviate drug craving and allows the brain to slowly recover. *Id.* The difference between methadone and other opioids is its long half-life which means that at the proper dose opioid-dependent patients on methadone have a modest level of sustained activation of opioid receptors. Thus the patient avoids the daily extremes of "highs" and then withdrawal as the drug wears off, enabling the patient to return to a more normal life of employment and sustained interaction. *Id.* at 52. As noted above, a variation on this theme is buprenorphine, a partial agonist. It binds to opioid receptors and produces a mild agonist effect. It thus limits the ability of an addict to obtain a drug high during use. Risk of the mimicry approach to addiction treatment is the physician prescribes a form of opioid to the patient in an effort to cure opioid dependence. *Id.*

Overdose Risks

The key risk in opioid overdose is respiratory depression through direct suppression of the respiratory centers in the brainstem and medulla. The sedation effect of the drug causes the patient to stop breathing. Jeanette M. Tetrault & Patrick G. O'Connor, *Management of Opioid Intoxication and Withdrawal*, ASAM, at 668. Overdose is managed by use of naloxone hydrochloride, a pure opioid antagonist that can reverse the central nervous system effects of opioid intoxication. *Id.*, at 670. Thus all opioids must be used sparingly in patients with impaired respiratory function. *The Pharmacology of Opioids*, at 142. Individualized dosing and reliance on regular clinical assessments are important, as diminished respiration occurs with opioids until tolerance develops. *The Pharmacology of Opioids*, at 143.

Respiratory depression manifests itself as low respiratory rate, hypoxia, and hypercapnia; it is the most frequent cause of death owing to opioid overdose. *Id.*, at 144. Respiratory depression is a potentially fatal side effect of opioid administration and demands awareness throughout treatment. Opioid-induced respiratory depression results from depression of brainstem respiratory responses to carbon dioxide. *Opioid Therapy of Pain*, at 1512. *See, e.g., Estate of Heisey v. Yovino*, 2014

WL 2619519 (Mich. App. June 12, 2014) (recognizing that Dilaudid (hydromorphone) “acts on the brain to suppress ventilation and ‘you don’t breathe nearly as vigorously’”); *Montoya v. Walgreen Co.*, 2018 WL 2214662 (N.M. App. Apr. 9, 2018) (involving death from respiratory depression due to methadone toxicity).

A physician should consider risks of opioid treatment including dependency, overdose, death, diversion to street and interaction with other medications. He or she should monitor drug seeking behaviors (multiple pharmacies or physicians for opioid access, claims of lost or stolen medications, positive urine results for medications not prescribed, negative results for prescriptions prescribed, early refill requests, and hospitalizations for substance abuse). *Ruben v. Arizona Med. Bd.* 2019 WL 471031 (Ariz. App. Feb. 17, 2019). “Opiate-naïve” individuals should receive additional oversight. They are more likely than others to suffer negative effects from a mistaken overdose of narcotics. See *Lane v. Provo Rehab. & Nursing*, 414 P.3d 991, 995 (Utah App. 2018) (involving alleged deprivation of opportunity to be saved by timely administration of naloxone).

Stated another way, patient behaviors that require prompt intervention include multiple early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician’s knowledge, intoxication or impairment, pressuring or threatening behavior, presence of illicit or unprescribed drugs in drug tests, unsanctioned dose escalation, deteriorating function, failure to comply with the treatment plan, drug diversion and prescription forgery. *Clinical, Ethical, and Legal Considerations in Prescribing Drugs with Abuse Potential*, at 1709. Most controlled-release opioids can be altered to become immediate-release drugs through chewing, crushing, snorting or extracting and injecting. Many persons who use prescription opioids to get high do alter them in some way. *Opioid Therapy of Pain*, at 1511.

Role of “Benzos”

It is not uncommon for addicted persons also to use a tranquilizer called benzodiazepine to manage anxiety and related disorders. “Benzos” may have central nervous system depressant effects like opioids. Product names include Alprazolam, Lorazepam Clonazepam, and Diazepam. Treatment for benzo addiction as a primary problem has steadily increased. It is not uncommon for addicted persons in methadone treatment or office-based buprenorphine treatment to continue to abuse benzos. Martha J. Wunsch, *et al.*, *Nonmedical Use, Misuse, and Abuse of Prescription Medications*, ASAM, at 516. Poisonings involving benzos have increased along with opioid analgesic overdose deaths, and benzos have increasingly been involved in opioid overdose deaths where methadone was identified. Thus for patients with therapeutic sources of benzos, careful coordination with prescribing physicians is indicated due to the potentially lethal combination of benzos with opioid agonist treatment. *Opioid Maintenance Treatment*, at 766. One court noted that benzos present a high risk of abuse, diversion and overdose. They provide sedation, anxiety relief and muscle relaxant properties. Due to risks of over-sedation and respiratory depression when benzos are taken in conjunction with opioids, their joint use should be avoided. *In the Matter of Johnson*, 2018 WL 3421269 (Minn. App. July 16, 2018).

Maintenance Treatment

Abstinence-based treatment of recreational opioid addiction has a high failure rate, so that medication assistance is recommended for most. *Comorbid Pain and Addiction*, at 1539. Abrupt

withdrawal of opioid pain medication without gradual tapering allegedly leading to suicide may support a professional negligence claim. *See Price v. Califano*, CA No. PC 07-1673 (R.I. Super. Ct. 2014).

Opioid maintenance treatment, on the other hand, is effective for the ongoing treatment of opioid dependent patients. *Management of Opioid Intoxication and Withdrawal*, ASAM, at 680. Opioid-based medically supervised withdrawal is based on the principle of cross-tolerance, in which one opioid is replaced with another that is slowly tapered. *Pharmacologic Interventions for Opioid Dependence*, at 736.

Maintenance treatment thus presents the odd-on-its-face idea that medications having a potential for abuse can be valuable therapeutic tools in the treatment of pain and other medical and psychiatric conditions, even in persons with substance use disorder. Thus any decision not to prescribe such medications must be made judiciously and with attention to appropriate assessment, informed consent and careful patient monitoring. *Clinical, Ethical, and Legal Considerations in Prescribing Drugs with Abuse Potential*, at 1703. Untreated pain and psychiatric conditions affecting patients with substance use disorders cause suffering, and are also strong triggers for relapse to substance abuse. The physician thus faces the dilemma of deciding whether such medications can be used safely in certain patients or, if not, how to provide effective treatments without the use of controlled drugs. *Id.* at 1704. Obviously dose level and duration of treatment are individualized clinical decisions. *Opioid Maintenance Treatment*, ASAM, at 762.

Reasons for discontinuation of medication therapy include resolution of the condition being treated, emergence of intolerable side effects, inadequate medication effect, failure to improve the patient's quality of life, despite aggressive titration, evidence of deteriorating function, or significant aberrant medication use. *Clinical, Ethical, and Legal Considerations in Prescribing Drugs with Abuse Potential*, at 1709.

Effective maintenance treatment requires attentive urine drug screening for compliance evaluation. In standard drug testing, an initial immunoassay screening test is followed by a more sensitive and specific confirmation test that is based on mass spectrometry. The data is highly accurate when both tests are used. If a specific drug is identified on the confirmation test, it was present in the donor's body. Robert L. DuPont, *et al.*, *The Science and Clinical Uses of Drug Testing*, ASAM, at 1718. Most positive test results are the result of very frequent drug use, as evidenced by the fact that most tests are conducted using urine, which has a window of detection of only a few days. *Id.*, at 1723. For hair testing, the window of detection is typically 90 days. *Id.* Also to be recognized is that fact that most tests include a cut-off concentration point for that test panel. If a drug is not detected, it does not establish that the donor did not use that drug within that detection window, only that the drug or drug metabolite was not in the sample at a concentration above the cutoff for that particular test. *Id.*

Opioid therapy should be tapered to avoid withdrawal and a rebound increase in pain. *Opioid Therapy of Pain*, at 1524. The goal of tapering is to provide stable but decreasing blood levels of opioid so as to prevent precipitous troughs. *Opioid Therapy of Pain*, at 1514. Many patients tolerate a 10% gradual reduction in opioid dosing every one to two days, with more gradual reduction near the end of tapering. *Opioid Therapy of Pain*, at 1514. If pain cannot be

satisfactorily managed without opioids, and the patient has unmanageable opioid misuse, referral for opioid antagonist treatment of addiction (e.g., use of naloxone (Suboxone)) should be considered. *Id.*, at 1524.

When a decision is made to discontinue medication therapy, any patient who has become physically dependent on a prescribed medication should be provided with a safety structured tapering regimen. Withdrawal typically can be managed on either inpatient or outpatient bases or through referral to an addiction specialist. When tapering, much smaller prescription allotments, more frequent check-ins and drug screens may be required. If the patient is not able to comply with the tapering plan, discontinuation of prescribing and referral for detoxification or for substitute agonist therapy with methadone or buprenorphine may be advisable. *Clinical, Ethical, and Legal Considerations in Prescribing Drugs with Abuse Potential*, at 1709.

It is important to note that withdrawal of opioids used for pain can be legally supervised by any physician with a DEA license; however, detoxification from opioids as a component of addiction treatment can only be done with buprenorphine in a waived buprenorphine provider and with methadone by a licensed treatment center. *Opioid Therapy of Pain*, at 1514.

Pain increases stress and anxiety and may become a significant risk factor for relapse in those in recovery and for aberrant use in those with active abuse or addiction. *Opioid Therapy of Pain*, at 1514. Many clinicians and individuals in recovery believe exposure to opioids – even if not the patient’s drug of choice – may lead to relapse. However, the distress of inadequately treated physical pain may also pose a risk of relapse. *Id.*, at 1515. If a patient is dependent on opioids, it is usually necessary to continue opioids, even if the acute pain situation is resolved. Opioids can be either tapered gradually to prevent withdrawal symptoms or continued at a dose that avoids withdrawal but does not over-sedate the patient. Abrupt cessation of opioids will usually cause acute increase in pain due to withdrawal. *Id.* Opioids for pain treatment can be continued after discharge of the patient from an acute pain trauma or event, opioids cannot be provided for treatment of addiction after discharge, except from a licensed addiction treatment program (methadone treatment) or from a certified buprenorphine provider. *Id.* Opioids must be discontinued if an individual is found to be diverting them, as misuse in this manner is both illegal and presents significant risk to the public health. A physician who knowingly prescribes opioids to a person who is diverting them may be liable to charges of drug trafficking. *Id.*, at 1517.

Clinic Management Best Practices

Before a patient is prescribed the first opioid prescription, patients should be informed of the clinic’s policies to prevent non-medical use. They may include:

- Patients must bring medication to every appointment to validate the date of fill, dosage instructions, pharmacy location, and amount of remaining medication.
- Patients should be required randomly to bring medication remaining for a count to reconcile dosing instructions.
- Patients should expect to provide a sample for urine drug testing with laboratory confirmation at random intervals or when abuse is suspected.

- Patients should be required to use one pharmacy for all controlled substances, and pharmacies should be asked to contact the physician if prescriptions are presented for contraindicated medications or attempts for an early refill.
- Patients should be informed the amount of medication may be minimized and refills limited to decrease diversion to family and friends.
- Increased time between physician visits and increased amounts of medication may be “earned” as the patient complies with policies to reduce nonmedical use.
- Physicians should utilize a state prescription monitoring program (“PMP”) for consultation at entry to treatment, when there is a concern about abuse, and randomly. Patient awareness of PMP monitoring may discourage abuse.

Nonmedical Use, Misuse, and Abuse of Prescription Medications, at 519-520. Universal precautions in prescribing controlled drugs include:

- The physician should conduct an initial patient assessment and risk stratification, and make a diagnosis with an appropriate differential;
- The physician should discuss the proposed treatment plan with the patient, and obtain informed consent;
- Decisions should be documented in a written treatment agreement;
- An appropriate trial of medication would be initiated;
- The patient’s response to therapy should be monitored;
- Based on the patient’s response, the physician should decide whether to continue, revise or terminate medication therapy; and
- Careful and complete records must be kept of the initial evaluation and of each follow-up visit.

Clinical, Ethical, and Legal Considerations in Prescribing Drugs with Abuse Potential, at 1704.

A written opioid treatment agreement is a valuable tool that can help ensure that the patient understands the potential risks and benefits of treatment. It may also mitigate the risks of treatment. Management of medication refills, process for dose/frequency changes, medication security, appointment frequency and urine toxicology screens, attendance at cognitive-behavioral and co-occurring disorder groups, avoidance of illicit substance use, conditions under which opioids will be continued, and conditions under which opioids will be discontinued, should all be addressed in the agreement. *Opioid Therapy of Pain*, at 1520.

Many states have created Prescription Drug Monitoring Programs designed to track controlled substance prescriptions. *Legal and Regulatory Considerations in Opioid Prescribing*, at 1548. They are designed to help clinicians track when patients are receiving prescriptions from multiple physicians and/or multiple pharmacies. *Id.*, at 1549. See mpalliance.org.

Facts that may be considered in evaluating a physician’s compliance with good standards of opioid-prescription practice include:

- Dosage propriety
- Refill management
- Trial of OTC medications, PT or other non-opioid measures first
- Management of sleep apnea
- Pill count monitoring
- Medication seeking from other physicians
- Hospital discharge timing
- Addiction behavior monitoring
- Addiction monitoring charting
- Overdose symptom recognition
- Starting naïve patients at high dosages
- Prescribing without requisite licensure
- Prior pain medicine records gathering
- Treatment contract/plan promulgation
- Pill return security compliance
- Consideration of family member inputs
- Underlying diagnosis determination
- Consideration of dangers of continuing therapy
- Use and monitoring of oxygenation
- Consideration of synergistic effect of concomitant medications or alcohol
- Use of fentanyl patches by known abusers
- Pharmacy coordination reviews
- Pain medicine referral omission
- Risk assessment prior to prescription
- Risk assessment when dosage increased
- Management at maximum daily dose
- Sale to “the street” diversion monitoring
- Timeliness of overdose antidote application
- Prescribing without therapeutic rationale
- Management of pill destruction
- Urine screen management
- Response to urine screen refusal
- Pre-signed prescription pads
- Re-dispensing of medications
- Drug-seeking behavior evaluation

Because there is an inherent risk of dependence and/or addiction associated with long-term use of opioids, a primary care physician, for example, must explain that risk to the patient. A physician must be informed of the need to monitor such patients’ progress and adjust the analgesic as indicated. A physician who treats addiction but has no registration to prescribe buprenorphine for treatment of opioid dependence may be seen as harming the patient by blocking access to an important therapy. *Ethical Issues in Addiction Practice*, at 1687. Clinicians should establish clear guidelines with every patient at the beginning of treatment, renew the understanding of those guidelines periodically, and address clinical issues of noncompliance during the course of treatment. *Ethical Issues in Addiction Practice*, at 1688.

Drug seekers are constantly on the lookout for blank prescription forms and also the names of physicians who recently retired or left the state, or died. Therefore storing forms in a safe place is a sound practice. *Clinical, Ethical, and Legal Considerations in Prescribing Drugs with Abuse Potential*, at 1710.

Factors that contribute to inappropriate prescribing of medications include: (a) physician uncertainty as to prevailing standards of care, (b) inadequate medical evaluation, (c) unclear or conflicting clinical guidelines, (d) physician concern that prescribing adequate amounts of medication will result in unnecessary scrutiny by regulatory authorities, (e) physician misunderstanding of the causes and manifestations of drug dependence and addiction, (f) physician fear of causing addiction or being deceived by a patient, (g) physician fear of patient confrontation, and (h) inadequate physician education about regulatory policies and processes. *Clinical, Ethical, and Legal Considerations in Prescribing Drugs with Abuse Potential*, at 1704.

Errors or omissions in opioid prescription practice may lead to board discipline complaints or to professional negligence or malpractice claims. A number of cases have evaluated physician conduct in the opioid management practice context.

Board Discipline

Addiction medicine specialists may face disciplinary sanctions for violation of federal or state law, and regulations promulgated by state boards of medical practice and pharmacy. *See In re Proctor*, 2019 WL 1212252 (Mich. App. Mar. 14, 2019) (affirming discipline for improper prescription of methadone but commenting upon the “lack of settled science on controlled-substance prescribing”). Discipline was imposed where the physician’s:

“[P]ractice of prescribing opioids ignored a number of “red flags,” that indicate that his patients were seeking controlled substances for non-therapeutic purposes. [The doctor] requested MRI reports from his patients at the time of their initial presentation, but made little to no effort to secure any charting of prior pain management physicians. [He] ignored point-of-care urine screens that indicated patients may be taking prescriptions, or other opioids, that he was not prescribing. [The doctor] required the execution of a pain management contract, but did little to enforce the terms of these agreements. Physical examinations were never performed, pursuant to the testimony of the patients highlighted in this hearing, and this is corroborated by the medical records that include no indication that physical examinations were performed. [His] medical records hardly ever included diagnoses, and medications were increased without documented rationale.”

Hannan v. Delaware Brd. Med. Licensure and Discipline, 2018 WL 1037463 *1 (Del. Super. Ct. Feb. 23, 2018).

In *Grafilo v. Cohanshoet*, 243 Cal. Rptr. 3d 807 (Cal. App. 2019), the court quashed subpoenas issued to a pain management physician for charts of patients treated. A complaint alleged the doctor “prescribes huge quantities of narcotics to patients without giving exams, tests, x-rays or even bloodwork. A loved one went to this doctor and is now in rehab. Not once did this doctor examine him, [or] look at charts. He only went by a complaint of pain and started prescribing narcotics at \$400 a visit every two weeks.” The patients refused to sign authorizations allowing disclosure of the charts. Court held that the patients’ privacy interests overcame the state’s interest in reviewing the records. Request for a chart subpoena also was denied in *In re Petition of Atty General for Subpoenas*, 2019 WL 942947 (Mich. App. Feb. 26, 2019) on state and federal process grounds against an argument “the national opioid epidemic was such a threat” proper procedure was not required.

In re Proctor, 2019 WL 1212252 (Mich. App. Mar. 14, 2019) the court affirmed board discipline against an addiction medicine specialist on grounds: (1) a family medicine physician could offer expert opinion testimony against the licensee when the physician treats patients using controlled substances and he was not offering addiction medicine specialty opinions, (2) the licensee prescribed controlled substances in Michigan when his DEA address was New York, (3) he prescribed non-liquid form methadone for at-home maintenance treatment, (4) he dispensed Suboxone to patients in improper circumstances, (5) he did not maintain destruction records on

morphine pills returned to him by a patient, and (6) in other manners the physician breached the standard of care in medication prescription practices.

Failure to document thorough patient evaluations, to establish an individual treatment plan, to reevaluate at regular intervals, to chart medical necessity for use of more than one controlled substance, to document non-opioid attempts at analgesia, and to document refills and visits to obtain refills may trigger discipline. *See Armstrong v. Louisiana Brd. of Med. Exmnr.*, 868 So. 2d 830 (La. App. 2004). Failure of a board to articulate the applicable standard of care in a disciplinary proceeding precludes discipline unless the physician admits a violation. *Rich v. Tennessee Brd. of Med. Exmnr.*, 2010 WL 3565668 (Tenn. App. Sept. 14, 2010) (involving alleged methadone care violations). Standard of care compliance can be shown by testimony detailing care of the patient, the patient's progress under the medications prescribed, and that the treatment was within the SOC. *Hoover v. Agency for Health Care Admin.*, 676 So. 2d 1380, 1384 (1996) (involving charges seeking discipline for Schedule II substance practices).

Substantial evidence supported a board's order for revocation where the physician practiced with a primary goal of prescribing controlled substances to patients rather than with the primary goal of providing proper healthcare to the public, where the physician did not support his prescribing practices with proper documentation and record keeping and failed to diagnose other medical conditions unrelated to the prescribing of controlled substances, where the physician continued to prescribe controlled substances and directed the other physicians in his practice to continue prescribing large quantities of controlled substances, even after those physicians began to question his prescribing practices, and where the physician ignored clear signs of noncompliance and inappropriate drug screens. *See Moses v. Kentucky Brd. of Med. Licensure*, 2016 WL 551431 (Ky. App. Feb. 12, 2016). *See also Kozachuk v. Maryland St. Brd. of Physicians*, 2017 WL 6371685 (Md. App. Dec. 13, 2017) (involving physician disciplined for prescribing oxycodone at bars and restaurants); *Thomas v. Illinois Dep't of Fin & Prof'l Reg.*, 2017 WL 3481977 (Ill. App. Aug. 11, 2017) (involving suspension for many dosage increases without support in the record).

A physician's license was revoked in *Fisher v. West Virginia Brd. of Osteopathic Med.*, 2016 WL 3136851 (W. Va. App. June 3, 2016) where he failed to secure or destroy returned medications, re-distributed returned medications, prescribed opioids without adequate monitoring, failed to monitor patient use by pill counts, urine screens, or pharmacy reports, increased opioid dosages without contacting prior physicians, provided opioids knowing the patient was obtaining same from multiple providers and using different pharmacies to fill prescriptions, provided two immediate release opioids at the same time, and continued to prescribe after violations of the drug agreement. *Accord, Alsager v. Washington Brd. of Osteopathic Med. & Surg.*, 2010 WL 1223128 (Wash. App. Mar. 30, 2010) (involving scant attention given by physician to prescribing practices involving seven pain/anxiety patients).

License revocation may follow where the physician failed to: (1) request medical records of each patient to evaluate previous treatments for pain, (2) document a detailed medical history of the patient's complaint, (3) adequately perform an initial physical examination, (4) develop and document a personalized treatment plan, (5) discuss reasonably foreseeable side effects of the prescribed medications and document those discussions, (6) document and discuss reasonable alternative treatments, (7) safeguard against potential complications by ordering liver tests to check

for side effects of the medications, and (8) order urine tests to monitor for abuse or diversion. *Cotropia v. Texas Med. Brd.*, 2018 WL 4087408 (Tex. App. Aug. 28, 2018).

Revocation is also appropriate where the physician: prescribed combinations of medications that increased the risks of addiction, CNS and respiratory depression, and even death; prescribed Soma and Xanax to patients without considering that the patients were also being prescribed opioids by other physicians, the combinations of which could be fatal; prescribed controlled substances to patients who were clearly abusing and/or diverting such medications; failed to evaluate patients for potential drug interactions or substance abuse issues through the use of monitoring programs; failed to inform patients of potential side effects of medications prescribed; failed to inform or offer alternative treatments or therapies in lieu of controlled substances; and diagnosed patients with panic disorder without sufficient documentation to justify the diagnosis. Furthermore, there was evidence that petitioner stole medications prescribed for his patients and wrote prescriptions for controlled substances on a prescription pad from a facility where he no longer worked and that was no longer open for business. *Iyer v. West Virginia Brd. of Med.*, 2018 WL 2175546 (W. Va. May 11, 2018).

A physician's license was revoked where the doctor failed to get records of prior pain management physicians, ignored point of care urine screen data, where meds were increased without a documented rationale, where the pain management contract was not enforced, where physical examinations were not performed, where out of state patients were cared for, and where prescriptions were provided and negative screens resulted suggesting street diversion was occurring. *See Hannan v. Delaware Brd. of Med. Licensure*, 2018 WL 1037463 (Del. Feb. 23, 2018).

Ethical challenges facing the clinician may occur in circumstances in which the patient is obligated to report progress to an external agency (e.g., a court or child welfare agency) and that report, if accurate, could contain damaging information – such as multiple missed appointments or toxicology screens that are positive for drugs – a patient may ask the clinician to either omit or misrepresent the damaging information. *Ethical Issues in Addiction Practice*, at 1686. “Pill mill” evidence receives special scrutiny. *See Mosuro v. Bureau of Prof. & Occ. Affairs*, 2016 WL 5944995 (Pa. Commonwealth Ct. Oct. 13, 2016) (involving physician who received a flat fee for each prescription written).

Professional Negligence Claims

Several cases have evaluated opioid prescription practices in the context of professional negligence or malpractice claims when patients have been injured or died allegedly as a result of those practices. The stakes can be high. Punitive damages may be awarded in egregious cases. *Koon v. Walden*, 539 S.W.3d 752 (Mo. App. Oct. 24, 2017). And one court has held that evidence of a nationwide “opioid epidemic” is relevant information for the jury to consider. *See Koon v. Walden*, 539 S.W.3d 752 (Mo. App. 2017) (noting the trial judge found the evidence somewhat prejudicial but the probative value outweighed the prejudice). In another case the court allowed parents' negligent infliction of emotional distress claim to go forward, finding they were within the zone of danger during and after their son's tonsillectomy and adenoidectomy when he died from respiratory depression when given opioids during the procedure. *See Armstrong v. A.I Dupont Hosp.*, 60 A.3d 414 (Del Super. Ct. 2012).

Negligence may be found as a matter of law where the physician knowingly violated Schedule II regulations leading to a patient's opioid addiction. *See Taglieri v. Moss*, 842 A.2d 280 (N.J. App. 2004) (involving prescriptions for 840 Tylox plus 2,920 Percocet, for a total of 3,760 units over a seven-month period). Prescribing a fentanyl patch for post-operative or acute pain, or for use in conjunction with other opioids, supported a patient's verdict in *Welch v. Epstein*, 342 S.C. 279, 536 S.E.2d 408 (App. 2000) (recognizing its hypoventilation risk). An accidental overdose is not an unforeseeable result of prescribing, or over-prescribing, opioid painkillers to a patient who displays signs of addiction. *Halloran v. Kiri*, 2019 NY Slip Op 4769 (N.Y. Sup. Ct. Apr. 17, 2018), *aff'd*, 173 A.D.3d 509 (App. June 13, 2019) (adding that because decedent's use of illicit drugs was not unforeseeable, her drug use was not an intervening cause and did not amount to a separate act of negligence that independently caused her death); *accord Rice v. West 37th Grp. LLC*, 96 A.D.3d 500, 949 N.Y.S.2d 7 (N.Y. App. 2012) (finding accidental overdose was foreseeable consequence of ladder fall injury opioid treatment, presenting a jury issue).

Physicians of course ought to obtain informed consent in prescribing opioids when risk of respiratory depression is present. *See, e.g., Baugher v. Alta Bates Summit Med. Cntr.*, 2016 WL 728719 (Cal. App. Feb. 24, 2016) (involving administration of Dilaudid and Ativan to prepare chronic pain patient for MRI).

The starting point in the professional liability analysis is to determine the applicable standards of care.

Standard of Care Sources

The Centers for Disease Control recommend healthcare providers prescribe opioids at the lowest effective dose.⁵ The National Institute of Health recommends that providers treat pain using non-addictive alternatives to opioids and prescribe narcotics or medications with abuse potential for no more than seven days. *Conti v. Zamilus*, 2018 WL 6181363 (S.D.N.Y. Nov. 26, 2018) (noting that defendant repeatedly met with plaintiff, adjusted plaintiff's MSContin dosage, referred plaintiff to other providers, and renewed plaintiff's MSContin prescriptions).

The Federation of State Medical Boards promotes its Model Policy for the Use of Controlled Substances for the Treatment of Pain. *See* www.fsmb.org. The American Pain Society and the American Academy of Pain Medicine produced Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain in 2009. In 2012 the American Society of Interventional Pain Physicians released its Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain. State medical policy can vary widely from state to state, and thus prescribers need to be aware of the legal statutes in their state. *Legal and Regulatory Considerations in Opioid Prescribing*, at 1547.

Louisiana, I suppose as an example of its code grounding in law, has had a comprehensive statute governing physician responsibilities when patient substance abuse appears likely:

⁵ The dosage of pain-relieving medication is often measured in units of morphine milligram equivalents ("MMEs").

[I]f the physician reasonably believes that [the] patient is suffering from addiction or drug abuse, [the physician] shall obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type or types of drugs are to be screened. Evidence or behavioral indications of addiction, drug abuse or diversion of controlled substances by a patient being treated for chronic or intractable pain shall be followed by tapering and discontinuation of controlled substance therapy, and referral to an addiction medicine specialist, a pain management specialist, a psychiatrist, or other substance abuse specialist, or by an immediate referral to an addiction medicine or other substance abuse specialist for treatment. 46 La. Adm. Code § 6921 C provides that controlled substance therapy shall thereafter be reinitiated only upon the written concurrence of a pain management specialist based upon his physical examination of the patient and the review of the referring physician's medical records.

Jarrott v. Louisiana Bd. of Med. Exmnrs, 19 So. 3d 526, 529-530 (La. App. 2009) (citing also 46 La. Adm. Code § 6921 B; involving prescriptions of OxyContin, methadone, Lortab, Norco, Valium, Xanax and Soma).

The Diagnostic and Statistical Manual of Mental Disorders (DSM V) provides this definition of substance use disorder:

- Opioids are often taken by the patient in larger amounts or over a longer period than was intended.
- There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
- A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
- Craving, or a strong desire or urge to use opioids.
- Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
- Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
- Important social, occupational, or recreational activities are given up or reduced because of opioid use.
- Recurrent opioid use in situations in which it is physically hazardous.
- Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- Tolerance, as defined by either of the following:
 - A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
 - A markedly diminished effect with continued use of the same amount of an opioid. . . .
- Withdrawal, as manifested by either of the following:
 - The characteristic opioid withdrawal syndrome.

- Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.

Day v. Commonwealth, 2019 WL 1872117 *1-2 (Ky. App. Apr. 26, 2019).

Causation

If plaintiff is able to offer a prima facie case of professional negligence (standard of care and breach) he or she must also offer evidence of causation, i.e., did the physician's conduct have a substantial part in bringing about plaintiff's harm? Many defense verdicts flow from the key defense of no-causation.

A court properly enters judgment notwithstanding the verdict on causation grounds when expert testimony does not show: (1) a tie between failure to identify addiction to opioids and overdose suicide, (2) patient would have seen an addiction medicine specialist had the pain medicine physician made the referral, (3) patient would have entered detox had the physician intervened, (4) what the addiction medicine specialist would have done to treat the addiction, and (5) the outcome would have been different if patient's expert's advice had been followed. *Guerra v. Advanced Pain Centers S.C.*, 122 N.E.3d 345 (Ill. App. 2018).

Failure of plaintiff to offer expert testimony on proximate cause dooms a plaintiff's verdict. *See Guerra v. Advanced Pain Centers S.C.*, 122 N.E.3d 345 (Ill. App. 2018) (noting that no witness testified that if she had been weaned from opioid medications the patient, who had a history of depression, would not have committed suicide by overdosing on Tylenol, a non-opioid).

Causation was not shown in *Gregory v. Greater S.E. Comm. Hosp.*, 697 A.2d 1221 (D.C. App. 1997) where the patient overdosed by injecting drugs in the hospital. The record was insufficient to support a reasonable inference the patient had lost all volition and so was powerless to resist the yearning for opioids. Thus his act was a voluntary, efficient intervening cause that produced his death. Causation also was not shown where the patient repeatedly failed to comply with the physician's opioid exit strategy, where the patient's death was caused by medications prescribed by a different physician, where the patient refused the physician's entreaties that she visit a pain clinic, urine screens may or may not have been helpful, and where family contact may not have determined which pharmacies the patient obtained her medications from. *See Posner v. Walker*, 930 So. 2d 659 (Fla. App. 2006). Similarly, the court ruled in *Estrine v. VHS Huron Valley-Sinai Hosp., Inc.*, 2016 WL 7607475 (Mich. App. Dec. 29, 2016) that a medical malpractice physician could use a patient's past opioid abuse as evidence his exaggerated pain complaints were caused by that, and not by the physician's purported negligence.

A jury verdict for the defense on no-causation grounds was affirmed in *Guerra v. Advanced Pain Centers, S.C.*, 122 N.E.3d 345 (Ill. App. 2018), where the jury found the decedent patient was 50% responsible for her own death and awarded no damages. The majority held that plaintiff's error in failing to call an addiction medicine specialist to prove the defendant's actions caused the patient's death supported the contributory negligence finding. No causation can also be found when substance use timing evidence is presented. *See Procaccini v. Lawrence and Mem. Hosp.*, 168 A.3d 538, 543 (Conn. App. 2017) (ruling evidence supported view decedent consumed fatal dose of methadone prior to – and not after - ED admission).

A no-cause verdict may also obtain where the defense offers proof that the patient's death or injury was caused by unrelated medical conditions. *See, e.g., Creech v. Columbia Med. Ctr.*, 411 S.W.3d 1 (Tex. App. 2013) (involving argument death was caused by unrelated cardiac event); *Page v. Niagara Falls Mem. Med. Ctr.*, 2019 NY Slip Op. 05448, 174 A.D.3d 1318 (App. July 5, 2019) (involving delay in administering Narcan; SJ granted on cause grounds because plaintiff did not show brain injury resulted from adverse respiratory event).

Claiming that a patient's misuse of illicit drugs and other non-prescribed medications constituted a superseding cause of the patient's death ordinarily will present a jury issue. *Halloran v. Kiri*, 2019 NY Slip Op 4769 (N.Y. Sup. Ct. Apr. 17, 2018), *aff'd*, 173 A.D.3d 509 (App. June 13, 2019) (refusing summary judgment).

Expert Witness Testimony

As is the case in most professional liability claims, expert opinion testimony is ordinarily required for plaintiff to present a professional negligence claim against a physician in an opioid overdose case. *See, e.g., Love v. Waring*, 560 S.W.3d 614 (Mo. App. 2018) (involving the biomedical interaction of 13 medications, their side effects and doses necessary to manifest the side effects); *Trotter v. Baton Rouge Gen. Med. Ctr.*, 2016 WL 4160758 (La. App. Aug. 5, 2016) (involving alleged failure to administer or order the administration of an opioid or benzodiazepine antagonist). Summary judgment is often proper in the absence of expert opinion testimony. *See Lewis v. U.S.*, 2018 WL 2164508 (N.D. Tex. Apr. 30, 2018) (noting that VA policy requires drug screens, informed consent for long-term opioid therapy for pain, and opioid pain care agreements). Rarely will the common knowledge exception to the expert witness requirement apply in these cases, given their physiologic and chemical complexity. *See Patrick v. U.S.*, 2019 WL 1994468 (S.D. Ala. May 6, 2019) (ruling spinal cord injury patient given opioids could not rely upon common knowledge exception when dentist perforated buccal surface of tooth).

The scope of expert foundation is fairly wide in opioid overdose professional negligence litigation. So, for example, experts in pathology, toxicology, pharmacology, and internal medicine were qualified to testify as to the defendant's standard of care in a hospice and palliative care setting. *See Causey v. Sanders*, 998 So. 2d 393 (Miss. 2008) (involving a lethal dose of Dilaudid). But that scope is not without limits. *See Richardson v. Contra Costa County*, 2012 WL 1654959 (Cal. App. May 11, 2012) (ruling a pharmacologist cannot opine on the medical standard of care in Narcan intervention in a suspected opioid overdose case).

Contributory Negligence

In some cases patient contributory negligence may be present. *Koon v. Walden*, 539 S.W.3d 752 (Mo. App. Oct. 24, 2017) (involving patient who withheld information to the physician, and took higher doses than prescribed). But contributory negligence of the patient may not go to the jury if the factual basis for same is equivocal. *See Mullins v. Comprehensive Pediatric & Adult Med., Inc.*, 2009 WL 737915 (Ohio Mar. 19, 2009) (involving methadone care while the patient was abusing other drugs).

Limitations Statute

A court rejected an argument the limitations statute for a medical malpractice claim was tolled due to alleged opioid-induced insanity in part because the patient “was competent to testify during the period for which she claims the toll.” *See Liberatore v. Greuner*, 55 Misc. 3d 361 (N.Y. Sup. Ct. 2016).

Other Defenses

Michigan, which has a “wrongful conduct” defense, precludes claims if plaintiff engaged in criminal conduct that caused plaintiff’s damages. *See Estate of Errett v. A Forever Recovery, Inc.*, 2017 WL 2348723 (Mich. App. May 30, 2017) (granting summary judgment when the patient overdosed on cocaine and heroin during aftercare; it “would be a ‘mockery of justice’ to shift the blame of a person relapsing and engaging in illegal drug use to those treating the drug addiction, and would condone illegal drug use).”

Some courts allow the doctrine of avoidable consequences to be applicable for jury consideration. Under this doctrine a patient’s failure to mitigate damages by securing mental health treatment or by using opioid prescriptions as instructed may preclude the claim. *See Komlodi v. Picciano*, 89 A.2d 1234, 1253 (N.J. 2014) (also allowing superseding/intervening cause to go to the jury where the patient opened a Duragesic patch and consumed it).

Summary Judgment

Opioid-related professional negligence claims may be amenable to defense summary judgments. But summary judgment will be denied where plaintiff’s experts thoroughly lay out the defendant’s departures from standards of care in the administration of opioid medications. *See, e.g., Revich v. Long Island Spine & Ortho., P.C.*, 2012 NY Slip Op 30862 (N.Y. Sup. Ct. 2012) (involving 20 prescriptions for Vicodin, 10 prescriptions for Methadone and 1 for 50 Percocet tablets for “occasional left ankle pain”, a total of 31 prescriptions over seven months). Summary judgment will also be denied where the patient’s motion submissions establish triable issues of fact concerning the standard of care and causation based upon the expert opinion proffers. *See Place v. Bernstein*, 2013 WL 3777256 (Cal. App. July 18, 2013) (involving detoxification care for the patient’s OxyContin addiction). And, summary judgment was denied the defendant physician under New York law where the patient died as a result of an acute intoxication by the combined effect of fentanyl, heroin, oxycodone, and Alprazolam allegedly due to negligent prescription of excessive doses of opioid-based controlled substances. *See Halloran v. Kiri, Halloran v. Kiri*, 2019 NY Slip Op 4769 (N.Y. Sup. Ct. Apr. 17, 2018), *aff’d*, 173 A.D.3d 509 (App. June 13, 2019). Summary judgment was reversed in *White v. Scaff*, 2012 WL 2608626 (Tex. App. July 5, 2012) where substantial factor causation could be shown from reliable expert opinion where the patient died from an accidental overdose of OxyContin and hydrocodone.

Criminal Prosecution

Board discipline complaints and malpractice claims are not the only risks presented by opioid prescribing practices. Criminal charges for unlawful administration, dispensing, delivery, and prescription of controlled substances are also within the prescriber’s risk spectrum. *See, e.g.,*

Commonwealth v. Radecki, 180 A.3d 441 (Pa. Super. Ct. 2018) (involving psychiatrist convicted of Suboxone and Subutex prescriptions); *U.S. v. Jain*, 2019 WL 1110800 (D.N.M. Mar. 11, 2019) (finding physician prescribed opioids for no legitimate medical purpose and who failed to exhaust conservative treatment options).

Insurance Coverage

Sometimes insurance coverage issues are triggered by opioid prescribing overdose claims. For example, failure by a pain management physician to disclose opioid overdose deaths of patients, medical board and DEA investigations regarding same in an application for professional liability insurance may allow the insurer to avoid coverage via rescission. *See Admiral Ins. Co. v. Fisher*, 2018 WL 2688182 (W. Va. June 5, 2018).

Conclusion

Defense of opioid professional negligence and board discipline complaints presents challenges given adverse opioid notoriety in the media, the prevalence of prescription medicine substance abuse, and the counter-intuitive treatment of opioid addiction by administration of opioid medication. But the latter is well-grounded in science and is necessary. Counsel competence in the medicine of opioids, recruitment of appropriate forensic expertise, investigation into patient contributory and other fault, thorough evaluation of causation alternatives, and clear, confident advocacy of the value and necessity of opioids are the right prescription for successful defense outcomes in these cases.