

Beyond the Psychedelic Renaissance

Service

Psychedelics &
Emerging Therapies

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FIVE LEGAL CONSIDERATIONS FOR PIONEERING A PSYCHEDELIC-ASSISTED THERAPY CLINIC

Psychedelics are gaining more attention every day—by both interested consumers and by potential and practicing providers—as more therapeutic benefits are uncovered. As with administering any class of drugs, being in the business of providing psychedelics carries responsibilities. If a psychedelics provider does not follow guidelines or ethical norms, the potential for litigation exists. The psychedelics provider has duties before, during, and after administering psychedelic-mediated therapy, all of which could lead to litigation if breached. Additionally, many psychedelics are currently illegal; however, MDMA-assisted psychotherapy has completed Phase IIIb clinical trials, and the world is eagerly awaiting for the results to be published.

What is currently legal are ketamine clinics. If you own or operate one of the estimated 1,500 ketamine clinics in the U.S. that provides cutting-edge Ketamine-Assisted Psychotherapy (KAP) to treat patients suffering from PTSD, suicidal ideation, severe anxiety, and other mental health disorders, you are exposed to a myriad of liabilities that could put you at risk of a lawsuit. With regulations and federal oversight trailing far behind the demand for KAP, clinics are basically operating independently in what some consider to be the wild, wild west.

Because only ketamine clinics can operate legally in the United States at this time, this article will focus on risks to ketamine clinics, covering five important legal considerations for parties wishing to open such a clinic.

1. Corporation formation considerations

Because the clinics that are prescribing and administering ketamine could be participating in the corporate practice of medicine—depending on ownership

structure and the clinic's location—corporate formation issues are relevant and important to consider. The corporate practice of medicine is a legal doctrine stating corporations and other non-professional entities may be prohibited from practicing medicine or employing physicians to furnish professional medical services. The doctrine varies from state to state. For instance, in Texas, the prohibition of the corporate practice of medicine is derived from several statutory provisions including Tex. Occ. Code Ann. §§ 155.001, 155.003, 157.001, 164.052(a)(8), (13), and 165.156. 22 Tex. Admin. Code § 177.17. State law varies on what is permissible under the corporate practice of medicine. For example, in Minnesota, not-for-profit corporations can practice medicine, but for-profit corporations cannot. Minn. Stat. Ann. § 147.081 (West). Alternatively, in Florida there is no prohibition against the corporate practice of medicine. Florida Statutes Chapter 458 (West). In Florida, corporations and investors can freely invest in and own medical practices that employ physicians. Id.

The fiduciary relationship between clinician and patient is a serious one, and penalties for violating the corporate practice of medicine can range from suspension of a physician's medical license, voiding illegal contracts, or even imposing a criminal sentence for the unlicensed practice of medicine. If you want to set up a clinic, it is best to check with your legal professional about the structure of your managed care arrangement in order to protect your practice from running afoul of your state's corporate practice of medicine and potential allegations of the unauthorized practice of medicine. You will also want to review this issue in the event of a buyout or merger.

2. Recommending psychedelic-assisted therapy: state by state considerations

Psychedelic-assisted psychotherapy is a new modality of treatment requiring coordination between a physician who is able to prescribe the drug and the psychotherapist who will be administering the therapy. Therapists (besides psychiatrists who are licensed to prescribe medication) may work with a patient and get to a point where, in their best judgment, the therapist would like to recommend that the patient seek psychedelic therapy. Whether a therapist (who is not a physician) can do so will depend on the state in which they practice. A sampling of state law, such as the one below, illustrates the variety of laws and gray areas that exist in this regard.

California

While there is no guidance in California as to ketamine recommendations, California has the same rule as other states that the therapist has no prescribing power. Cal. Bus. & Prof. Code § 2904 (West). As far as recommendation restraints, therapists in California are not allowed to testify outside of their area of expertise. *Cooper v. Board of Medical Examiners* (App. 1 Dist. 1975) 123 Cal.Rptr. 563. California has a rule that only an attending physician can recommend medical cannabis (Cal. Bus. & Prof. Code § 2525.2 (West)), but that seems to be the only substance that has a specific recommender.

Colorado

Colorado statutes contained in Article 245 of Title 12 govern powers of mental health professionals. In Colorado, therapists have no prescribing power. Colo. Rev. Stat. Ann. § 12-245-210 (West). § 12-245-302 created a state board of psychologist examiners. Both the statutes and regulations are silent as to ketamine or the proper recommendation process from therapist to physician.

Missouri

As with the other states, therapists cannot prescribe medication in Missouri. Mo. Ann. Stat. § 337.060 (West). Missouri's statute seems to be even broader in that it prohibits psychologists from engaging "in any manner the practice of medicine..." This language might be construed as to prohibit making recommendations of medications such as ketamine.

Wisconsin

Wisconsin also does not have statutes or regulations about therapists recommending medication. However, "unprofessional conduct related to the practice under a credential issued under ch. 457, Stats., includes, but is not limited to, engaging in, attempting to engage in, or aiding or abetting the following conduct: (1) Performing or offering to perform services for which the credential holder is not qualified by education, training or experience." Wis. Admin. Code MPSW § 20.02.

With the wide variation and nuances in state law, it is advisable to check with your legal professional to determine the landscape of what is allowed within the parameters of your practice before recommending a patient seeking psychedelic-assisted therapy, if you are a therapist without the ability to prescribe controlled substances.

3. Physician-psychotherapist agreement considerations: splitting fees

Ketamine clinics and psychotherapists must also comply with other state laws on professional entities and fee-splitting that are similar to the corporate practice of medicine in that not all psychotherapists are licensed to practice medicine. Because of the coordination that will need to occur between physicians and therapists, professionals may wonder whether fees can be split between the two for this new form of treatment.

As with the corporate practice of medicine, this will vary from state to state. For instance, California has restrictions on what types of fee splitting are allowed. California Business and Professional Code § 650 states: "(a) Except as provided in Chapter 2.3...the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to

any person, irrespective of any membership, proprietary interest, or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.” By contrast, Wisconsin’s statute prohibits fee splitting stating: “(1) Fee splitting. Except as otherwise provided in this section, no person licensed or certified under this chapter may give or receive, directly or indirectly, to or from any person, firm or corporation any fee, commission, rebate or other form of compensation or anything of value for sending, referring or otherwise inducing a person to communicate with a licensee in a professional capacity, or for any professional services not actually rendered personally or at his or her direction.” Wis. Stat. § 448.08.

There are no statutory or regulatory fee splitting prohibitions in the following states: Alaska, Arkansas, Connecticut, Colorado, Indiana, Iowa, Louisiana, Maine, Massachusetts, Mississippi, Missouri, New Hampshire, New Jersey, North Dakota, Oregon, Pennsylvania, South Carolina and Wyoming. However, it is possible that similar prohibitions may be found in a state’s case law, attorney general opinions, or other sources of legal authority. Professionals seeking to incorporate psychedelic-mediated therapy into their practice should consult with their legal professional who is familiar with their state regulations before entering into a business arrangement where fees are split.

4. Insurance coverage

Despite ketamine infusion therapies entering the mainstream, as with most new interventions, it is considered high risk; therefore, clinics and practitioners require specialized insurance policies. Below are the essential coverages your clinic needs to protect itself from costly and damaging litigation.

Professional Liability/Errors & Omissions (E&O) Insurance

Most licensed healthcare professionals have some type of malpractice policy, which from a technical standpoint is often referred to as Professional Liability/E&O insurance; however, be aware that if you are new to offering KAP through your private practice or a specialized clinic, your existing malpractice policy may not cover any claims associated with this emergent, “high-risk” treatment. It is recommended that you talk to an independent insurance broker with specialized knowledge of the psychedelic medicine industry to evaluate your policy and determine if you have or need additional coverage.

In an industry like psychedelic medicine, Professional Liability/E&O insurance is critical. Many licensed professionals provide their therapies either onsite or remotely through telemedicine and assist their patients throughout the course of their therapy. Patients require precise dosing and treatment, and there is no room for error. In the event of a claim, your policy will cover both court costs and settlements, up to the amount specified by the insurance contract. Professional Liability insurance policies can also be designed to include coverage for HIPAA violations, including expenses associated with legal proceedings, fines, and penalties.

General Liability Insurance

This type of policy is essential to protect clinics from a variety of claims including personal injury, bodily harm, property damage, and other situations that may arise including contractual obligations, slander, libel, copyright infringement, and more.

With a comprehensive, psychedelic medicine-specific General Liability insurance policy in place, the insurance company, not the clinic, will pay for medical expenses and property damage claims from third parties, in addition to hefty legal fees and fines.

Directors & Officers (D&O) Liability Insurance

Many officers and directors require a company to have D&O coverage, often with excess limits. It's also a likely prerequisite if your clinic is looking to secure venture capital or funding from investors. D&O insurance protects your clinic's C-suite and board, as well as their spouses and estates, from being personally liable in the event your clinic, or one of its healthcare practitioners, is sued by investors, employees, vendors, competitors, customers, or other parties, for actual or alleged wrongful acts in managing the company. In the event of litigation, a comprehensive D&O policy will cover legal fees, fines, settlements, and other related costs.

Product Liability Insurance

This is a specialized coverage designed to protect your clinic from claims that can happen anywhere along the supply chain, including product contamination, mislabeled medicine, false advertising, or defective products/ingredients. Ketamine's "off-label" status puts practitioners at high risk for legal claims for a variety of reasons. From an insurance perspective, the product risk exposure is great in this industry due to the possible side effects of ketamine. With proper coverage, your insurance company—not your clinic—will pay for damages and legal expenses if you are sued up to your policy limits. Your product liability policy will also cover any medical expenses for those who are harmed by the administered treatment. The need for different product liability coverage depends on the legality of the active ingredient in the state in which the clinic operates.

Cyber Defense and Data Breach Insurance

Given the vast amount of patient information and data that every healthcare practice is required to collect through an Electronic Health Records system, ketamine clinics are prime targets for cybercrime and data breaches. Even an accidental breach like a software malfunction or a lost laptop could result in costly litigation; furthermore, a data breach can be deemed a HIPAA violation regardless of whether the clinic was responsible for the breach. Today, a single violation can result in fines up to \$50,000, to a maximum of \$1.5 million per year. These risk factors are why a cyber liability policy should be part of your overall risk management strategy.

5. Incorporating digital health tech in your practice (apps & devices)

Digital therapeutics, like most new telehealth programs, are racing to keep up with medical needs and concerns. For example, at the height of the COVID-19 pandemic, nearly 40% of Americans reported struggling with mental health or substance abuse issues.[1] Accordingly, many online therapy providers began to spring up, making therapy more accessible for many people. However, concerns about prescription practices began to emerge, as well, leading to the federal investigation of at least one online therapy company. Typically, federal law requires that a doctor would see a patient in person before prescribing controlled drugs like Adderall. However, regulations were relaxed to help remove hurdles to mental health care. Fewer hurdles, though, also resulted in allegations of unethical prescribing by some companies who were believed to be inadequately evaluating a patient before prescribing medicine.[2] These allegations are an important reminder of the highly regulated nature of medicine, especially when controlled substances are being prescribed, and the need for digital therapeutics to have clear policies in place regarding assessments that can and cannot take place virtually.

Many practitioners are choosing to use digital health technologies in their practice. There are no federal privacy laws however there are at the state level. Some lawmakers are trying to rein in health data sharing. California State Assembly member Rebecca Bauer-Kahan introduced a bill in February that could redefine “medical information” in the state’s medical privacy law to include data gathered by mental health apps. Among other things, this would prohibit the apps from using “a consumer’s inferred or diagnosed mental health or substance use disorder” for purposes other than providing care. It is advisable that clinicians choose vendors that have the appropriate certifications to ensure privacy and address cybersecurity issues and work with regulatory counsel to ensure compliance with evolving legal standards for digital health technologies.

Conclusion

Psychedelic-assisted psychotherapy holds the promise of providing relief to sufferers of PTSD, suicidal ideation, depression, chronic pain, and other disorders. The psychedelics at issue are still undergoing clinical trials and none may be used outside of a research setting, with the exception of ketamine. Many ketamine practitioners also hope to provide other forms of psychedelic-assisted therapy when available. These clinics represent a new modality of treatment and may be considered high risk. This article just covers a few of the legal considerations for starting and operating such a clinic. Compliance will vary from state to state, and it would be best to consult your regulatory professional for guidance as to best practices specific to your situation to avoid liabilities that could potentially shutdown your clinic.

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[1] Mark Czeisler, Rashon Lane, & Emiko Petrosky et al., *Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic*, *Morbidity and Morality Weekly Report* 2020; 69:1049–1057 (June 30, 2020).

[2] Emily Henderson, *Digital mental health companies draw scrutiny and growing concerns*, *News-Medical.net* (July 8, 2022).