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Key Legal Considerations Relating to Ketamine Behavioral Health Platforms

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In the last few years, we have seen an uptick in behavioral health groups focused on psychedelic treatments. There are now at least five (5) psychedelic-assisted therapy platforms traded on NASDAQ with numerous others listed on the Toronto Stock Exchange and elsewhere.[1] Ketamine treatments, in particular, have garnered considerable attention from patients, providers and investors. Treatment models range from more traditional psychotherapy and infusion services similar to those offered by Columbia University[2] to telemedicine-enabled psychotherapy coupled with mail-delivered tablets of ketamine under the Mindbloom model.[3] However, despite the growth in adoption, Ketamine remains a controlled substance and ketamine behavioral health remains an industry with material regulatory risks.

We have set forth certain key considerations for various stakeholders involved with ketamine behavioral health.

1. **Legal Status and Reimbursement**

Ketamine is a Schedule III controlled substance.[4] Currently, with certain exceptions, the use of ketamine for depression and related behavioral health matters is "off label." This means that although ketamine is approved by the FDA for some medical uses, it is not specifically approved to treat depression. While the practice of prescribing off-label drugs is legal and common, there is an inherent level of risk when such drug is a controlled substance with a history of recreational abuse. Accordingly, the American Psychiatric Association has issued guidelines for clinicians who wish to use ketamine for such purposes.[5]

Notably, ketamine infusions or prescriptions for behavioral health matters are generally not reimbursable by Medicare or other federal health care programs. As a result, in such circumstances the federal Anti-Kickback Statute and Stark Law may not be applicable. Reimbursement from commercial payors is also uncommon, and most practices are "cash-pay." Nevertheless, state anti-kickback statutes, self-referral laws, patient brokering acts, and similar laws would remain applicable particularly if they are "all-payor" in scope.

2. **Ketamine Treatments Constitute the Practice of Medicine**

Ketamine prescription and administration, whether intravenous, oral or nasal, constitutes the practice of medicine. Accordingly, issues such as provider licensure, scope of practice, physician supervision, prescriptive authority and the establishment of a physician-patient relationship, among other factors, are material to the operation of a practice. Such laws and regulations are largely governed at the state level, and there may be (i) considerable variations among state laws and (ii) frequent updates to such laws. For example, Virginia allowed a COVID-19-related telemedicine waiver to expire on June 30, 2021.[6] Several other states have either rescinded telemedicine waivers or allowed them to expire.[7] Other states may continue to allow looser restrictions on telemedicine, prescriptions of controlled substances and other areas of state law that may be relevant to ketamine behavioral health platforms.

3. **Corporate Practice of Medicine and Potential Solutions**

Numerous states prohibit the corporate practice of medicine ("CPOM"), which means that corporations and other non-professional entities may be prohibited from practicing medicine or employing physicians to furnish professional medical services. Because ketamine behavioral health platforms furnish medical services, they must comply with state CPOM prohibitions and related laws relating to professional entities and fee-splitting.

There are numerous, fairly common methods of complying with CPOM restrictions, including by way of allowing non-physician investors to own in a management company, which enters into an exclusive, long-term management services agreement with a physician practice owned by a physician. Because state laws vary widely with respect to CPOM restrictions, it is important to review state laws carefully and structure for specific requirements.

4. **Regulatory Licensure**

In many states, operating a ketamine clinic does not require a specific regulatory facility license. Assuming compliance with related laws, a ketamine clinic could largely operate with the federal DEA licenses and state controlled substance licenses of its providers. However, in certain states an outpatient treatment center permit may be either necessary or desirable. Yet again in other states like Florida, a specific license may be required for medical practices that are not owned by physicians.[8] Often times, the process of obtaining such license requires disclosure of non-physician ownership. Finally, depending on the model of the ketamine practice, facility-level DEA licenses and pharmacy permits may be required.

We recommend a careful review of a ketamine behavioral health platform's model against the backdrop of federal and state laws in order to develop optimal and compliant legal structures.

[1] https://www.forbes.com/sites/willyakowicz/2021/07/29/ketamine-clinic-company-field-trip-health-debuts-on-nasdaq/?sh=33ebc9c41625.

[2] https://www.columbiadoctors.org/specialties/psychiatry-psychology/our-services/ketamine-program.

[3] https://www.mindbloom.com/.

[4] https://www.dea.gov/drug-information/drug-scheduling.

[5] https://pubmed.ncbi.nlm.nih.gov/28249076/.

[6] https://www.dhp.virginia.gov/Boards/Medicine/AbouttheBoard/News/COVID19/Content-398041-en.html

[7] https://www.beckershospitalreview.com/telehealth/where-the-us-stands-on-telehealth-coverage-5-states-that-let-orders-expire-or-kept-expansions.html.

[8] http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=%3E2004-%3ECh0400-%3ESection%20991#0400.991.

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