Starting a Ketamine Clinic – What You Need to Know
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Presented by Hilary Bricken, Ethan Minkin, and Vince Sliwoski

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Vince Sliwoski 0:04

Everybody, welcome to the webinar today on starting ketamine clinic. I'm Vince Sliwoski. I'm a partner with Harris Bricken here in the Portland office and I'm joined by two industry leading colleagues very experienced business and healthcare lawyers who have been doing a lot of work. Over the years with ketamine clinics, you'll see Hilary Bricken on on your screen, she's in our Los Angeles office, and then you'll see Ethan Minkin also in your screen, and then he is down in our Phoenix, Arizona office. Before I get going too much on that, I want to say stay tuned for a couple of upcoming webinars we have this is part of a series, we're actually always doing webinars, I call this series, but the next one is building a cannabis business in New York. That one is on Thursday, September 23. And then the one after that is cannabis litigation, what you need to know. And that's Tuesday, October 19. And you can also follow us on social media, we're at the canon law blog, we're on Twitter, LinkedIn, and everywhere else. So excited to be here with you today, we've got about 250 attendees, which is great. A lot of you guys submitted questions in advance, which is also great, we're going to get to as many as we can and kind of organize them and try to weave them in through the presentation, which is going to be conversational. You can also submit questions during the webinar at any point, you just type them in, and I'll see them and we'll ask them or try to weave them in as appropriate. And if we have time, we'll leave some time at the end to cover anything we haven't yet covered. So that's kind of a big picture. I wanted to start at a really high level, and discuss the current schedule, status of ketamine and off label use. I think I would give us some context for everything else that we'll talk about. That's probably more detailed throughout the presentation. So I'm hoping that maybe Ethan could start with that, if that's all right.

Ethan Minkin 1:57

Absolutely. Thank you, Vince. Let's start with what off label me. Every drug has a label on it. Every drug comes with an IF view which are instructions for use. And within those documents, it tells you what a drug can be used for. Before a drug can be approved for to hit the market, the FDA looks at all of that literature has to approve it in advance. So off label simply means just that it's used for an indication that's not a label, not in the instructions for use. Now, there's a lot of statistics about use of off label medications. And if you just Google off label percent, you'll find all different kinds of studies. But just to give you a quick sampling, there's one study that estimated that 21% of all office space prescriptions are for off label. There was a separate study that found 40 to 80% of psychotropic medications, you know that those use for different mood disorders and depression were used on an off label basis. There was one last one that's a little more troubling, and this was in the primary care setting that found that 84% of off label prescriptions for like antidepressants had no strong clinical evidence of efficacy. And we'll kind of talk about some liability issues as we move on. So what is ketamine? ketamine is a schedule three controlled substance scheduled three means that there's a low to moderate risk of addiction, physical addiction and psychological addiction. Schedule three obviously, is is lower than schedule one and two that have much higher potential for addiction. Some examples of other schedule three drugs would include testosterone, steroids, Cody and with if you have 90 milligrams or less of COVID in a

medication, ketamine was approved and has been used extensively as a surgical anesthetic for many, many years. Recently, there was an approved version of ketamine and that's it nasal spray is called s ketamine and that is actually indicated for certain disorders. Now, what is ketamine be used for is a question we all get and it's being used for a wide variety of disorders, for mood disorders, to pain relief to addiction and so on and so forth. One thing that we highly recommend we're actually going to step back a bit. Just for clarity to a physician has the absolute right to write a prescription for off label purposes that is not illegal. There's you know, the only issues around off label from a liability perspective, at least is efficacy. And, you know, what we recommend, and this kind of goes hand in hand with marketing materials is that a provider, look for peer reviewed articles, trials, and so on and so forth, so that they can convince themselves that it's safe and effective for the particular disorder it's being used for. We also recommend when you're putting your marketing literature together, that you actually footnote it as well, to say, you know, this is the source where I found this information. Currently, we're unaware of any clinical trials for other indications for the use of ketamine. And that makes sense because the cost to to get a new disorder approved is extremely expensive. And ketamine is being used for all different reasons right now. And so there's really no incentive for drug makers to go through the additional expense of additional clinical trials for different indications. So that's, that's really the current status of ketamine.

Vince Sliwoski 6:12

Okay, so then let's talk a little bit about the advent of ketamine infusion therapy, right, and specifically clinics, which is really what we're here to talk about today. I understand you're talking about off label use that these clinics are essentially possible, because of off label use. Could you guys talk a little bit about that Hilary already, I don't care who.

Hilary Bricken 6:33

Yeah, when we started exploring this practice, and just from a very high level, this is really kind of an emerging medicine. At the end of the day, and Ethan mentioned, the dissociative anesthetic typically used in surgery, but actually, it's a psychedelic at its base. So that's why it's getting a lot of traction, because other psychedelics like MDMA, and psilocybin, are getting very serious looks with legitimate clinical research from the federal government. Yes, because of the off label use, these clinics are possible within the applicable standard of care, depending on the risk tolerance of the physician that's willing to explore this particular off label application. But also, because we don't have anything spot on from the FDA regarding regulations around these clinics. So they're relatively easy to set up. As a result, there are other federal and state laws that we're going to talk about today that impact their setup. But that's why I think we're seeing a very quick onboarding and proliferation of these clinics. And when we looked at the data, which there's not a lot out there on ketamine clinics, again, because this is emerging, and it's new and novel with this application for mood disorders. But as of 2015, there were only about 300 of them across the United States. And you can only imagine how much that number has increased, really, with this anecdotal study of its efficacy for mood disorders, and just kind of to bring it home for everybody on the off label use, because that conversation can be a little protracted. Many people who

are looking at ketamine, even the physicians are coming from areas like cannabis and other kind of auto emerging medicines in this legal Penumbra. And it's not like those medicines, because it is a schedule three controlled substance. But when you think of off label, the classic example and many people don't know this, or or just aren't aware, Viagra actually is an off label application. And it's a failed part medication. But when the drug company went back to retrieve the samples, after trying to go through drug trials, the test subjects would not surrender the medication, because it had other obvious collateral side effects that were beneficial sexually. So now we know obviously, it's an erectile dysfunction drug, but that was discovered through off label applications. So to Ethan's point, these clinics are legit, as far as federal scheduling goes, and we'll talk about licensing with the DEA and AppStore, the drug and all of the record keeping and bookkeeping that you have to do to adhere to storing and basically administering a schedule three controlled substance. But just because it's not being used as a dissociative anesthetic, does not mean that these are illegitimate where people get into trouble is within the applicable standard of care and interactions with patients and their medical malpractice conduct and whether or not they're being negligent with how they're administering it, because Ethan and I will talk about this today. There's no succinct standard of care, and there probably won't be as physicians and healthcare practitioners experiment with this off label application for different disorders.

Vince Sliwoski 9:39

That's really helpful. And it's interesting you mentioned so our firm and I didn't address this in the in the intro, but we've been kind of in controlled substances for a long time, right? Like Hillary I know has been doing cannabis work, literally since 2010. Ethan has a classic healthcare background and I think because of that, and because you guys started writing about ketamine, you years back, we started getting a lot of people calling about it a few years ago, and we've done a lot of deals in the space over the last few years, it seems like it's really ramping up. It's kind of the tip of the spear, with respect to psychedelics, and just a whole mix of things. So I kind of want to hear from you guys about what kind of deals have we been doing? Can you give us sort of an overview? Are these like big msos? Or are they little shops? Where are they? What does anything you want to say about the deal to be helpful?

Hilary Bricken 10:27

Yeah, I'll leave with that one. And Ethan can kind of fill it in as well. And we're kind of getting into some of these other areas that are going to impact how these clinics are set up, because it's very state law dependent. So it does the health care overview does share that with things like cannabis where cannabis is very localized, and the states are in control of policy and law. It's the same thing when it comes to, for example, the corporate practice of medicine. And that's going to dictate a lot of the deals that go down in this particular space. But what are we seeing lately, we're seeing a lot of m&a, we're seeing a lot of third parties, especially publicly traded companies coming down from Canada that want to be in the psychedelic space, buying up what are commonly known as medical services organizations or management services organizations, which today we're going to call msos. The reason why they're pursuing msos, and not the medical practices themselves, is because oftentimes, state law prohibits them from venturing, or owning stock or units in an actual local practice because of the corporate

practices medicine. And we'll get into what that means and what these structures look like together between the medical practice. And then this MSO that provides goods and services. We're also going to talk about how to diligence these opportunities so that you know what you're getting into, because anything can echo this. Every time we've gotten a term sheet from folks who want to do a deal with a medical practice with an MSO. They always set it up incorrectly, right, these third parties are always taking equity in the medical practice. And in many states, you cannot do that at all. So the deal has to be reworked. And a lot of them turn into acquisitions of the MSO, or asset purchase agreements for all of the resources and goods and contracts and everything related to the MSO that will be leased and stole back and used in servicing the medical practice. So that's typically what we're seeing out there. But most of the deals are dictated by the corporate practice of medicine, which we're going to discuss it a little bit.

Ethan Minkin 12:33

I agree with Ellery, we're seeing all kinds of deals. We're doing them from coast to coast from California to New York and all the way down to Florida and everywhere in between. And so it's become a very active space, for m&a activity and also for startups. We help you know, clinicians getting their practices up and running. It'll be helpful on the acquisition side as well. We've also seen an Advent recently of telemedicine and having ketamine clinics done via telemedicine and we're going to talk about that later as well. But that introduces some other regulatory and legal hurdles that you have to be cognizant of.

Vince Sliwoski 13:16

And we got a lot of questions about those hurdles. We have questions about licensing to start with physician and facility licensing. We got questions about federal agencies like the DEA and the guy questions about state agencies. I don't think I'm gonna read all those questions, because there's too many in there. A lot of them are redundant, but just more generally, how does it work? How does licensing work? How do you open a clinic Can one of you guys talk about that?

Ethan Minkin 13:41

The licensing, you know, and it's really gonna vary from state to state. Some states like Arizona, you can have the clinic portion owned by non healthcare providers. But if you want to do that, in Arizona, you have to get an outpatient treatment center license, they're not difficult to get. It's not a complicated application at all. Other states like Florida, if what you're doing is providing pain treatment as part of ketamine, you may need that pain treatment, Pain Treatment Center license as well. So it really is going to vary from state to state. Oftentimes, when the physician just zones by himself or with a group, there's exemptions to licensure, at least at the state level. So it's really going to be in some states have no licensing requirement for the clinic itself. So it's really gonna be dependent upon what state you're in. then beyond that, there's a whole panoply of licenses. And you typically need if you're going to see Medicare patients, for example, you need a Medicare provider ID. And those again, not difficult to get.

But what does get tricky is when you have transactions where there's either a change in control, a change in ownership or a change in information, and there's no universal definition, it's going to vary from state to state. The feds have their own definitions. And sometimes those definitions vary from agency to agency. But it's something that if you're doing a deal, you need to look closely at that those type of licenses, you're also going to need. If you're billing insurance and Medicare, you'll need a National Provider ID, which is administered through Health and Human Services. In addition, as already been alluded to, if you're holding controlled substances, you'll need some kind of DEA approval, sometimes it's the physicians that hold the license. Other times, it's the physician and the clinic that holds the license. So it really just depends on how you're set up, where it's going to be stored. And again, these are not difficult licensed to procure. But they take a little bit of thought and some guidance. There's also, in addition to that, what we see often two are clear waivers, which relate to clinical laboratories. And physicians can do certain kinds of tests in their offices and not have to be CLIA certified, which is a very difficult, expensive and time consuming process. So you can get the CLIA waiver that allows you to do certain limited tests. And again, if you're having a transaction, you have to look very, very closely at these different change and control change of ownership provisions. One thing you have to pay close attention to is the timing aspect. Some require notification, but filings prior to the closing. Other ones require at post closing typically within 30 days. So licensing is very important. And it's it's oftentimes driven by state and federal law.

Vince Sliwoski 16:45

And then what about the filings that are required? like Hillary mentioned, we do a lot of work with these people who were, say buying Academy and clinic. When you're in a transaction, do you have to make filings before that transaction closes? Can you close without certain licenses? Can you talk a little bit about that concept?

Ethan Minkin 17:04

Yeah, no, absolutely. And you're right. I mean, some require pre closing amendments to be filed with the relevant agency. So far, most that I've seen are post closing like Medicare's post closing your NPI numbers post closing, your clear. waivers are post closing. And so for the most part, you have 30 days post closing to make these filings. One exception would be like in Florida. It's HCA is their agency down there that oversees licensing, and that requires pre closing notification and approval. But so far, that's the only one I know of that's a pre closing type requirement.

Vince Sliwoski 17:53

And if you close with missing one of these requirements, what happens?

Ethan Minkin 17:57

Well, that's a good question, I'd be interested depends is the answer I B, they do have the right to impose certain penalties. I've never seen a situation where they refuse to approve it. You know, even if you're late, and Medicare, I've had clients that have taken a year or two to do the filing for a variety of reasons, and they bring us in to help kind of clean up the mess. So for the most part, you're not gonna lose the right to do what you're doing. But you got to be careful, like, for example, with Medicare, I mean, you want to make sure your billing under the proper Medicare ID number and that you're properly approved. Or you can get into all kinds of issues. And sometimes what happens is, you can enter into certain management agreements, but this is actually goes beyond really what we're talking about today. But there are ways around it and different types of transactions and nine ways to deal with Medicare. But that's, that's really one of your most important if you're seeing Medicare patients.

Vince Sliwoski 18:56

And I take it when you guys represent buyers in these transactions, who is discussed, you have a diligence process where you get a lot of the information you'll need to apply for license, is that right?

Ethan Minkin 19:05

Absolutely. Well, we send out our due diligence, right at the beginning of the deal. One of the things we always ask for the licensing files, because for example, dot typical Medicare, but what often has to happen is you're gonna have new board members, let's say and when you have to do with the Medicare license, which is the form 855 is you have to remove the old directors and then put in the new directors. Now, that sounds simple. It typically is but if you have one mistake, if you miss someone's middle initial, if you transpose A letter by accident, they will find that and they will you'll get a deficiency notice so so that's why it's so important to get a hold pre closing of the licensing application files on the seller. So you can see what was done. You can see what licenses are being held and you can see you know, it's what Some licenses will have statutory references, for example, for timing, right, like when it has to be filed. So there's a lot of information you can glean from getting those application files.

Vince Sliwoski 20:12

And then I'm going to talk about something that might be a little different. But I want to get into that point that Hillary raised earlier about the corporate practice of medicine, the types of applications Ethan was just talking about, is not an audit for who's actually owning these things. Right. It's more about you that you have your correct licenses, how do you figure out who can own these business?

Hilary Bricken 20:34

I'll take that one. So just a very high level. For people that are coming into the healthcare space in the United States that have no point of reference, they're totally new, but they've got a lot of money to

spend. Healthcare is extremely regulated in the US from top to bottom, probably one of the most regulated industries that is out there. So for my earlier discussion points, not just anybody can own a medical practice and in states that codify that in statute, case law, Attorney General opinions, it's called the corporate practice of medicine. And sometimes it's very explicit, sometimes it's created through series of court decisions, it is detrimental to violate the corporate practice of medicine. And the ones who will suffer are the licensed physicians in front of their state medical board. Plus, there are criminal ramifications for aiding and abetting in the unlicensed practice of medicine. So third parties need to be extremely aware of that and sensitive to that, in what are called the CPOM states. CPOM is the acronym for corporate practice of medicine. And unfortunately, for all of you, the major CPOM states are California, Texas, and New York, which is probably where a lot of our healthcare is going on. Luckily, Florida, not a CPOM state, which means that third parties can directly venture and finance with and for these physicians, different set of priorities. However, the focus is really with the CPOM pitfalls. What does it mean, at the end of the day? Yes, it means that physicians and lay people cannot venture together, but it's more than that. physicians, when they practice, if they want to do it through a business, it has to be a very particular business codified in statute, okay, typically a medical professional Corporation, or its equivalent, depending on the state, not just any physician or healthcare provider can own equity in these businesses, the statute will control and enumerate who can participate. But typically the rundown is that 51% of the cap table has to be held by the physicians that practice in the subject area of the business, okay. So if it's an anesthesiologist practice, 51% of the cap table must be anesthesiologists, the minority, the 49%, also cannot just be anybody. But typically, luckily, it doesn't have to be medical physicians, it can be other licensed health care providers, like psychologists, nurses, the list is very long, it's just dictated by statute within a given state. So that's one side of seafoam. But it's very important because when you do any deal, relative to a ketamine clinic, and a medical practice is involved. And we'll get into this, the diligence dictates that you also diligence, the medical practice, because these are the guys who have control of the drugs. They're the ones administering the treatments, they're the ones with the malpractice liability, and you're going to be attached to that as the MSO. So you also have to diligence the medical practice. And it better be in line with those very basic bright lines under CPOM. But going beyond the whole point of this MSO structure, which is typically called the friendly PC model. Third parties cannot practice medicine. So even if you're not in the cap table of the professional company, Corporation, whatever it is in your state, you still cannot dictate medical decision making. For the Docs or for the staff, you strictly must stay in your lane regarding the provision of Administrative Services only. So think back off the support, maybe marketing support, although even that can get kind of crosswise with CPOM depending on who has the ultimate say over the content of the marketing, but you cannot hire and fire medical staff. You cannot mess with medical records. Those belong to the PC, the PC deals with them. I say PC, I mean professional Corporation. All of the clinical decision making must stay with the physicians even down to the selection and choice of medical equipment. Okay, now, how can the MSO really interact with the PC and make any money to very good question that we're still trying to figure out on a single basis if it's not high volume if you're not servicing multiple clinics in the CPOMstate is It's very difficult to turn a profit. And Ethan's going to get into this a little bit later. But even things like profit sharing and fee splitting, eliminated. In most CPOM states, California is a glowing exception, actually, because we're very strict CPOM state. But even we let third parties take a piece of the gross revenue generated by the medical practice for certain services rendered by third parties that are not licensed physicians, so long as it's reasonably

commensurate with the fair market value of the services rendered, and has nothing to do with patient referrals. So it's a very narrow opportunity to make some money based on how the medical practice is actually doing. But in most other states, like Texas, New York, depending on the other facts and what the MSO was doing, if the MSO was providing too many management services, and fee splitting, we're going to have a soupon problem. And this is a very long way of saying these are extremely fact intensive analyses. So one contract may not violate some con, even though we've got a bunch of provision of management services, because the MSO has not spilled over into clinical decision making other contracts, similar set of facts, depending on the power of the MSL, in practice, if there's a really robust power of attorney, for example, if we have, you know, total control of all medical records, and we're the MSO, probably going to have a CPOM problem, or if the MSO was allowed to take on the marketing campaign by itself. And it's literally generating the content around the efficacy of ketamine. Huge CPOM problem in a CPOM state. So for diligence, and when, again, people are entering healthcare in the US, they must, must begin with a CPOM analysis, if you do not do that you are entering a world of pain, whether you are the MSO, or the physicians that are going to do business with the MSO. But that I would say, in a nutshell, is the corporate practice of medicine, which is wildly complicated. And I'm not doing it in a men's service. But it is localized. It's very state oriented. So if you're looking at doing business with a professional Corporation, or physicians, please, please, please start with CPOM laws in that state.

Vince Sliwoski 27:14

That's a great summary for a complex topic. I you know, I think and I think we understand more generally corporate backs medicine, talk, governance ownership, and it says, What about fee splitting? You mentioned Ethan, we'll talk about that. Can you talk about that?

Ethan Minkin 27:27

Yeah, and sort of, say one or two things about CPOM as well. You typically see the case law rise when there's going to be a falling out, or when there is a falling out between the MSO and the professional entity. Most of these don't have a ton of case law. But the saints that do have the case law, you want to look at it very, very closely, because oftentimes, it will help dictate what the management agreement looks like. And where it gets tricky to is. The one the courts typically do is they look at the totality of the circumstances, they don't just look and say there's no bright line test for most states, like if you do X, you're in trouble. They look at it more globally, typically. So it depends. Some of the services provided by the MSO is really it's gonna come down to risk tolerance as well. And so it is a very complicated area. And it's something I agree with Hillary, it's step one, anytime a new deal comes through the door. Anytime a physician wants to set up a clinic, that's the first thing you really need to do is explore see pop now fee splitting really goes hand in hand with CPOM and it's fee splitting. There's the federal aspect that we'll get to but we'll start with the state level. And it typically prohibits a professional from dividing his or her fees with other people. And it's typically we'll see the not always but sometimes you'll see these prohibitions within the definition of unprofessional conduct. Like in Arizona, if you look up the Arizona regulations and statutes for physicians under there, you'll see that fee splitting is prohibited.

The basic premise again, is that you can not fit you know, split provider cannot split those fees with other people that that does not mean that a provider can't pay for service, right? I mean, even if you're dealing with an MSO providers going to lease space from someone, they may have their own you know, billing company that they contract with, they may have a You are a company that they contract with. And so, when you look at things individually, there's no issue it's when you kind of package them all together into the MSO where you start seeing potential you know, both CPOM and fee splitting issues. Now, the best and Hillary alluded to this earlier, the really the gold standard in setting fees for the MSO is procuring a fair market value valuation. There are firms throughout the United States that do this. And they will help you come up with what the fair market value is. Now, the typical model is the cost plus model that Hillary talked about where it's the actual cost of the service plus some margin on top of that, so the MSO can make money. There are other models as well, again, as Hilary talked about, there's the epic decision out of California. And that revolved around damages. So taking a percent and the total revenue of the medical practice that the court found in that case, that the profit margin was 12.8%. And the court found that to be reasonable now is 15%. Okay, is 20%. Okay, is 25%. Okay, I mean, we just don't know. But we do know that 12% apparently is fine, given those services. But I couldn't agree with Hillary more that these are incredibly fact intensive situations, and that you really have to look at each one individually to make these tight terminations. So that's really on the state level. Now, on the federal level, you have the federal anti kickback statute, and the federal anti kickback statute says you cannot pay or receive money for referrals period, now is not just pays any form of remuneration. So it's not just cash, that can be gift cards. There can be free dinners, there can be vacations, and so on and so forth. So it's a very expansive statute, and it is a criminal statute, the Federal anti kickback statute. So you want to be very, very careful now, it typically comes into play when you have federal money involved. So for example, Medicare money, Medicaid, money, VA and champions money, that would all trigger not only the federal anti kickback statute, but a whole host of other federal fraud statutes.

Some of those statutes include I will go into greater detail one is the False Claims Act. And the classic example of false claim is if you didn't see the patient, but you billed Medicare, nonetheless, whatever, whenever you have an anti kickback violation, you typically will also see a claim by the federal government for a false claim being filed. The third major area under the federal laws are the stark laws. And that prohibits someone a provider, or a family member, or a provider from referring a patient to a facility where they have an indirect or direct ownership interest. And to trigger the stark statutes, though it has to be one of the 10 enumerated services listed under the statute. So far, Hillary and I have been unable to find any link between ketamine treatments and the stark law. So that's good. I think it's one area that you don't need to necessarily worry about now.

Vince Sliwoski 33:17

Ethan, somebody asked a question about marketing ketamine clinic and liability under the stark law. Does that make any sense to you or I may not be understanding the question.

Ethan Minkin 33:29

Yeah, I mean, it's going to become more when you talk about marketing and referrals from that. So over to the PC is where you'd see the anti kickback statute public display. I again, I don't see how the stark law comes in. Because if you look at the list of the 10, designated health services, it doesn't, it doesn't appear there. Now. We it's not uncommon. And we have, we have plenty of clients and deals that we've seen where you have Medicare money involved and VA money involved. So this is not just some mere, you know, academic exercise, it actually does happen. And the scary thing is there's been some recent case law about what a referral is. And the Seventh Circuit, federal district court came up with an incredibly broad definition of what a referral is, and it's not, you know, you think traditionally referral is, you know, one doctor calls another doctor and sends a patient over, right, that's your kind of traditional definition of a referral. But according to the Seventh Circuit, it goes much, much deeper than that. And so you really got to look at these things closely. Now. If you do have a facially or facial violation of anti kickback statute, there are safe harbors. They're both regulatory and statutory safe harbors, and in particular, there's a management services safe harbor that you can fit under. Now to enjoy the protections under a safe harbor. You have to meet every single element if you miss one out. If you don't get the protection, now, for the management services agreements, there are seven elements, and so are very, very easy. The agreement has to be more than a year, it has to be a written agreement. I mean, those are just easy things. The hard part though, is the fair market value piece once again. And if you are confronted with a potential anti kickback issue, and you're trying to fit within the management services Safe Harbor, the only way I know of to really protect yourself is by commissioning an appraisal, and making sure those fees are fair market value. I will mention too, I mean, I don't want to go too far afield here. But it's also important for practices to remember, there are compliance. And compliance plans have seven elements and the Office of Inspector General, which is the investor the investigation, arm of Health and Human Services has published compliance guidance for all different aspects of the healthcare industry. There's pharma, there's hospital, there's physician practices. And if you have and you follow your compliance plan, if there is a violation down the road, the feds will look at your compliance plan as a mitigating factor. So it can really help to reduce your exposure either criminally or civilly. And so we strongly recommend that any ketamine practice any healthcare provider, for that matter, have a compliance. But now the nice thing about the feds is that they recognize that not all practices are created equally. So there's a big difference between a solo physician and a huge group practice. And so the feds don't expect those compliance plans and what happens within those compliance plans to be identical. So there's a lot of flexibility in how you design those. But again, the compliance plan, look at the federal fraud and abuse laws. And you'd also look closely at CPOM fee splitting, and other issues as well. And you'd want to train all your employees, you want to have written policies and procedures and so on and so forth. And if you do those things, you know, it's not only good business, right, but it also protects you down the road.

Vince Sliwoski 37:24

They're talking about healthcare, and you're talking about compliance and such, we should probably at least mentioned HIPAA briefly. Could you? Well, first of all, can you tell people what HIPAA is? Because sometimes people are confused about it and what it means and then who does it apply to? does it apply

to like these MSO owners of the ketamine clinics or just the doctors are just some information that would be helpful? We have questions around that.

Ethan Minkin 37:47

Yeah, HIPAA is the Health Insurance Portability and Accountability Accountability Act of 1996. It applies to covered entities, covered entities are providers, insurance company and clearing houses, and it applies anytime. Once through they refer to protected health information pH I, you know that that covers a wide range or information, where you see the interaction between the MSO and the provider entity. The MSO is typically what's considered a business associate of the covered entity. If you are a business associate, which is typically someone who helps with healthcare operations that's exposed to phsi. You absolutely need what's called a business associate agreement, which lays out the relationship and how pH I can and can't be used. I can tell you unequivocally, I've seen hospitals being audited, that didn't have one VA in place and the Office of Civil Rights, which is again his house and Health and Human Services, and they are the enforcement arm for HIPAA, they've levy severe penalties, I'm talking hundreds of 1000s of dollars into the millions for not having a business associate. Also in 2013, HIPAA was amended. So now a business associate has primary liability as if it was a covered entity. So it's incredibly important that you're cognizant of HIPAA, and not only Cognizant, but then you need the full panoply of policies and procedures and training and so on and so forth to make sure you don't trip HIPAA, you have unfair, you know, breaches happen all the time. You can Google it, you can see it. And so we highly, highly, highly recommend for all of our clients is that they procure cyber liability insurance without HIPAA carve outs. You also want first person liability, which means if there's a breach of contract, you're covered because typically the insurance would only relate to indemnity claims from third parties, but with the cyber liability insurance you can have first party insurance which protects again for Indirect breach by the insured, which, which you want. You also you want that for several reasons. One is, you know, again, OCR penalties could be accent expensive. But also, if there's a breach the beneficiaries, there's not a private way a private cause of action within HIPAA. But beneficiaries can nonetheless, Sue under state law, Tort Claims, invasion of privacy, and so on and so forth. So you really want to make sure you have that insurance in place. My understanding, it's not that expensive. But any provider I'm sorry, any business associate and covered entity would be wise to secure that insurance.

Vince Sliwoski 40:41

That's a great summary. So let's say I am an MSO, or a person that's interested in getting into the ketamine space. I know you guys have done a lot of deals, Hilary's done a ton of deals. What What should people be asking? Like, what are the big diligence items, when you're looking at a clinic or a provider?

Hilary Bricken 40:59

Healthcare is really interesting. And I'll just say off the bat, when Ethan and I have done these deals, what we typically run into is a corporate team of attorneys that do transactional work, they're seasoned in m&a, but they have no healthcare background at all, it makes the diligence incredibly difficult, because in addition to sending your typical m&a diligence that you would if it was any other run of the mill company, even for the MSO, you have to include the healthcare aspects around compliance, which are voluminous, and just so everybody on the webinar knows, maybe a few years ago, many of these clinics were just self pay, because insurance companies were not willing to reimburse based around these experimental treatments, that is changing rapidly. And these clinics want those insurance dollars, because it's a more guaranteed lucrative way to generate a living. So all of these federal triggers around taking federal money for insurance are very, very real, and will include this in our diligence. And corporate counsel just ignores it as if it's not applicable or not going to have any kind of collateral effect on the MSO depending on what the PCs doing, for example, but I would say right off the bat, you need to develop the healthcare section of your diligence, which needs to include CPOM, and depending on the insurance being accepted by the PC, obviously talk about Stark anti kickback and fee splitting as well. But also the local and state laws, right even around things like fictitious business names belonging to professional Corporation, which only they can get that have to be approved notoriously by medical boards, that's super unique, right to the healthcare space to sort of skip that, even if you're just buying the assets of the MSO. or buying the MSO is a huge mistake, because you're basically in bed liability wise, with the professional Corporation and the physicians. The other thing, the number one thing to get value out in the relationship period is a copy of the existing management services agreement. And I cannot tell you how many MSA is even an I have gotten a hold of that blatantly violates HIPAA, they don't even pay attention to what the dates have been, or what the parameters are in the relationship. And everybody's got an attitude of let's make it work, which is very typical in m&a. But without that health care kind of presence in the background. This is a very stupid thing to neglect or just completely ignore. And also, sometimes we get pushback on this, you have to diligence, the professional Corporation, even if there's sensitive information there, sign an NDA, to make them feel better. But you have to know for example, how they bill how they code so that you can determine how you're going to make money if you're going to do billing and collections for them. You need to know what kind of insurance they're taking and for who, and then obviously, basically, their billing practices in general are going to be key to some of the services that the MSO can provide. And if they're not willing to share that it's a huge red flag, because there are ways to get around. For example, confidentiality restrictions in those insurance provider agreements by signing NDA is that you have to know that even as the MSO. And then I would say the last one in my little list here and Ethan already mentioned it is just get a VA in place at the outset of the relationship. It's even more important than an NDA, depending on the type of information that's going to be swapped that is oftentimes neglected. And sometimes even the law firm that's reviewing the diligence needs to have a VAA in place, which again is neglected by run of the mill firms that are just dipping their toe in health care, frankly, probably pretty recklessly.

Vince Sliwoski 44:40

So we're probably scaring people and that's a good thing. I think. Is there a way I have a question here, you guys probably talked about what if somebody wants to keep it really simple, right? This person says

they're just a single physician, practicing with no partners. You want to do a cash clinic which must be no insurance. Can they kind of avoid A lot of the landmines that you guys have been talking about, or are there still things that they need to be careful about and watch out for? How would you answer somebody like that?

Ethan Minkin 45:09

Yeah, I mean, it's a good question. I mean, in a situation where you have a single physician and or management company, you cut out see PA, and then fee splitting right away. And so definitely simplify things. to a great degree, you know, there's still gonna be licensing issues, there's still gonna be liability issues, there's still going to be marketing issues. So I mean, you definitely cut down if if there's a management services organization involved in the structure. But again, there's still are other issues that you really need to be cognizant of. And there's things that we've been talking about. So yeah, but it does simplify things. Absolutely.

Vince Sliwoski 45:55

No, go ahead, finish your thought.

Ethan Minkin 45:58

I was gonna say, you know, if you're doing cash only, that also helps simplify things. You take out all the federal money, you take out the commercial carriers, you know, billing insurance, and I agree with Hillary, I mean, it's a great way to drive volume for your clinic. But it's also you've got all the headaches, right? Because you're going to do the billing, or you're going to go find a third party that's going to do the billing for you. You've got all the federal fraud and abuse statutes that may apply for taking federal money. So if you're able to do it on a cash only basis, and we've seen plenty of clinics and we have plenty of clients, that's cash only, and if you can make it that way, hey, more power to you.

Vince Sliwoski 46:39

Okay, let's transition and we have a bunch of questions about telehealth and ketamine and some of the questions are pretty simple, like, Is it lawful to prescribe ketamine, over telehealth platforms? And then others are just more about the whole apparatus? Are we seeing people do marry the two concepts telehealth and ketamine? And are we is it changing pretty fast? Like you just talked about? People billing insurance and such? What are what are some general thoughts on that?

Hilary Bricken 47:06

Yeah, so basically, we're dealing with two terms, right telemedicine, telehealth, they're synonymous, but really the more updated term is telehealth, right, and this is the delivery of medical services basically over a synchronous internet connection with the patient. It's extremely popular it was already popular prior to Coronavirus. But now with the advent of not being able to see people in person and the convenience of it, telehealth has picked up a lot and it's still an emerging area within healthcare because of the nature of the technology and whether or not patients are really getting bonafide health care depending on the position of what the physician is doing. So just generally, it is okay depending to prescribe ketamine via telehealth with some extreme caveats. Okay, so put the telehealth in a box put the ketamine in a box. Let's start with telehealth. Every state just like C bomb has its own telehealth laws. And they're going to determine physician licensing that's required to prescribe or treat via telehealth. It's also going to dictate what informed consent looks like to just use the telehealth. I'm not talking about informed consent to use ketamine which you also need. This is separate and distinct, just to be able to access the telehealth medical services. On top of that, again, you've got differing applicable standards of care just for the use of ketamine with this off label context. But then also in the context of telehealth in we've had a couple people approaches where they want to be able to have the physicians prescribe the ketamine and then have patients take it remotely without being monitored at all. That's hugely problematic on multiple levels. Not to mention, the applicable standard of care, I don't think necessarily supports that model. But also the malpractice issues associated with patients dosing themselves without any guidance or access to emergency services through a third party going to be really problematic. But let's talk about the reason why there's been an uptick with the delivery of home health services via telehealth for ketamine. It's because of COVID. Okay, the prescription online prescription of controlled substances heavily regulated, the DEA is not a fan. And in 2008, they passed the Ryan White Act, which basically dictates that there's a new sheriff in town with online prescriptions of controlled substances. The main linchpin among other items that have to be checked to do this is that you need to do a synchronous physical exam of the patient prior to prescribing controlled substances over the internet. However COVID with the emergency orders that have come down The fence, basically, certain tenants of the ryan Height Act have been suspended. So now that synchronous physical exam, not as big as priority, and certainly states are interpreting it differently, but it's created a proliferation of turnkey ketamine services, because essentially, physicians can kind of skate past what the riot Height Act would have prevented with online prescriptions, which again, once those exemptions are lifted, Once COVID is hopefully resolved, you're going to see some of these companies that claim to be providing telehealth ketamine services exclusively, really suffer, because they're immediately going to have to come back down to earth and abide by the ryan Hyde act. Now, there were going to be exceptions, the DEA was supposed to make them in their administrative rules that support the statute, that for certain online providers, that synchronous physical exam wasn't necessarily required, meaning you could just prescribe, let's say, via phone, or you can do the exam in increments without the patient having to be live over a synchronous connection like this. But that has not been created yet by the DEA. So there's no necessary safe harbor outside of the COVID exemptions, which will go away for some of the behavior that we're seeing in the telehealth space relative to ketamine. It is the Wild West, to be honest with you, that's my position on it. And some people are taking severe advantage of the exceptions to the right height act, while COVID is rampant.

Vince Sliwoski 51:34

You mentioned the states have been looking at those exceptions or interpreting them a little bit differently. If I understood you correctly, do states themselves also regulate telemedicine or issue guidelines or administrative rules in and around providing that kind of service?

Hilary Bricken 51:51

Oh, yes, 100%. And obviously, they can't affirmatively conflict with federal law. But for all telehealth providers, this is very standard, the applicable standard of care and the interactions with the patient should be just like they're in the examination room with them live, it should not differ whatsoever despite the technology. So you still have to have a prior examination of the patient that in some states can be asynchronous, but typically it must be synchronous, so live like this so that they can determine how to treat the patient. So states absolutely have a say they regulate it more than the federal government does. But in particular, the online prescribing of controlled substances, the feds are very up in arms about it generally because there was a lot of abuse via telehealth before the Rhian Height Act of 2008. So that was meant to mitigate, you know, this kind of pill mill style prescribing online without actually having to see the patient. But it was basically the brakes put on because of Coronavirus.

Vince Sliwoski 52:52

Got it Okay, that's really helpful. Tell you what guys, we have, I think eight minutes left and we've got a lot of questions. And what I'm gonna do now is kind of go through like speed round. And you guys can tell me if you can answer these questions or not, neither of you can answer them. I don't care, but I'm just gonna start reading them off. So one question I got is what extra insurance coverage? Should psychologists get to run a practice offering ketamine assisted psychotherapy? What legal services do you provide for practitioners running in practice that involves ketamine assisted therapy?

Ethan Minkin 53:27

I've been on the insurance piece we highly recommend obviously, the cyber liability, you're going to need malpractice insurance and you're going to want general liability insurance. So pretty much what you would typically have with any other practice with regards to the legal services we provide, we provide the full panoply from you know, helping set up a company and a clinic from day one to doing m&a deals, and so on and so forth. And litigation, unfortunately, but that happens as well. So we deal with all aspects of as Hilary has mentioned, she's become an expert in telemedicine now, so we really do cover it all. Anything rather Hilary?

Hilary Bricken 54:08

No, you know, I would just say that this is this is a very hot area, it's a hot area for attorneys. It's a hot area for people looking to diversify within the psychedelic space. The problem is, is that it lives in a various stablished regulatory sphere. So even though it may seem novel, and this really kind of sexy avant garde thing, it lives in a pretty antiquated space. So I would just proceed with extreme caution, even though it may look very good. And because other psychedelics are kind of on the cutting edge, and there's no law regulation around them. This psychedelic is very different. At the end of the day.

Vince Sliwoski 54:44

Somebody asked Hilary about something you were just talking about. They said could you please elaborate what a synchronous exam is in telemedicine?

Hilary Bricken 54:52

A synchronous exam is a live exam. So it would be real time between the two of us where I'm asking you if I'm the physician, I'm asking you questions in real Time that amount to basically what would be a physical examination if you were right in front of me. And you synchronous would be more like patient calls leaves a message saying what their symptoms are. You call them back or you text them and you say, okay, read your chart. This is what I think should happen based on what you've told me. That's an asynchronous exam where it's not real time, but it's basically gathered over time via a series of messages that are not last.

Vince Sliwoski 55:25

Got it. Okay, that's helpful. And then a related question to what you were also just talking about with respect to different kinds of psychedelic drugs and cannabis. Somebody asked, How does the medical ketamine industry compared to the medical cannabis industry in terms of regulation, patient access clinic access to Business Services, like banking, etc? Kind of a broad question, but any big picture thoughts you may have?

Hilary Bricken 55:49

Well, 100%, they could not be more different. ketamine is a lawful prescription drug, depending on the circumstances. These clinics have full access to banking. They have full equitable treatment of taxation by the federal authorities. cannabis is a schedule one controlled substance, it's completely illegal outside state law gets none of those benefits. So again, just to be very clear, ketamine is not an illegal controlled substance is a lawful schedule three that can be prescribed under the supervision of a physician. And there's some nuances to that, for example, nurse practitioners may be doing the infusions, but it's always in collaboration with a doctor. So cannabis and ketamine could not be more different. ketamine could not be more different than MDMA and psilocybin, because it's already scheduled on a lower

schedule, and physicians can prescribe it, and they have the absolute right to do so in an off label capacity. So in some ways, it's the most liberated, psychedelic, but again, it's also the most regulated out of the ones that I just mentioned. And obviously cannabis is a different controlled substance altogether.

Vince Sliwoski 56:53

Somebody just has the federal law preempts state laws, they're asking about telehealth exemption, but just in general, because federal law preempts state laws with respect to ketamine.

Ethan Minkin 57:07

I mean, generally, if there's a conflict between federal law and state law concerning the same topic, federal law controls, but you know, it's it's a preemption analysis is never an easy analysis. So there's really not a one size fits all answer, you really have to kind of dig into the statutes, make sure that they're actually covering the same exact subject area to see if the state law somehow frustrates the federal law. And if it does, and the federal law will control.

Vince Sliwoski 57:39

I think that's a good way to summarize it. Maybe the last question I'm going to get to this person says I'm one half owner of a small ketamine clinic now, I'm very interested in what you found, as cautions potential FDA and DEA oversight issues down the road insurance, which we talked about, and licensing of practitioners working in my clinic, how would you guys answer a question like that?

Hilary Bricken 58:03

I mean, in addition to CPOM, to me, is the biggest threat of all, because it's so sensitive, and it's so specific to a state where services in one state won't violate it. But the same services in another are dead bang, giveaway for a huge problem. But I would say one of the biggest issues that we're going to see that's going to emerge, marketing around the efficacy of ketamine until and you know, I we've esketamine out of this, because it's been approved and gone through drug trials. But for essentially this off label application, we are seeing some extreme claims being made about the efficacy of ketamine. And those parties are probably going to have to roll some of that back, unless they have very good anecdotal scientific evidence to support it, and even then, maybe not. So we're starting to just see more kind of outlandish claims about it because people will drive patient traffic. And that's very entrepreneurial. But that does not mean that it's actually allowed. And that's one area where the FDA, the FTC, can get very active.

Ethan Minkin 59:06

The nice thing too, is I mean, with this particular question, generally speaking, the FDA does not have authority over physicians. Now, there's exceptions to that, like a physician worked for a pharma company and was out marketing, well, then, you know, they would be covered by the FDA regs and they FDA authority, but generally speaking, the FDA doesn't have regulatory authority over health care providers. Now, as Hillary alluded to, there is the FTC. And when you're making claims that really aren't supported, you run into all kinds of issues with both federal and state consumer protection laws. You can also run into issues with FTC investigations. I've seen that firsthand, with a client who was investigated for claims made about a certain drug, and it was very expensive. The investigation the penalties were extremely hefty. And so it just underscores the importance of veto scrubbing your marketing materials because violations do happen. And you know, they can be extremely expensive. You can lose your license to practice I mean there's all kinds of ramifications.

Vince Sliwoski 1:00:13

Okay, you guys, that's it. We got to a lot of questions. We didn't get to other questions. But let me tell you there is a wealth of information on this stuff on our blog, which is actually called the Canna law blog. Hilary has written dozens of articles. Ethan's written dozens of articles, other attorneys in our firm have written relevant articles. So you can find stuff there. If you're interested in starting one of these businesses, or just improving best practices, any kind of stuff, call or email a call or email Hillary or Ethan directly. I'm sure they'd be happy to talk to you about it. And we just want again, appreciate everybody joining a final reminder, we do have two other webinars coming up on somewhat related topics. There's a building a cannabis business in New York on September 23. Cannabis litigation, October 19. Thank you very much. We'll replay this video on our blog if you were missed anything or we were talking too fast. Otherwise, we'll see you all out there.

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