



PSYCHEDELIC MEDICINE YEAR-END ANALYSIS AND 2024 OUTLOOK

Navigating the Opportunities, Challenges and Unique Risks of Providing Breakthrough Treatments

In Partnership with:



Synopsis:

The psychedelic revolution continued to gain momentum in 2023 due to extensive research and clinical trials, grass-roots reform movements in several states, and a growing number of entrepreneurs, therapists and medical professionals entering the emerging market to provide breakthrough treatments and experiences. Cutting-edge industries like psychedelic medicine trigger excitement, and present new and significant opportunities. However, navigating this complex and ever-evolving space also comes with unique risks and challenges.

In this year-end analysis and 2024 outlook, R&A PYSINS, an independent insurance broker that has been at the forefront of the psychedelic movement, discusses the catalysts that could propel the industry forward, emerging opportunities and challenges, and the role insurance will play in ensuring the long-term viability and success of psychedelic ventures.

Catalysts: Continued Push for Psychedelic Research & Reform

Psychedelic medicine's renaissance is fueled by groundbreaking research. Numerous clinical studies have shown that substances like psilocybin, MDMA, and ketamine are effective in treating patients suffering from chronic pain and mental health disorders, such as anxiety, depression, and PTSD. In 2023, lawmakers in several states - across both sides of the aisle - filed a series of bills aimed at promoting and expanding research for psychedelic therapies.

As research advances and continues to produce positive results, credibility grows and, in turn, more policymakers line up to advocate for its medicinal uses. The push for legislative reform in the U.S. has been progressing in a rapid, patchwork fashion, and it's also garnered some big wins over the last few years. To recap the recent highlights:

- Oregon was at the forefront of the psychedelic movement when it became the first state to decriminalize "magic" mushrooms in 2020 for adult personal use and establish a regulatory framework/governing body, called the "Psilocybin Services Program," to license and regulate the manufacturing, transportation, delivery, sale, and purchase of psilocybin products and treatment services.

Applications for licensure began in January 2023 and by June, the first legal psilocybin service center to open its doors. (As of August 2023, there were seven (7) licensed psilocybin service centers in Oregon).[i]

- Colorado soon followed in Oregon's footsteps with voters approving Proposition 122: Access to Natural Psychedelic Substances, which decriminalized five (5) "Natural Medicines," starting with psilocybin and psilocyn.

Champions of psychedelic drug reform hope that these legislative feats will lead to a domino effect resulting in other states to follow their path this year – which could ultimately put pressure on the Federal government to take meaningful action towards legalization.

- Colorado: Under the new law, adults 21 and over can access psychedelic treatments at certified centers under the care of licensed facilitators. This is the most extensive psychedelic legalization measure to pass so far in the U.S. Colorado will begin accepting licenses for licensed facilitators, licensed facilities, and other associated licenses on December 31, 2024, which blows the top wide open for new business opportunities and psychedelic ventures in that state.

Opportunities: Will 2024 be a Milestone Year for the Psychedelic Legal Reform?

From local ballots to Capitol Hill, 2024 is shaping up to be an important year for psychedelic drug policy reform. The regulatory landscape will play a crucial role in defining the future of the industry and unlocking new opportunities.



Going into 2024, we are paying close attention to the Food and Drug Administration (FDA) and the following states who want an early jump on the action:

- ➔ **MDMA:** In December 2023, [MAPS Public Benefit Corporation](#) announced that the FDA granted “Breakthrough Therapy” status to MDMA for PTSD. If health practitioners can provide MDMA-assisted therapy as early as 2024, this undoubtedly will be another major catalyst for industry growth.[ii]
- ➔ **Massachusetts:** In October 2023, [Massachusetts for Mental Health Options](#) received approval from the state attorney general to pursue a ballot initiative for the 2024 elections that would legalize the possession and supervised use of natural psychedelics, including psilocybin mushrooms. Backed by a national political action committee, their goal is: “To expand mental health treatment options in Massachusetts by providing new pathways to access natural psychedelic medicine therapy.”[iii]
- ➔ **California:** The state is taking a slightly different approach with a citizens-led measure called the [Psychedelic Wellness and Healing Initiative of 2024](#) that would “legalize psilocybin for adult and therapeutic use, commit \$5 billion to create a state agency focused on advancing research and development of psychedelic therapies, [and importantly] expand the types of businesses that could legally operate in the space.”[iv]
- ➔ **Missouri:** We anticipate Missouri being key battleground for the psychedelics reform movement with republican lawmakers championing proposals and filing bills to legalize psilocybin in 2024 and fund clinical research trials.

“ *Most of us in the industry agree that legalization of psilocybin at the federal level won’t happen for years. Nevertheless, these massive clinical trials and grassroots movements will continue to be important catalysts for bringing new psychedelic therapies from the margins to the mainstream.* ”

Biggest Risks and Liabilities for Psychedelic Ventures:

Within this burgeoning industry that is projected to reach 1.8 billion USD by 2028[v] comes the critical need for specialized insurance coverages to protect against the distinct risks associated with psychedelic substances.

It's not surprising that the number one risk for all psychedelic ventures is medical malpractice.

Malpractice occurs when a healthcare professional commits a negligent act or omission during the treatment of a patient that deviates from accepted norms of practice, i.e., the standard of care, and causes injury or harm to the patient.

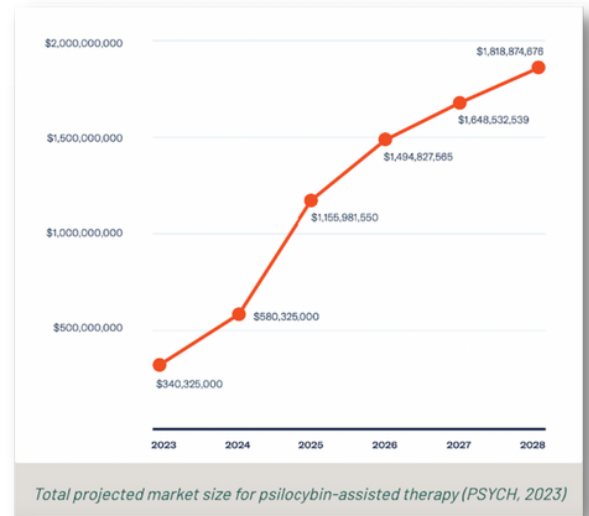
Given that psychedelic-assisted therapies are relatively avant-garde treatments, the profound issue is how this industry defines the "standard of care." It's largely a gray area that leaves practitioners very exposed to litigation.

In addition to the threat of malpractice claims, there are other major risk factors, which include:

- Bodily injuries or property damage incurred by a patient or employee on the premises.
- Cyber fraud, including HIPPA violations from data breaches and other cybercrimes.
- Unlawful employment practices, including claims of sexual assault.
- Misuse of company funds/wrongful acts in managing the company.
- Product contamination, recalls, mislabeled products, and false advertising.

Despite all the opportunities of this burgeoning industry, as psychedelic-assisted therapies progress from the margins to the mainstream, the risks only increase. The above scenarios represent only some of the many potential liabilities that practitioners could face. Risk management is key, as is a solid understanding of what insurances you need to protect your clinic and practitioners.

R&A PSYINS can guide you as to what Business Liability Insurance coverages you need and develop a customized risk management program to ensure you are fully protected.



BUSINESS LIABILITY INSURANCE
The Only Way to Protect
Your Psychedelic Business.

Challenges Specific to Ketamine (and Solution):

Ketamine has been legal in the U.S. for years. Specifically, it is a Schedule III substance under the Controlled Substances Act. In 2019, the FDA approved a variation of ketamine, called Spravato, for treatment-resistant depression. As a result, there's been unprecedented growth in the number of private and nonprofit clinics that offer (KAT) and Ketamine Assisted Psychotherapy (KAP). Today, an estimated 1,200 to 1,500 ketamine clinics operate in the U.S., compared to 60 clinics in 2015.



Access to Coverage: Despite ketamine infusion therapies entering the mainstream, as with most new interventions, it's considered high risk. Therefore, clinics and practitioners require specialized insurance policies, which we outline below. One of the most significant challenges Ketamine clinics faced in 2023 was securing the necessary insurance coverages to protect their business from costly litigation and remain in compliance with state and federal HIPPA regulations.

Solution: It is important to know that insurance for licensed medical professionals is available. As one of a few insurance brokers that offers coverage to ketamine clinics and practitioners nationwide, R&A PSYINS saw a significant uptick in the number of policies it was able to write in 2023 and anticipates that access to additional insurance coverages will increase in 2024.

Challenges Specific to Psilocybin and Psychedelic Retreats (and Solution):

Operating in the Gray Area: Cultivators, manufacturers, and distributors seeking to penetrate the psilocybin market must be aware of the risks and legal challenges associated with operating in what is considered the "gray area," or the space where legality is not clearly defined or varies significantly across jurisdictions.

For example, psychedelic retreats are increasingly popular in countries such as Jamaica, Costa Rica, Mexico and the Netherlands, where many psychedelic substances are not illegal. They are also starting to pop up in certain areas of the U.S., where psychedelics have been decriminalized.

While some regions are moving towards decriminalization or legalization for medical and therapeutic purposes, others maintain strict prohibitions. This legal ambiguity poses challenges for businesses seeking insurance coverage.



Challenges Specific to Psilocybin and Psychedelic Retreats (and Solution):

Product Liability Challenges: From an insurance perspective, the product risk exposure is great in this industry due to the possible side effects of psychedelic medicines, even natural substances like psilocybin.

For businesses involved in the production or distribution of psychedelic substances, comprehensive product liability coverage is essential. This includes coverage for potential adverse reactions, inadequate warnings, and issues related to inconsistent potency.



Solution: Insurance providers experienced in the psychedelic space, such as R&A PSYINS, can offer guidance on compliance and help businesses adapt their coverage to meet the evolving regulatory requirements. **We are currently able to write insurance policies for licensed professionals of psilocybin-related treatments in both Oregon and Colorado, as well as in countries where the specific psychedelic substance being administered is not illegal.**

Opportunity: Increased Access to Insurance Coverage

Considering where the cannabis industry was five (5) or so years ago, there are a number of parallels (and lessons to be learned). As it relates to insurance, accessing essential coverages can be difficult, but certainly possible with the right professional guidance. Traditional insurance carriers view psychedelics as a high-risk, long game. Many are taking a “sit back and watch how public policy takes shape” approach. They are also keeping a close eye on if the advanced research and clinical trials expose any significant risks and liability landmines.

The good news is there are more options by the day for insuring psychedelic ventures. As the industry prepares for more FDA-approved psychedelic therapies to become a reality and more states to legalize psychedelic drugs for mental health treatments, access to critical insurance coverages will continue to grow.

R&A PSYINS, a division of Rahn & Associates, has decades of experience providing specialty lines of insurance coverages for highly regulated and complex industries, such as psychedelic medicine. By leveraging our extensive network and long-standing relationships with industry-leading insurance companies, we are able to work together to develop new insurance products that will protect psychedelic ventures from costly claims and litigation.

In Summary:

This is an exciting time to be a part of a cutting-edge industry that has the real potential to treat millions of American's mental health disorders without relying on Big Pharma drugs. While there are too many factors and moving pieces to predict exactly what will transpire in 2024, given the meaningful headway the psychedelic medicinal industry made in 2023, R&A PSYINS reasonably anticipates - and is cautiously optimistic - that further progress will be made in 2024 and beyond.

As more treatment centers, clinics, retreats, cultivators and distributors pierce through the regulatory landscape to be a part of this burgeoning industry, the need for specialized insurance coverages to address the unique risks and shield psychedelic ventures from potential lawsuits will be paramount.

Working with an insurance broker experienced in psychedelic medicine is critical. R&A PSYINS is at the forefront of this movement and provides psychedelic ventures throughout the ecosystem with Business Liability Insurances. If you have questions or would like to schedule a free consultation, please [click here](#) or call (954) 790-6604.



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[i] <https://www.opb.org/article/2023/08/26/psilocybin-service-centers-oregon-open/>

[ii] <https://maps.org/news/media/press-release-fda-grants-breakthrough-therapy-designation-for-mdma-assisted-psychotherapy-for-ptsd-agrees-on-special-protocol-assessment-for-phase-3-trials/>

[iii] <https://www.psychedellicweek.com/p/mass-boston-ma-psychedelic-ballot-mental-health>

[iv] <https://www.marijuanamoment.net/california-campaign-to-legalize-psychedelics-submits-final-version-of-proposed-2024-ballot-measure/>

[v] <https://www.filament.health/news/2023-psychedelic-industry-outlook>