

A Psychedelic Shift: Will Mushrooms Transform Mental Health Care?

Regulatory Update:

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Public and scientific interest in the medicinal potential of hallucinogens like Psilocybin and LSD is surging, challenging the long-standing barriers set by their [Schedule I](#) classification under the Controlled Substances Act. This classification has hampered [mental health research](#) and alternative medicine for decades by labeling these substances as having high abuse potential and no medical use. However, momentum is shifting, evidenced by the FDA's June 2023 [draft guidance](#) for conducting clinical trials for psychedelics. While this doesn't alter existing laws, it does suggest a future willingness for national approval of such substances deemed safe and effective. Pharmaceutical companies, in various stages of development for psychedelic-based drugs, have made significant strides, with several already conducting clinical trials in the United States, all under the auspices and with the express approval of the FDA.

Among the array of potential drug candidates, psilocybin stands out as the clear frontrunner. Its reputation for safety, coupled with promising indications in treating conditions such as [depression](#), anxiety, PTSD, and [anorexia](#), prompted the Food and Drug Administration (FDA) to designate psilocybin as a breakthrough therapy in 2018 and 2019. But the journey from drug development to final approval and deployment is arduous and often spans one to two decades to bring a new pharmacological compound to market. Meanwhile, there exists a [growing body of studies](#) supporting the use of psilocybin, extracted from natural fungal forms, to effectively treat mental health disorders. The pressing need for "medicinal mushrooms" is particularly evident for those caught in the relentless grip of depression or suffering from incapacitating PTSD, especially as current treatments frequently fall short. In the last two decades, [suicide rates have doubled](#), and during the Covid-19 pandemic, [anxiety rates tripled](#), with deaths attributed to [drug overdoses increasing by 50%](#). This underscores the imperative for more effective solutions, as existing measures continue to leave many individuals isolated and struggling. Reflecting the movement to decriminalize "medical marijuana" twenty-five years prior, state authorities are once again at the forefront, advocating for the availability of psilocybin for medical use. However, early evidence indicates that there will be significant differences in how "medicinal mushrooms" will be administered to those in need.

In November 2020, Oregon's voters passed [Measure 109](#), which authorized the creation of a program to permit licensed service providers to administer psilocybin-producing mushroom and fungi products to individuals 21 years of age or older (source). Additionally, the state passed [Measure 110](#), which decriminalized personal possession of all drugs, shifting the focus from penalizing drug addiction to emphasizing addiction treatment and support. These groundbreaking decisions were mirrored in other cities, including [Denver](#), Colorado; [Santa Cruz](#), California; and [Washington, D.C.](#). These jurisdictions chose to decriminalize psilocybin or designate the 'cultivation, distribution, or possession' of hallucinogenic mushrooms as one of the 'lowest law enforcement priorities.' Eventually, Colorado followed Oregon's example in 2022, when [voters approved](#) a ballot measure to legalize the supervised use of psilocybin at state-approved centers.

In Oregon, the regulation of psilocybin use in therapeutic settings falls under the jurisdiction of the Oregon Health Authority (OHA). Starting on January 2nd, 2023, the agency began accepting applications for [four different licenses](#) related to psilocybin use, encompassing manufacturing, laboratory testing, service site establishment, and treatment facilitator approval. All four licenses must be approved before a commercial cycle can be initiated, and patients can gain access to psilocybin. The OHA anticipates that treatment will become available [at some point in 2023](#).

The Oregon Model

There are several distinct differences between Oregon's psilocybin therapeutic framework and the regulations governing medical marijuana. The minimum age for access to psilocybin services is 21, and a person must also have a referral from a licensed

health care provider. In contrast, the minimum age for medical marijuana is 18, while the age for recreational use is 21. Psilocybin cultivation in Oregon is restricted to a single strain of fungi, *Psilocybe cubensis*. Meanwhile, the highly dynamic marijuana industry offers hundreds of different strains, each with variations in THC, CBD content, and other cannabinoids. New strains are continually being developed and brought to market.

The Oregon Health Authority (OHA) will oversee a system that tracks psilocybin mushrooms from spore to sale, adding another layer of distinction from marijuana regulations. However, the most significant difference relates to administering treatment. Patients will be required to consume psilocybin on-site, unlike marijuana, which can be purchased and consumed at home. The psilocybin treatment includes a [two-session requirement for patients](#):

Preparation Session: The patient meets with a licensed facilitator to prepare for the experience.

Administration Session: The client consumes the product at the service center and begins their session with a licensed facilitator.

Following the administration session, the client is offered an optional follow-up “Integration Session” to explore additional peer support and other resources. This comprehensive approach emphasizes a continuum of care that sets Oregon’s psilocybin therapeutic model apart from traditional medical marijuana practices.

Psilocybin: From Colorado to California

Sometime in late 2024, the Colorado state government is slated to begin accepting licensing applications for “healing centers,” which will be staffed by licensed “facilitators” authorized to provide psilocybin and supervise its use. Currently, a 15-member [Natural Medicine board](#), consisting of physicians and other experts, is collaborating with the state to draft rules and regulations. It seems reasonable that they are closely monitoring the developments in Oregon, waiting for Oregon’s facilities to become operational before finalizing their recommendations for establishing a legal framework governing psilocybin policy. Meanwhile, a [gray market](#) for psilocybin microdosing and other psilocybin services has emerged in Colorado, facilitated by the drug’s recent decriminalization. It is anticipated that a state-approved regime, along with access for approved patients, will be established by mid-2025.

The timeline for psilocybin regulation in California appears to be somewhat longer than in Oregon and Colorado. In both of those states, successful voter initiatives compelled state authorities to create frameworks for the medical use of psilocybin. California may follow a similar path. In June 2023, the Attorney General of California announced that they had reviewed a proposed statutory [initiative related to psilocybin](#) and released a summary on its website. This summary provides an overview of the proposed changes to state law related to psilocybin, including removing criminal penalties and requiring regulation of its cultivation and sale. If the initiative qualifies for the ballot, it would be voted on by California voters in a future election.

Meanwhile, the California legislature may choose to act independently. In the 2020-2021 session, a bill ([SB 519](#)) was introduced that would have decriminalized multiple hallucinogens, including MDMA, LSD, and psilocybin. Despite several iterations and committee enthusiasm, the bill was eventually put in suspense. However, the California legislature is currently considering an attempt at decriminalizing certain psychedelics ([SB-58](#)). Critics of the bill are concerned that decriminalizing hallucinogens without simultaneously introducing a framework for medical use could open the floodgates for unsupervised drug sales to minors and vulnerable populations. Such worries may persuade the legislature to pursue a regulatory medical framework concurrently or for a ballot initiative compelling them to do so. Much depends on how Oregon’s rollout goes. A successful rollout of medical psilocybin programs in Oregon will likely exert pressure on California lawmakers to swiftly adopt something similar. Conversely, if things don’t go well in Oregon, it could deter or significantly slow down the process in California, leading to a more cautious approach to implementing similar legislation.

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