

Oregon Finalizes New Regulations To Implement Psilocybin Services Act

Oregon became the first state to offer controlled use of psilocybin to the public on January 1, 2023. Psilocybin is a Schedule I psychoactive substance that is illegal at the federal level. Notwithstanding this federal illegality, psilocybin's potential medical uses are being explored in medical research centers, and the substance is currently undergoing clinical trials, being designated by the U.S. Food and Drug Administration (FDA) as a breakthrough therapy. As part of a series of state initiatives aimed at improving access to mental healthcare, Oregon passed the Psilocybin Services Act as a ballot measure in 2020. This law directed the Oregon Health Authority (OHA) to license and regulate the manufacture, transportation, delivery, and purchase of psilocybin products and the provision of psilocybin services within the state. As of January 2, 2023, the OHA has begun accepting applications for licensure, with new psilocybin service centers expected to open later this year.

OHA Regulations

The OHA [announced](#) on December 27, 2022, that it had finalized regulations to implement the Psilocybin Services Act. The agency's announcement noted that the department had received over 200 comments and held more than six hours of public hearings as part of the rulemaking process. The agency also noted that the "rules are a starting place for the nation's first regulatory framework for psilocybin services," and the OHA "will continue to evaluate and evolve this work" as the program is rolled out.

Under the new [regulations](#), the agency will issue four types of licenses: those for manufacturers, laboratories, service centers, and facilitators, respectively. As the agency [explained](#), psilocybin products must be cultivated or processed by licensed manufacturers and tested by licensed and accredited testing laboratories before being sold to licensed service centers. Service centers are the only licensees authorized to sell psilocybin products to clients; these products can only be consumed by clients at the licensed service center during administration sessions. Licensed facilitators, in turn, would run these sessions.

In compliance with the new regulations, clients aged 21 years or older can obtain psilocybin services after first completing a preparation session with a facilitator. Clients can only access psilocybin at a licensed service center during an administration session. The dispensary model of commercial sales is prohibited.

Compliance Considerations

Even with Oregon's new regulations, psilocybin remains a Schedule I controlled substance at the federal level, meaning that Oregon's state-licensed program conflicts with federal law. Therefore, individuals and businesses seeking to comply with Oregon's new program remain subject to the federal Controlled Substances Act (CSA) and the myriad penalties related to that statute.

Stakeholders looking to comply with Oregon's state law and regulations should familiarize themselves with the new rules applicable to psilocybin services. Among other things, psilocybin available for sale in Oregon must:

- Provide required information on its labeling, including the quantity of psilocybin analyte (which cannot exceed 25 mg per serving).
- Avoid labeling that would be attractive to minors (e.g., cartoons).
- Not display any false or misleading content on its labeling and packaging, including unsubstantiated health claims.

As the agency acknowledged, Oregon is likely to face challenges in developing the nation's first psilocybin services program. [Colorado](#) passed the Natural Medicine Health Act (NMHA) as a ballot proposition in the 2022 election, which decriminalized personal use of certain substances, namely psilocybin, in the state and called for a regulated program to access these "natural medicines." The Colorado government is forming a Natural Medicine Advisory Board to advise on the development of the state's regulated access program, which may face issues similar to those of Oregon's program. Colorado's forthcoming regulations to implement the NMHA are expected in 2024. Elsewhere around the country, state bills are under consideration in seven states regarding psilocybin, including in part: proposals in [California](#) and [New York](#) to legalize the possession and transfer of certain substances such as psilocybin; and a [bill](#) in Arizona that would see \$30 million appropriated for clinical research into the medicinal properties of psilocybin.

Companies looking to comply with any state program regarding psilocybin should pay close attention to developing regulations in this area and note that these programs remain illegal under federal law.

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Authors



[Andrew J. Kline](#)

Senior Counsel

AKline@perkinscoie.com [303.291.2307](tel:303.291.2307)



[Thomas \(Tommy\) Tobin](#)

Counsel

TTobin@perkinscoie.com [206.359.3157](tel:206.359.3157)



Holly Martinez

Associate

HMartinez@perkinscoie.com [503.727.2281](tel:503.727.2281)

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