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Secretary of State

STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Oregon Health Authority- Public Health Division	333
Agency and Division	Administrative Rules Chapter Number

Oregon Psilocybin Services Operational Rules

Rule Caption

Statutory Authority: Oregon Laws 2026, Chapter 109, ORS 413.161, ORS 475A.235, ORS 475A.245, ORS 475A.250, ORS 475A.255, ORS 475A.290, ORS 475A.305, ORS 475A.325, ORS 475A.338, ORS 475A.340, ORS 475A.370, ORS 475A.372, ORS 475A.374, ORS 475A.377, ORS 475A.380, ORS 475A.385, ORS 475A.400, ORS 475A.480, ORS 475A.483, ORS 475A.486, ORS 475A.590, ORS 475A.594, ORS 475A.598, ORS 475A.626

Other Authority:

Stats. Implemented: ORS 413.161, ORS 475A.235, ORS 475A.245, ORS 475A.250, ORS 475A.255, ORS 475A.290, ORS 475A.302, ORS 475A.305, ORS 475A.310, ORS 475A.325, ORS 475A.338, ORS 475A.340, ORS 475A.370, ORS 475A.372, ORS 475A.374, ORS 475A.375, ORS 475A.377, ORS 475A.380, ORS 475A.385, ORS 475A.400, ORS 475A.450, ORS 475A.460, ORS 475A.480, ORS 475A.483, ORS 475A.486, ORS 475A.504, ORS 475A.590, ORS 475A.594, ORS 475A.598, ORS 475A.626

Need for the Rule(s): The rules are needed to implement ORS 475A, the Oregon Psilocybin Services Act ("the Act") and to implement Oregon Laws 2026, Chapter 109 (HB 4040). ORS 475A created a first of its kind regulatory framework for licensed production of psilocybin products and sale of psilocybin products and services to clients. The Oregon Health Authority (OHA) adopted rules in 2022, 2023, 2024 and 2025 that address a variety of subject matter including requirements for licensure, storage and security, standards for psilocybin products, packaging and labeling requirements, safety standards and guidelines for provision of psilocybin services, client rights and informed consent processes, facilitator duties, compliance, product tracking and transportation. These proposed 2026 rules supplement prior rules and make further refinements. The proposed rules address all aspects of implementation. The proposed rules are necessary to effectively implement the Act because they make important changes to the previously adopted rules that will provide greater clarity and efficiency of operations for both licensees and the Medical Cannabis & Psilocybin (MCAP) section formerly known as Oregon Psilocybin Services Section (OPS) of the OHA. Proposed changes such as streamlining client to facilitator ratios for groups sessions and allowing live music during administration sessions increase flexibility for licensees while continuing to center client safety. The rules also implement Oregon Laws 2026, Chapter 109, Sections 36-39 (House Bill 4040). The proposed rules implement this legislation by making changes to align with revised statutory language for facilitators who hold other license types, changes to reporting average doses, and describing requirements for individuals who want to apply for facilitator licenses in Oregon, including completion

of facilitator training programs that have been approved by other states and meet or exceed Oregon requirements.

Documents Relied Upon, and where they are available:
Oregon Laws 2026, Chapter 109 (House Bill 4040):
https://olis.oregonlegislature.gov/liz/2026R1/Downloads/MeasureDocument/HB4040
ORS 475A: https://www.oregonlegislature.gov/bills_laws/ors/ors475a.html

Statement Identifying How Adoption of Rule(s) Will Affect Racial Equity in This State:

The proposed rules will impact all psilocybin manufacturers, psilocybin service centers, psilocybin facilitators, psilocybin testing laboratories, permitted workers, psilocybin training programs and clients receiving psilocybin services in Oregon. MCAP supports the Oregon Psilocybin Advisory Board, a governor appointed advisory board that serves four-year terms and makes recommendations to OHA pursuant to ORS 475A. MCAP considers recommendations made by the board as rules are drafted. MCAP also has engaged with impacted communities throughout the rulemaking process and prior to beginning official rulemaking, including public listening sessions, partner meetings, and presentations to community organizations who are likely to be impacted by proposed changes to implementation of ORS 475A. MCAP engaged communities through Rule Advisory Committees held on November 2 and November 4, 2026. MCAP will continue to engage communities via the public comment period which begins on December1, 2026, and concludes on December 21, 2026. Public hearings will take place during this time and offer Spanish interpretation, American Sign Language interpretation, and Communication Access Realtime Translation (CART captioning), as well as any other request language or accessibility requests. MCAP's outreach helps to ensure that the rules are informed by a wide range of perspectives, including underrepresented communities.

The proposed rules may have both positive and negative racial equity impacts. Throughout the rulemaking process, MCAP has attempted to craft rules that support equity and promote public safety without creating unnecessary costs that lead to reduced access for clients. Some rule amendments that are intended to provide flexibility or address concerns of licensees are likely to have a positive impact. Other rule amendments may create increased costs of compliance.

To the extent that increased cost of compliance is passed onto clients, the increased cost could have a greater impact on underserved individuals, lower income individuals and communities who have experienced historic and contemporary inequities and marginalization. If access to regulated psilocybin services decreases, clients may be more likely to seek out unregulated psilocybin services which leads to increased risk to client and public safety.

Some rule changes offer more flexibility to licensed businesses. These changes could expand the options for psilocybin services to make services more accessible to a broader range of clients. For example, rules have been relaxed around incorporating music into psilocybin services to allow for experiences that may be more inclusive of different cultures and historical practices. Rules have also been streamlined for group administration sessions which could allow for more cost-effective group administration sessions. The changes implementing legislation for dual licensed facilitators will have a positive impact on health equity by removing barriers to becoming a psilocybin facilitator for

individuals who hold credentials issued by clinical licensing boards and allowing those facilitators to provide expanded services during preparation and integration sessions. Likewise, the proposed rules addressing out-of-state training programs will expand opportunities for facilitators that have completed training by other state approved psilocybin facilitator training programs to be licensed in Oregon, which may increase the number of facilitators licensed by MCAP. The proposed rules add client responsibilities to the existing client of bill of rights, including the responsibility to refrain from making offensive comments regarding personal traits such as race, ethnicity, gender, language, accent, disability, sexual orientation, gender identity. This addition supports inclusive spaces for clients seeking psilocybin services and has a positive impact on racial equity.

Many of the proposed rule changes are technical in nature. While some of the changes may ease licensees' administrative burden in complying with regulations, other changes create new requirements that may increase administrative burden.

Fiscal and Economic Impact:

Licensed businesses and state agencies will incur costs to comply with the proposed rule changes. The overall fiscal and economic impact of the proposed rule changes on licensees cannot be quantified at this time because OHA does not have access to information regarding licensees' operational costs. The rules are necessary to implement ORS 475A and 2026 legislation. Less restrictive operational rules could carry a lower cost of compliance. However, less restrictive operational rules could also create higher risks of negative impacts to public health and safety for clients and communities.

The regulated market for psilocybin products and services is still relatively new and fluctuating. MCAP continues licensing new manufacturers, service centers, and facilitators and renewing licenses for all license types. However, some businesses, specifically service centers, have closed. Like all new businesses, psilocybin businesses, including facilitators, incur significant start-up and ongoing business costs. MCAP lacks sufficient data to determine how much these costs will be influenced by rule requirements and how much costs will be affected by other factors, such as psilocybin's status under the Federal Controlled Substances Act and the subsequent challenges of banking, liability insurance, high rent costs, and tax filing issues. Existing businesses that become licensed psilocybin businesses will also incur costs for additional equipment and modifications to their facilities.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

   MCAP will incur costs to implement these rules. This activity is required by statute. MCAP will devote resources to revising its internal licensing database to track new requirements, licensing and inspecting premises, monitoring compliance, developing forms and other resources, and providing technical support to licensees. The costs to local governments are unknown, but likely very small, if any. The public will incur costs to the extent that increased costs of compliance with the proposed rules are passed on to members of the public who intend to participate in psilocybin services.

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2. Cost of compliance effect on small business (ORS 183.336):
a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:

MCAP estimates that many licensed psilocybin businesses meet the definition of small businesses. As of [DATE], 2026, there are [#] psilocybin businesses in Oregon, including psilocybin facilitators. The number of licensees has fluctuated, and at this time MCAP cannot accurately predict how many licensed psilocybin businesses will operate in Oregon going forward.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

The rules contain some additional reporting and documentation requirements to support client and public safety, while other requirements have been streamlined. The new requirements create costs of compliance; however, these costs are offset to some degree by improved efficiency due to rule revisions. MCAP lacks sufficient data regarding cost of operation to accurately predict the net cost of compliance.

c. Equipment, supplies, labor and increased administration required for compliance:

Some of the proposed rules could lead to increased costs for equipment, supplies, labor, and administration. For example, the rules require additional information to be printed on product labels.

How were small businesses involved in the development of this rule?
Small businesses participated in the rule advisory committee.

Administrative Rule Advisory Committee consulted?: Yes.

If not, why?:

Signature Printed name Date

DRAFT