

This draft is being provided to a Rules Advisory Committee for discussion of the impact of proposed rules. The statement may be revised prior to filing. All highlighted portions will be completed prior to filing.

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
Number

Administrative Rules Chapter

Oregon Psilocybin Services

Rule Caption

Statutory Authority: [This section will be completed prior to filing]

Other Authority:

Stats. Implemented: [This section will be completed prior to filing. HB 4040 is Oregon Laws 2026, Chapter 109]

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 (“the Authority”) 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 and support the Act’s goals of promoting access and equity while protecting health and safety. The proposed rules increase license fees significantly in order to support program sustainability. 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 Oregon Psilocybin Services Section (OPS) of the Oregon Health Authority. The proposed changes increase flexibility for licensees while continuing to center client safety. The rules also implement Oregon Laws 2026, Chapter 109 (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

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receiving psilocybin services in Oregon. OPS 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. OPS considers recommendations made by the board as rules are drafted. OPS 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. OPS engaged communities through Rules Advisory Committees held between July 4 and July 9, 2026. OPS will continue to engage communities via the public comment period which begins on September 1, 2026, and concludes on September 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.

On balance, the proposed rules will affect equity negatively. Some rule amendments that provide flexibility or address concerns of licensees are likely to have a positive impact, but any positive impact is outweighed by the negative impact created by increased fees. The proposed rules double license fees as well as increase fees for changes. The proposed rules also eliminate reduced fee provisions which are available under current rules for nonprofits, veterans, applicants receiving Supplement Security Income, and applicants receiving Supplemental Nutritional Assistance Program. These reduced fees were adopted in 2022 and were designed to encourage lower income applicants and individuals with diverse life experience to become licensed, specifically for licensed facilitators that represent diverse lived and professional experiences that provide culturally responsive services and health and behavioral health services to communities. The elimination of reduced fees not only impacts licensees directly, but also the clients they serve as clients from certain communities may have more difficulty locating a psilocybin facilitator who provides culturally and linguistically responsive services or shares racial, ethnic, language, disability, sexual orientation, gender identity, or other identities/experiences that may support trauma-informed and person-centered services. The fee increases affect the cost of doing business for all licensees, including those who were not eligible for reduced fees. To the extent that this increased cost is passed onto clients, the increased cost is likely to have a greater impact on underserved individuals, lower income individuals and communities who have experienced historic and contemporary inequities and marginalization.

OPS expects an increase in licensing fees to reduce the overall number of licensees and create a more significant budget shortfall for the program. This will have a detrimental impact on many people. For example, students that have completed psilocybin facilitator training programs in Oregon in order to become licensed facilitators who cannot afford the increased licensing fees would lose value of their educational completion, which is estimated at \$10,000-\$15,000/student. As of [date], 2026, OPS has licensed [number] facilitators since January 1, 2023. Related sectors, including real estate and tourism, would also experience negative impacts. Public agencies that may be affected due to loss of revenue include the Higher Education Coordinating Commission (HECC), Oregon Department of Agriculture (ODA), and Oregon Department of Revenue. The number of licensed facilitators has grown since the Oregon Legislature passed HB 2387 in 2025 and HB 4040 in 2026 to expand client access to health and behavioral health services provided by dual licensed facilitators, which means that individuals holding dual licenses may experience a reduction in the services they are able to provide, including those licensed under the Oregon Medical Board; Oregon Board of Licensed Professional Counselors and Therapists; Oregon Board of Naturopathic Medicine; Oregon Board of Psychology; Oregon State Board of Nursing; State Board of Licensed Social Workers; State Board of Pharmacy; Occupational Therapy Licensing Board; and Oregon Board of Physical Therapy.

The negative impact is offset to some degree by rule changes intended to offer more flexibility to licensed businesses. These changes could expand the options for psilocybin services to make services more accessible to a broad range of clients. For example, rules have been relaxed around incorporating music into psilocybin

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services and streamlined for 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 OPS.

Many of the proposed rule changes are technical in nature. While some of the changes may ease licensee's administrative burden in complying with regulations, other changes create new requirements that may increase administrative burden. In addition to raising fees, some of the proposed rules may create an increased cost to comply with regulation. To the extent that cost of regulation is passed onto clients, the rules may have a negative impact on underserved individuals, lower income individuals and communities who have experienced marginalization. Throughout the rulemaking process, OPS has attempted to craft rules that promote public safety without creating unnecessary costs for licensees that may be passed onto clients.

Fiscal and Economic Impact:

Licensed businesses and state agencies will incur costs to comply with the rules. While the overall fiscal and economic impact of the rules cannot be quantified at this time, the impact on the regulated community is likely to be significant due to increased fees. 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 rules could create higher risks of negative impacts to the public health and safety for clients and communities.

The regulated market for psilocybin products and services is still relatively new and fluctuating. OPS continues licensing new manufacturers, service centers, and facilitators and renewing licenses for all license types. However, some businesses, specifically service centers, have closed down. Like all new businesses, psilocybin businesses, including facilitators, incur significant start-up and ongoing business costs. It is difficult 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 costs of rent, and tax filing issues. Existing businesses that become licensed psilocybin businesses will also incur costs for additional equipment and modifications to their facilities.

Because ORS 475A creates a fee-based structure, licensing fees must cover the costs of the administration of the Oregon Psilocybin Services section's work. Affordability is a concern for licensed businesses and small businesses that plan to apply for licensure; however, no other funding exists to subsidize these costs.

Statement of Cost of Compliance:

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

OPS will incur costs to implement these rules. This activity is required by statute. The extent to which these rules create costs that are beyond the statutory requirements is unknown. OPS will devote resources to revise its internal licensing database to track new requirements, licensing and inspecting premises, monitoring compliance, developing forms and other resources, and providing technical support to

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licensees. The costs to local government are unknown, but likely very small, if any. The general public will incur costs to the extent that increased fees and costs of compliance with the proposed rules are passed on to members of the public who intend to participate in psilocybin services.

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:

OPS estimates that many licensed psilocybin businesses will meet the definition of small businesses. As of [Date], 2026, there are [number] psilocybin businesses in Oregon. The number of licensees has fluctuated, and at this time OPS 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 safety, while other requirements have been streamlined. Most notably, the proposed rules create new requirements for designating products for low dose administration sessions. The new requirements create costs of compliance; however, these costs are offset to some degree by improved efficiency due to rule revisions. OPS cannot accurately predict the net cost of compliance. Any increased cost of compliance is relatively minor compared to the cost of increased fees.

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

Some of the rule requirements could lead to increased costs for equipment, supplies, labor, and administration. The rules require additional information to be printed on product labels. However, OPS cannot predict what portion, if any, of a businesses' overall cost will be impacted.

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

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310. ARC 925-2007