



NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333

OREGON HEALTH AUTHORITY

PUBLIC HEALTH DIVISION

FILED: 08/28/2026 4:11 PM

ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Oregon Psilocybin Services

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/21/2026 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Filed By:

Public Health Division
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 09/15/2026

TIME: 6:00 PM - 7:30 PM

OFFICER: Staff

REMOTE HEARING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 1-669-254-5252

CONFERENCE ID: 1614161945

SPECIAL INSTRUCTIONS:

This hearing is being held remotely via Zoom.

Join ZoomGov Meeting

<https://www.zoomgov.com/j/1614161945?pwd=W3laY7iAcu968MxOeN8blGE8wy6oOT.1>

Call in: 1-669-254-5252 (US)

Meeting ID: 161 416 1945

Passcode: 372792

To sign up to provide oral comments at the hearing, please visit

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Administrative-Rules.aspx> or send an email to publichealth.rules@odhsoha.oregon.gov.

OHA welcomes all participants. If you have any questions about accommodations or need any assistance to participate, please contact the Oregon Psilocybin Services team at 971-673-0322, 711 TTY, or

OHA.Psilocybin@odhsoha.oregon.gov, at least 48 hours before the meeting. Every effort will be made to provide services to requests received at least 48 hours in advance, however submitting your request as early as possible is greatly appreciated.

DATE: 09/16/2026

TIME: 12:00 PM - 1:30 PM

OFFICER: Staff

REMOTE HEARING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 1-669-254-5252

CONFERENCE ID: 1602796776

SPECIAL INSTRUCTIONS:

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<https://www.zoomgov.com/j/1602796776?pwd=AQncb2Baa7l6aJ0MUydnN1YpRqINgX.1>

Call in: 1-669-254-5252(US)

Meeting ID: 160 279 6776

Passcode: 767758

To sign up to provide oral comments at the hearing, please visit

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Administrative-Rules.aspx> or send an email to publichealth.rules@odhsoha.oregon.gov.

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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 increase license fees significantly as the authorizing ballot measure anticipated the program would be self-sustaining and currently is not. 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. Some of 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 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 who are likely to be impacted by proposed changes to implementation of ORS 475A. OPS engaged communities through Rule Advisory Committees held between July 6 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.

The proposed rules will have many impacts on racial equity. Throughout the rulemaking process, OPS has attempted to craft rules that support equity and promote public safety without creating unnecessary costs that lead to reduced access for clients. While intended and needed to help move the program further toward self-sustainability, the increased fees in the proposed rules will likely have a negative impact on licensees and clients. Some rule amendments that are intended to provide flexibility or address concerns of licensees are likely to have a positive impact.

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 Supplemental Security Income, and applicants receiving Supplemental Nutritional Assistance Program. In the current biennium approximately thirty-two percent of the license transactions have been for a reduced fee. 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 and 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. 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 broad 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. 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. However, the positive impact of increasing opportunities for dual licensed facilitators and expanding options for training should be considered in the context of increased licensed fees which are likely to reduce the overall number of licensed facilitators.

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. 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.

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 operational rules could also create higher risks of negative impacts to public health and safety for clients and communities.

OPS initially established fees for training program curriculum approval, annual license fees, change fees and worker permits in 2022. Under the current rules, the fee for training program approval is \$500. The proposed rules would change the existing fee to \$1,000. The proposed rules would create a new fee of \$500 for changes to training program curriculum. Under the current rules the non-refundable application fee for all license types is \$500. The proposed rules would change the existing fee to \$1,000. Under the current rules, the fee for a facilitator license is \$2,000. The proposed rules would change the existing fee to \$4,000. Under the current rules, the fee for service center, manufacturer and laboratory licenses is \$10,000. The proposed rules would change the existing fee to \$20,000 for service centers and manufacturers, and \$20,000 for laboratories. Under the current rules, the applicant change fee for licenses is \$250. The proposed rules would change this fee to \$500. Under the current rules, the change of location fee is \$500. The proposed rules would change the existing fee to \$1000. Under the current rules, the site inspection fee for changes to licensed premises is \$500. The proposed rules would change the existing fee to \$1,000. Under the current rules the fee for worker permits is \$25. The proposed rules would change this fee to \$200. All fee increases will be effective on January 1, 2027, except for the laboratory license fee which is effective January 1, 2029.

The proposed rules also eliminate reduced fees for eligible licenses, which include veteran, low-income, and non-profit

organization applicants. All applicants will now pay the amounts listed above.

OPS expects that an increase in licensing fees may reduce the overall number of licensees and create a more significant program budget shortfall. This may have a detrimental impact on licensees and clients that want to access psilocybin services. This impact is likely to be more acute for communities already experiencing access challenges. Students that have completed psilocybin facilitator training programs in Oregon 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 per student. As of August 4, 2026, OPS has licensed 649 facilitators since January 1, 2023. Licensed service centers have made significant investments in their premises and will be unable to recoup those investments if they are forced to close. 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 (DOR). The number of licensed facilitators has grown since the Oregon Legislature passed House Bill 2387 in 2025. House Bill 4040, passed in 2026, could further expand client access to health and behavioral health services provided by dual licensed facilitators. However, individuals holding dual licenses may experience a reduction in the services they are able to provide due to increased license fees, 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 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. 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 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.

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.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) 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 licensees. The costs to local governments 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)(a) OPS estimates that many licensed psilocybin businesses meet the definition of small businesses. As of August 25, 2026, there are 422 psilocybin businesses in Oregon, including psilocybin facilitators. 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) 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. OPS cannot accurately predict the net cost of compliance.

(c) 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. However, OPS cannot predict what portion of a business' overall costs will be impacted.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses participated in the rule advisory committee.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-333-1010, 333-333-2010, 333-333-2400, 333-333-2410, 333-333-3010, 333-333-3020, 333-333-3030, 333-333-3035, 333-333-3040, 333-333-3050, 333-333-3070, 333-333-3300, 333-333-4000, 333-333-4010, 333-333-4060, 333-333-4070, 333-333-4100, 333-333-4110, 333-333-4120, 333-333-4200, 333-333-4250, 333-333-4280, 333-333-4300, 333-333-4310, 333-333-4400, 333-333-4480, 333-333-4520, 333-333-4650, 333-333-4660, 333-333-4810, 333-333-4900, 333-333-4910, 333-333-4930, 333-333-5000, 333-333-5040, 333-333-5050, 333-333-5070, 333-333-5120, 333-333-5130, 333-333-5200, 333-333-5230, 333-333-5240, 333-333-5250, 333-333-6030, 333-333-6100, 333-333-6150, 333-333-6160, 333-333-7020, 333-333-7050, 333-333-7090, 333-333-7120, 333-333-8100, 333-333-8200, 333-333-8210

AMEND: 333-333-1010

RULE SUMMARY: Amend OAR 333-333-1010: Amend definitions for "advertising", "curriculum", "financial interest", and "operational name". Create definitions for "individual applicant," "legal entity applicant", "primary point of contact", "psilocin analyte", and "total psilocybin equivalent".

CHANGES TO RULE:

333-333-1010

Definitions

For purposes of chapter 333, division 333, in addition to the definitions in ORS 475A.220, the following definitions apply:¶¶

(1)(a) "Adulterant" means:¶¶

(A) Chemicals, drugs, plants or substances that alter the potency, intoxicating effect, duration of effect, toxicity or potential for excessive use when added to psilocybin products.¶¶

(B) Any additives that are intended to manipulate the ratio of any analyte or to manipulate the ratio of compound relative to another analyte or compound present in the fungi used in extraction or processing.¶¶

(b) Adulterant does not mean naturally occurring substances contained in food items such as, but not limited to chocolate.¶¶

(2) "Adverse reaction" means an adverse behavioral or medical reaction that occurred during an administration session and does not require transport to a hospital.¶¶

(3) "Adverse behavioral reaction" means a client's behavioral reaction that required contacting emergency services