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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

FILED
08/29/2025 3:21 PM
ARCHIVES DIVISION
SECRETARY OF STATE

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Oregon Psilocybin Services

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/22/2025 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: 09/16/2025
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: 1619921633
SPECIAL INSTRUCTIONS:
This hearing is being held remotely via Zoom.
Join ZoomGov Meeting
https://www.zoomgov.com/j/1619921633?pwd=bbT1aWQnWZHHIwoH1QXsJZwdlO9kuz.1
Call in: 1-669-254-5252 (US)
Meeting ID: 161 992 1633
Passcode: 844346

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: 09/18/2025

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: 1614603080
SPECIAL INSTRUCTIONS:
This hearing is being held remotely via Zoom.
Join ZoomGov Meeting
Thursday, September 18, 12:00 PM – 1:30 PM (PDT)
https://www.zoomgov.com/j/1614603080?pwd=EV2eVfaKa7GjDGvIqCvbnDjucRY2IM.1
Call in: 1-669-254-5252 (US)
Meeting ID: 161 460 3080
Passcode: 829959

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 2025, Chapter 147 (HB 2387) and Chapter 236 (SB 907). 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 and 2024 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 rules supplement prior rules and make further refinements to requirements for training programs, licensees and permittees. 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 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 rules also implement Oregon Laws 2025, Chapter 236 (Senate Bill 907) and Oregon Laws, 2025, Chapter 147 (House Bill 2387). The proposed rules make changes to align with revised statutory language, address requirements for facilitators who hold other license types, require additional information on product labels, additional reporting by licensees and additional requirements for verification of property ownership.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Oregon Laws 2025, Chapter 236 (Senate Bill 907)
https://olis.oregonlegislature.gov/liz/2025R1/Downloads/MeasureDocument/SB907

Oregon Laws, 2025, Chapter 147 (House Bill 2387)
https://olis.oregonlegislature.gov/liz/2025R1/Downloads/MeasureDocument/HB2387/Enrolled
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, psilocybin training programs and clients receiving psilocybin services in Oregon. OPS 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 14 and July 17, 2025. OPS will continue to engage communities via the public comment period which begins on September 2, 2025, and concludes on September 22, 2025. 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 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 health licensing boards and allowing those facilitators to provide expanded services during preparation and integration sessions. This change benefits facilitators who hold these credentials as well as the clients they serve. The changes to reporting of veteran status are required to align with statute and may have a negative impact on health equity. Psilocybin remains a schedule one controlled substance, and veterans may be reluctant to access psilocybin services if they believe that reporting their veteran status could impact their eligibility to receive federal benefits. The impact of reporting other client information was addressed in a 2024 rulemaking. The changes to align with Oregon Laws 2025, Chapter 236 (Senate Bill 907) may have a negative effect on health equity. Some manufactures may experience a more onerous licensing process that requires the property owner's consent to be witnessed by a notary. The additional requirements to verify property usage would be experienced disproportionally by applicants who do not own the real property where their licensed premises is located.

The majority 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. Some provisions affect equity positively, such as allowing students to transfer training hours when a training program closes unexpectedly.

In general, 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. Because OPS is entirely fee-funded, the program's options for creating affordable license fees are rather limited.

In general, 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 lower income individuals including 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. Because OPS is entirely fee-funded, the program's options for creating affordable license fees are rather limited.

FISCAL AND ECONOMIC IMPACT:

Licensed businesses and state agencies will incur cost to comply with the rules. However, the overall fiscal and economic impact of the rules cannot be quantified at this time. The rules are necessary to implement ORS 475A and 2025 legislation. Less restrictive 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. Additionally, an appropriately regulated market may increase consumer confidence and encourage members of the public to access psilocybin services through the statutory model rather than seeking services in the unregulated market.

The regulated market for psilocybin products and services is still relatively new. Like all new businesses, psilocybin businesses, including facilitators, incur start-up 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. Existing businesses that become licensed psilocybin businesses will also incur cost 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 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, and educating licensees. The costs to local government are unknown, but likely very small if any. The general public may incur costs to the extent that the costs of compliance with the proposed rules is passed on to members of the public who participate in psilocybin services.

(2)(a) OPS estimates that many licensed psilocybin businesses will meet the definition of small businesses. As of August 26, 2025, there are 405 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) The rules contain additional reporting and documentation requirements required to align with legislation that will create additional costs for licensees. The rules contain additional reporting and recordkeeping activities that are not required by statute and streamline other requirements. 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, and it is difficult to determine the extent to which the rules impose additional costs beyond the costs required to comply with statute.

(c) 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 in order to align with legislation. However, OPS cannot predict what portion, if any, of a businesses' overall cost 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, 333-333-2030, 333-333-2080, 333-333-2400, 333-333-2410, 333-333-3010, 333-333-3035, 333-333-3085, 333-333-3300, 333-333-4000, 333-333-4060, 333-333-4070, 333-333-4100, 333-333-4120, 333-333-4130, 333-333-4200, 333-333-4250, 333-333-4480, 333-333-4520, 333-333-4620, 333-333-4630, 333-333-4640, 333-333-4650, 333-333-4660, 333-333-4820, 333-333-4910, 333-333-5000, 333-333-5020, 333-333-5120, 333-333-5130, 333-333-5150, 333-333-5200, 333-333-5230, 333-333-6150, 333-333-6200, 333-333-8000, 333-333-8200

AMEND: 333-333-1010

RULE SUMMARY: 333-333-1010: Amend definitions of "Training program" and “Unique identification number.”

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 or receiving care from a medical care provider that occurred during an administration session.¶
(4) "Adverse medical reaction" means a client's medical reaction that required contacting emergency services or receiving care from a medical care provider that occurred during an administration session.¶
(5) "Advertising" means publicizing the trade name of a licensee together with words or symbols referring to psilocybin or publicizing the brand name of a psilocybin product.¶
(6) "Aggregate," for the purpose of reporting 303 service center data and 303 client data, means to combine and categorize quantitative data in a manner that prevents a client or an individual from whom the data was collected, from being identified, taking into consideration how the data could be used in combination with other data sources.¶
(7) "Applicant" means an individual who applies for a facilitator license and an individual or legal entity who:¶
(a) Holds or controls an interest of more than 20 percent in the entity proposed to be licensed;¶
(b) Is entitled to receive 20 percent or more of revenue, profits or proceeds from the entity proposed to be licensed; or¶
(c) Is entitled to exercise control over the entity proposed to be licensed.¶
(8) "Attractive to minors" means:¶
(a) Cartoons;¶
(b) A design, brand or name that resembles a non-psilocybin consumer product of the type that is typically marketed to minors;¶
(c) Symbols or celebrities that are commonly used to market products to minors;¶
(d) Images of minors; or¶
(e) Words that refer to products that are commonly associated with minors or marketed by minors.¶
(9) "Authority" means the Oregon Health Authority.¶
(10) "Authorized Authority representative" means an employee of the Authority who is authorized to conduct inspections or investigations and otherwise enforce ORS chapter 475A and any rules adopted thereunder.¶
(11) "Batch" means a quantity of whole fungi from a harvest lot, or a quantity of psilocybin product from a process lot.¶
(12) "Billboard" means a large outdoor advertising structure.¶
(13) "Capsule" means a small soluble pill, tablet or container that contains psilocybin extract or homogenized fungi

and is intended for human consumption.¶
(14) "Cartoon" means any drawing or other depiction of an object, person, animal, creature or any similar caricature which may exhibit any of the following:¶
(a) The use of comically exaggerated features;¶
(b) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or¶
(c) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.¶
(15) "Chemical synthesis" means a method of producing psilocybin products using precursor ingredients rather than cultivation of fruiting bodies and mycelium, or a method of producing psilocybin products that results in psilocybin products that contain analytes or compounds that were not present in the source fruiting bodies, mycelium and other ingredients.¶
(16) "Client administration area" means any area within the licensed premises of a service center where:¶
(a) Psilocybin products may be transferred to a client.¶
(b) Psilocybin products may be consumed by a client.¶
(c) Administration sessions may take place.¶
(17) "Client" means an individual that is provided psilocybin services in this state. ¶
(18) "Client information form" means the form required by ORS 475A.350.¶
(19) "Client packaging" means packaging containing psilocybin products intended to be sold to clients.¶
(20) "Client records" means information held or known by a service center or facilitator, including 303 client data, that may be used to identify a client or prospective client, including any communication made by a client or prospective client and any information related to providing psilocybin services or selling psilocybin products to a client. ¶
(21) "Client support person" means a person who will be present during a client's administration session for any purposes described in OAR 333-333-5070.¶
(22) "Consultation" means feedback and discussion provided by an instructor, practicum site supervisor or lead educator to students regarding students' observation of clients receiving psilocybin services.¶
(23) "Control over the entity" includes but is not limited to the authority to bind the entity to contracts, obligations or debt and does not include a licensee representative acting under the direction of a licensee.¶
(24) "Cultivation batch" means a quantity of unharvested fruiting body or mycelium that is grown together under the same conditions, that may contain fungi that originates from diverse spores or mycelial tissue of Psilocybe cubensis.¶
(25) "Cultural equity" means values, policies, and practices that ensure all people, especially those who have been historically marginalized based on race, ethnicity, religion, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances are considered in the development of social pathways to health equity.¶
(26) "Culturally and linguistically responsive services" for the purpose of ORS 475A.210 to 475A.722 and these rules means psilocybin services offered by service centers and facilitators that are responsive to diverse cultural beliefs and practices, preferred languages, literacy, and other communication needs of clients.¶
(27) "Curriculum" means the topics, subjects, and activities that make up courses taught by a training program.¶
(28) "De-identified data" means data that cannot be reasonably used to infer information about, or otherwise be linked to, an identified or identifiable client, or to a device that identifies, is linked to or is reasonably linkable to a client.¶
(29) "Direct owner" means an individual, legal entity or partnership that holds an ownership interest in a business proposed to be licensed directly rather than holding that interest through ownership of or affiliation with another legal entity or partnership.¶
(30) "Disciplinary actions," for the purpose of ORS 475A.374, means any final order issued under ORS chapter 183 finding a licensee violated ORS chapter 475A or these rules.¶
(31) "Discount" for the purposes of ORS 475A.662(6) and OAR 333-333-4480 means offering for sale or selling a psilocybin product to a client at a price that is less than the price the service center paid for the product, inclusive of any rebates. ¶
(32) "Edible psilocybin product" means psilocybin extract or homogenized fungi that has been incorporated into a food product or potable beverage.¶
(33) "Elementary school":¶
(a) Means a learning institution containing any combination of grades kindergarten through 8.¶
(b) Does not mean a learning institution that includes only pre-kindergarten, only kindergarten, or only a combination of pre-kindergarten and kindergarten.¶
(34) "Extraction" means:¶
(a) The process of separating psilocybin from fungi by using a solvent; and¶

(b) Manufacturing psilocybin extracts.¶
(35) "Facilitator" means an individual that facilitates the provision of psilocybin services in this state.¶
(36) "Facilitation" means the provision of services to a client by a licensed facilitator before, during, and after the client's consumption of a psilocybin product during a preparation, administration, or integration session.¶
(37) "Financial interest":¶
(a) Means entitlement to receive a portion of revenue, proceeds or profits from a licensed entity or an entity proposed to be licensed; or¶
(b) A membership interest, partnership interest or other ownership interest in a licensed entity or an entity proposed to be licensed.¶
(c) Includes any individual person or legal entity that qualifies as an applicant under OAR 333-333-1010 or 333-333-4030.¶
(d) Does not include an investment interest that the investor does not control in nature, amount or timing.¶
(38) "Fruiting bodies" means the spore producing organs of the fungi Psilocybe cubensis.¶
(39) "Fungi" means the fruiting bodies or mycelium of the fungi Psilocybe cubensis.¶
(40) "Harvest" means the act of removing mycelium or fruiting bodies from a production environment for drying or processing.¶
(41) "Harvest lot" means a specifically identified quantity of fungi that is cultivated and dried under the same conditions and harvested within a seven calendar-day period at the same location within the licensed premises, that may be partially harvested, and may use the substrate material for multiple harvests.¶
(42) "Health equity" means the opportunity for all people to reach their full health potential and well-being without being disadvantaged by their race, ethnicity, religion, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities or other socially determined circumstances.¶
(43) "Homogenized fungi" means dried fruiting bodies or mycelium that have been mixed by powdering or other techniques which uniformly distribute psilocybin throughout the product. Homogenized fungi may be packaged in capsules and may contain inactive ingredients such as binders, dilutants and carrying agents.¶
(44) "Instructor" means an individual identified by a training program in a form and manner prescribed by the Authority who provides instruction to students. ¶
(45) "Intervention" means taking proactive steps to respond to the client's behavior, experience, or condition during an administration session.¶
(46) "Intoxicant" means any substance that has intoxicating effects, and includes alcohol, prescription drugs, non-prescription drugs and any other controlled substances. Intoxicant does not include caffeine or nicotine.¶
(47) "Laboratory" means a laboratory licensed under ORS 475A.594.¶
(48) "Lead educator" means a person affiliated with a training program who is responsible for tracking the progress of students throughout the program.¶
(49) "Licensee representative":¶
(a) Means an owner, director, officer, manager, employee, agent or other representative of a manufacturer, service center, or laboratory licensee.¶
(b) Does not mean a facilitator who provides services at a service center unless that facilitator is also an owner, director, officer, manager, employee, agent or other representative of the service center.¶
(c) Includes an independent contractor of a manufacturer, service center, or laboratory licensee who acts in a representative capacity.¶
(50) "Licensed premises":¶
(a) Means the area of a location that is licensed under ORS chapter 475A, including:¶
(A) All public and private enclosed areas at the location that are used in the licensee's operations at the location;¶
(B) All areas outside a building that are used in the licensee's operations at a location for which the Authority has issued a license for a manufacturer or service center; and¶
(C) For a location that the Authority has specifically issued a license for the operation of a psilocybin service center, any outdoor area of the location used to operate the psilocybin service center and provide psilocybin services to clients.¶
(b) Cannot include a residence.¶
(c) Cannot contain unlicensed areas within the boundaries of the licensed premises.¶
(51) "Licensee" means any person who holds a license issued under ORS chapter 475A and includes each individual and legal entity identified as an applicant on an application that the Authority has approved and each individual or legal entity who is added to the license as described in OAR 333-333-4200.¶
(52) "Limited access area" means any area of a licensed premises where psilocybin products or psilocybin waste are stored or produced.¶
(53) "Manufacturer" means a manufacturer licensed under ORS 475A.290.¶
(54) "Manure" means animal excreta, alone or in combinations with litter, such as straw and feathers used for

animal bedding, for use as a soil amendment or substrate. Manure does not include stabilized compost produced through a controlled composting process.¶
(55) "Marijuana" has the meaning given that term in ORS 475C.009.¶
(56) "Mycelium" means the fungal threads or hyphae of Psilocybe cubensis.¶
(57) "Nondirective facilitation" means a client-centered approach to facilitation in which the client makes decisions related to their participation in psilocybin services and the facilitator maintains a consistent disposition with a client, while avoiding giving the client direct advice or offering an interpretation of a client's statements, behaviors or needs unless appropriate for health and safety reasons. Nondirective facilitation does not prohibit a facilitator from offering options, resources, referrals or providing health and safety support to clients within their scope of practice. ¶
(58) "Non-profit entity" means a nonprofit corporation organized under ORS chapter 65, registered with the Secretary of State as a nonprofit organization, and registered with the Oregon Department of Justice as a charitable organization, if applicable.¶
(59) "Post-session reaction" means a medical or behavioral reaction occurring within 72 hours of the client's release from an administration session that was likely related to psilocybin consumption and resulted in contacting emergency services or the client receiving care from a medical care provider. ¶
(60) "Prospective client" means an individual who has not participated in a preparation session with a particular facilitator or service center and who contacts that facilitator or service center for the purpose of receiving psilocybin services. ¶
(61) "Operational name" means an individual, legal entity or business name listed on an application and license certificate of a service center, manufacturer or laboratory license that the licensee(s) will use for purposes of advertising and doing business with the public.¶
(62) "Oregon Psilocybin Services Act" means ORS 475A.210 to ORS 475A.722.¶
(63) "Pesticide" means any substance or mixture of substances included in ORS 634.006(8).¶
(64) "Permittee" means a person who holds a permit issued under ORS 475A.480.¶
(65) "Practicum site" means a licensed service center that provides practicum training.¶
(66) "Practicum site supervisor" means an onsite practicum supervisor of assigned trainees, who is affiliated with a training program or who is affiliated with a service center acting as a practicum site and who does not act as a facilitator while supervising students.¶
(67) "Preproduction process" means cultivation environments that are used to facilitate growth of mycelial tissue prior to that tissue being transferred to production growth medium. Examples include but are not limited to agar dishes and grain spawn.¶
(68) "Process lot" means homogenized fungi, psylocibin extract or edible psilocybin product of the same type that was processed at the same time using the same processing method, ingredients, and standard operating procedures.¶
(69) "Production process" means cultivation environments from which fruiting bodies or usable mycelium are harvested, including but not limited to substrates used in the production of fruiting bodies.¶
(70) "Psilocybin" has the meaning described in ORS 475A.220.¶
(71) "Psilocybin analyte" has the meaning described in OAR 333-064-0025. As used in these rules psilocybin analyte refers to content of psilocybin analyte as measured by potency tests required by OAR 333-333-7040.¶
(72) "Psilocybin extract" means:¶
(a) A substance consisting entirely of solid or liquid psilocybin and may include other compounds which were simultaneously extracted from fruiting bodies or mycelium of Psilocybe cubensis; and¶
(b) A substance consisting of solid or liquid psilocybin and may include other compounds which were simultaneously extracted from fruiting bodies or mycelium of Psilocybe cubensis and inactive ingredients that are used to form capsules, tinctures and other oral preparations.¶
(73) "Psilocybin services" means services provided to a client before, during, and after the client's consumption of a psilocybin product, including:¶
(a) A preparation session;¶
(b) An administration session; and¶
(c) An integration session.¶
(74) "Product tracking system" or "PTS" means the system for tracking psilocybin products required by ORS 475A.400.¶
(75) "Psilocybin product" means psilocybin-producing fungi, mycelium and mixtures or substances intended for human consumption that contain a detectable amount of greater than 1 part per million (ppm) of psilocybin analyte, including whole fungi, homogenized fungi, psilocybin extract and edible psilocybin products.¶
(76) "Psilocybin waste" means:¶
(a) Waste material that is a byproduct of manufacturing psilocybin products that contains a detectable amount of psilocybin.¶

(b) Partially consumed psilocybin products, excluding client packaging.¶
(c) Psilocybin products that a manufacturer, service center or laboratory disposes.¶
(d) Any psilocybin product that is required to be designated as waste by these rules.¶
(77) "Radio" means a system for transmitting sound without visual images, and includes broadcast, cable, on-demand, satellite, or internet programming. Radio includes any audio programming downloaded or streamed via the internet.¶
(78) "Registered agent" means an individual or business entity that is listed in a business registration with the Oregon Secretary of State to accept delivery of legal documents on behalf of the business. ¶
(79) "Residence" means real property inhabited by an owner, renter or tenant, including but not limited to manufactured homes and vehicles used as domiciles, and attached garages or other structures that may be directly accessed from any ingress or egress of a residence.¶
(80) "Responsible referral and support" means supporting the personal needs, growth, and wellbeing of others, particularly those going through temporal crises such as houselessness, illness or marginalization.¶
(81) "Safe" means a fireproof metal cabinet with a mechanical or electronic combination lock that is capable of storing psilocybin products and weighs at least 200 pounds.¶
(82) "Scope of practice" means practice boundaries related to psilocybin facilitation and avoiding the unlicensed practice of other disciplines including but not limited to medicine or psychotherapy. This definition is not intended to prohibit facilitators from holding other license types.¶
(83) "Secondary school" means a learning institution containing any combination of grades 9 through 12 and includes junior high schools that have 9th grade.¶
(84) "Service center" means a premises licensed under ORS 475A.305.¶
(85) "Severe adverse reaction" means an adverse behavioral or medical reaction that requires a client to be transported to a hospital.¶
(86) "Stabilized compost" means any organic material that has undergone the process to further reduce pathogens and has reached a stage of reduced biological activity as indicated by a lower temperature and a rate of respiration below that of active compost.¶
(87) "Sublet" means to sublease or otherwise allow a person who is not a licensee representative to exercise privileges that require a manufacturer, service center, facilitator or laboratory license on the licensed premises. Sublet does not include a facilitator providing psilocybin services at a service center.¶
(88) "Synchronous learning" means that students learn from their instructor at the same time as their fellow students.¶
(89) "Television" means a system for transmitting visual images and sound that are reproduced on screens, and includes broadcast, cable, on-demand, satellite, or internet programming. Television includes any video programming downloaded or streamed via the internet.¶
(90) "These rules" means OAR 333-333-1010 through 333-333-8250.¶
(91) "Tincture" means a liquid containing psilocybin that consists of either:¶
(a) A non-potable solution of at least 25 percent non-denatured alcohol, that is exempt from the Liquor Control Act under ORS 471.035; or¶
(b) A non-potable solution comprised of glycerin, plant-based oil, syrup and other ingredients.¶
(92) "Training, Licensing and Compliance System" means the online training, license and compliance portal maintained by the Authority to receive applications, communicate with applicants, licensees, permittees and training programs, and track compliance actions.¶
(93) "Training program" means a program ~~that has been approved to~~with an approved curriculum that offers training to psilocybin facilitators as described in ORS 475A.380.¶
(94) "Training program applicant" means a program that has applied to offer training to psilocybin facilitators as described in ORS 475A.380.¶
(95) "Training program director" means an individual affiliated with a training program who is responsible for student enrollment, tracking student progress and determining whether a student has successfully completed the training program. ¶
(96) "Training program responsible party" means an individual affiliated with a training program who is authorized to make decisions and responsible for the training program and serves as the primary point of contact during the training program application process and after the program is approved. This individual may hold other roles in the training program such as registered agent or training program director.¶
(97) "Unique identification number" ~~means a~~or "UIN" means the most recent unique number generated and assigned by the product tracking system for ~~the purpose of tracking psilocybin products within the product tr~~a psilocybin product and may include cultivation batches, harvest lots, harvest batches, process lots and products in client packaging ~~system~~.¶
(98) "Whole fungi" means dried fruiting bodies of Psilocybe cubensis, or portions thereof, that have not been homogenized.¶

(99) "Wood chips" mean substrates consisting primarily of wood products that have not been composted.¶
(100) "Worker permit" means a permit required by ORS 475A.480.¶
(101) "303 client data" means information that OAR 333-333-4900 requires service centers to collect from clients, store and maintain.¶
(102) "303 service center data" means information that OAR 333-333-4910(3) and (4) require service centers to compile, aggregate, compute and report to the Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.372, ORS 475A.374
Statutes/Other Implemented: ORS 475A.235, ORS 475A.372, ORS 475A.374

AMEND: 333-333-2030

RULE SUMMARY: 333-333-2030: Clarify requirements for manufacturer endorsements

CHANGES TO RULE:

333-333-2030
Manufacturer Endorsements
(1) A manufacturer may only produce, transfer, and sell psilocybin products if the manufacturer has received an endorsement from the Oregon Health Authority (Authority) for that type of product. Endorsement types are:¶
(a) Fungi cultivation;¶
(b) Psilocybin extraction; and¶
(c) Edible psilocybin production.¶
(2) An applicant for a manufacturer license must request an endorsement upon submission of an initial application but may also request to add or remove an endorsement at any time following licensure.¶
(3) To apply for an endorsement, an applicant or licensee must submit a form prescribed by the Authority that identifies the proposed endorsement.¶
(4) Only one application and license fee are required regardless of how many endorsements an applicant or licensee requests or when the request is made.¶
(5) An individual manufacturer may hold multiple endorsements.¶
(6) The Authority may deny a manufacturer's request for an endorsement or revoke an existing endorsement if the manufacturer cannot or does not meet the requirements of these rules. If the Authority denies or revokes approval, the manufacturer has a right to a hearing under ORS chapter 183.
Statutory/Other Authority: ORS 475A.235, ORS 475A.295
Statutes/Other Implemented: ORS 475A.235, ORS 475A.295

AMEND: 333-333-2080

RULE SUMMARY: 333-333-2080: Clarify requirements for food safety licenses and edible products

CHANGES TO RULE:

333-333-2080
Psilocybin Edible Manufacturing Requirements
(1) A manufacturer premises with an edible ~~psilocybin production endorsement may only process in a food establishment~~endorsement must be licensed by the Oregon Department of Agriculture (ODA) as a food establishment and must comply with the applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28. ¶
(2) A manufacturer with an edible psilocybin production endorsement may not use a psilocybin product to produce edible psilocybin products unless that psilocybin product was processed or cultivated in a food establishment licensed by the ODA in compliance with the applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-2400

RULE SUMMARY: 333-333-2400: Amend label rules to align with Oregon Laws 2025, Chapter 147 (HB 2387); clarify requirements for potency information

CHANGES TO RULE:

333-333-2400
Labeling for Sale to Client
(1) A label required by these rules must:¶
(a) Be printed or attached to client packaging containing psilocybin products.¶
(b) Contain all required information in a legible font at least eight points large.¶
(c) Be in English, though it may also be in other languages.¶
(d) Be unobstructed and clearly visible.¶
(2) A label may not:¶
(a) Display any untruthful or misleading statements including, but not limited to, a health claim that is not supported by the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims; or¶
(b) Be attractive to minors, as that is defined in OAR 333-333-1010.¶
(3) Required Information. All client packaging must display:¶
(a) The manufacturer's business or trade name and license number.¶
(b) One of the following product type names: whole fungi, homogenized fungi, psilocybin extract, or edible psilocybin product.¶
(c) The net quantity of contents using the metric system of measurement and expressed in terms of fluid measure if the item is liquid, or in terms of weight if the item is solid, semi-solid, or viscous.¶
(d) The quantity of psilocybin analyte contained in the product, expressed in milligrams, and calculated using laboratory test results required by OAR 333-333-7040.¶
(e) The psilocin content measured by quantity of psilocin analyte contained in the product, expressed in milligrams, and calculated using laboratory test results required by OAR 333-333-7040.¶
(f) A unique identification number as defined in OAR 333-333-1010.¶
(~~f~~g) The "best by" date indicating the time that the manufacturer has determined that their product will retain its original quality.¶
(gh) A statement that "Activation times for psilocybin products are variable and cannot be accurately predicted."¶
(~~h~~i) A statement that "The risks, benefits, and drug interactions of psilocybin are not fully understood, and individual results may vary."¶
(4) Client packaging for edible psilocybin products must be consistent with applicable state food labeling requirements for the same type of food product or potable liquid when the food product or potable liquid does not contain psilocybin.¶
(5) In addition to the information required by section (3) of this rule, a manufacturer may include values regarding available or potential psilocin or psilocybin content, including the total potential psilocin as defined in OAR 333-064-0025, on a label. If the label includes other values related to psilocin or psilocybin, the product information document required by OAR 333-333-2410 must include an explanation of how those values were calculated, including any formulas and assumptions that were used to calculate the listed values.
Statutory/Other Authority: ORS 475A.235, ORS 475A.626, Oregon Laws 2025, chapter 147
Statutes/Other Implemented: ORS 475A.626, Oregon Laws 2025, chapter 147

AMEND: 333-333-2410

RULE SUMMARY: 333-333-2410: Clarify requirements for product information document

CHANGES TO RULE:

333-333-2410
Product Information Document
(1) Manufacturers must provide a product information document with all products transferred to a service center that lists the following information in English on a printed or electronic document in 12-point font or larger.¶
(a) The manufacturer's business or trade name and license number.¶
(b) The business or trade name of the manufacturer that packaged the product, if different from the original manufacturer.¶
(c) One of the following product type names: whole fungi, homogenized fungi, psilocybin extract, or edible psilocybin product.¶
(d) Net quantity of contents using the metric system of measurement and expressed in terms of fluid measure if the item is liquid, or in terms of weight if the item is solid, semi-solid, or viscous.¶
(e) Results of all laboratory tests required by OAR 333-333-7040.¶
(f) Species of fungi.¶
(g) Harvest date for whole fungi.¶
(h) Date of manufacture for all products other than whole fungi.¶
(i) Unique identification number as defined in OAR 333-333-1010.¶
(j) List of all active and inactive ingredients in descending order of predominance by weight or volume.¶
(k) List of potential major food allergens by:¶
(A) Listing the name of the food source of any major food allergen at the end of or immediately adjacent to the ingredient list; or¶
(B) Placing the term for the appropriate major food allergen in parenthesis within the ingredient list after the common or usual name of the ingredient derived from that major food allergen.¶
(l) "Best by" date indicating the time that the manufacturer has determined that their product will retain its original quality.¶
(m) If the psilocybin product is perishable, a statement that the product must be refrigerated or kept frozen.¶
(2) Any information contained in a product information document must be compliant with these rules, including but not limited to OAR 333-333-6040(2).¶
(3) A facilitator must make reasonable efforts to provide a product information document for psilocybin products that may be consumed during an administration session during a client's preparation session and provide the client an opportunity to discuss the document. If a client does not receive a product information document during their preparation session, a facilitator must provide the client a product information document for psilocybin products that may be consumed during an administration session and provide the client an opportunity to discuss the document at another time prior to beginning their administration session. ¶
(~~3~~4) A service center must make reasonable efforts to translate the product information document to languages other than English and otherwise provide the product information document in an accessible format upon the client's request.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-3010

RULE SUMMARY: 333-333-3010: Clarify requirements for training programs to provide proof of licensure

CHANGES TO RULE:

333-333-3010
Psilocybin Training Program Curriculum Approval Process
(1) A training program applicant must submit the following to the Oregon Health Authority (Authority) to be considered for curriculum approval to train psilocybin facilitators:¶
(a) A completed application package, including a description of the proposed curriculum that shows the applicant meets the requirements of OAR 333-333-3050, OAR 333-333-3060, OAR 333-333-3070 and OAR 333-333-3090; and¶
(b) A US$500 non-refundable application evaluation fee paid in the form and manner specified by the Authority.¶
(2) Following receipt of the items described in section (1) of this rule, the Authority will notify a training program applicant whether its application is complete or incomplete.¶
(a) If an application is incomplete, the training program applicant will have 30 days from the date the notice is issued to submit a complete application. If the training program applicant does not complete their application within 30 days, the Authority will refuse to process the application. If the Authority refuses to process an application, the applicant may submit a new application, including a non-refundable application evaluation fee, for the program to be considered for approval.¶
(b) If an application is complete, the Authority will evaluate the training program application to determine if the curriculum meets the standards in OAR 333-333-3010 to OAR 333-333-3090.¶
(3) The Authority will notify a training program applicant in writing if its complete application for curriculum approval is approved or denied. If the application is approved, the approval is effective on the date of notice. The Authority may not retroactively approve or pre-approve training program applications.¶
(4) ~~For~~A training program~~s that~~ must, within 180 calendar days of receive~~d~~ing curriculum approval, pr~~ior to December 31, 2023, a training program must no later than June 1, 2024, provide documentation that:¶~~
~~(a) T~~ovide documentation to the Authority, in the form and manner prescribed by the Authority, one of the following:¶
(a) Documentation demonstrating the program has applied for a~~ny approvals required~~ license from the Higher Education Coordinating Commission in accordance with applicable law~~ governing the type of school or institution and paid any required application fees; or¶~~
~~(b) The program has requested a determination from the Higher Education Coordinating Commission that approval is not required in accordance with applicable law governing the type of school or institution.¶~~
~~(5) For training programs who receive curriculum approval after December 31, 2023, a training program must within 180 calendar days of receiving curriculum approval, provide documentation to the Authority that:~~s in ORS chapter 345 or ORS chapter 348 and any applicable Higher Education Coordinating Commission rules adopted under those chapters and paid any required Higher Education Coordinating Commission application fees and the program's application is pending, and the Higher Education Coordinating Commission has not yet issued a final order of denial.¶
(~~a~~b) ~~The program has applied for any approvals requi~~Proof of current licensur~~ed~~ from the Higher Education Coordinating Commission ~~in accordance with applicable law governing the type of school or institution and paid any required application fees; or~~as a career school.¶
(~~b~~c) ~~The program has requested a determin~~Documentation from the Higher Education Coordinating Commission that ~~approval~~the applicant is not required ~~in accordance with applicable law governing the type of school or institution~~to be licensed as a career school.¶
(~~6~~5) The Authority ~~may~~shall deny a training program application for curriculum approval ~~or revoke or suspend~~and shall revoke approval of a previously approved training program curriculum if:¶
(a) The training program or training program application does not meet the requirements of OAR 333-333-3010 to OAR 333-333-3090; ~~or~~¶
(b) The program instructors, staff or representatives have made false or misleading statements to the Authority, students or the public.¶
(c) ~~For training programs that received curriculum approval prior to December 31, 2023, a training program fails to comply with requirements of section (4) this rule.¶~~
~~(d) For training programs that received curriculum approval after December 31, 2023, a training program fails to comply with requirements of section (5) this rule.¶~~
~~(e~~A training program fails to comply with requirements of section (4) this rule.¶
(d) The Higher Education Coordinating Commission denies a training program's application for ~~any approvals required in accordance with applicable law governing the type of school or institution~~licensure under applicable

laws in ORS chapter 345 or ORS chapter 348, or any applicable Higher Education Coordinating Commission rules adopted under those chapters. .¶
(~~f~~e) A training program fails to maintain its approval status with Higher Education Coordinating Commission in accordance with applicable law governing the type of school or institution.¶
(~~7~~6) If the Authority denies an application or suspends or revokes a curriculum approval, the Authority will provide notice of the denial, suspension or revocation and the training program has a right to a hearing under ORS chapter 183.¶
(~~8~~7) For applications approved prior to January 1, 2025, training program curriculum approval has a term of five years from the date of initial approval.¶
(8) Programs whose curricula approval has been denied or revoked by the Authority may not reapply for a period of one year from the date of the final order denying the application for curriculum approval or the date of the final order revoking the application for curriculum approval. ¶
(9) For new or renewal applications approved on or after January 1, 2025, training program approval has a term of one year from the date of initial approval.¶
(10) If the requirements of OAR 333-333-3010 to OAR 333-333-3090 change substantively during the term, the Authority may require training programs to resubmit an application for approval.¶
(11) Training programs that cease enrolling students or cease offering instruction to enrolled students must provide written notice to the Authority in the form and manner prescribed by the Authority. Training programs may request to surrender their training program approval pursuant to the requirements of OAR 333-333-4280.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3035

RULE SUMMARY: 333-333-3035: Adjust process for training program curriculum approval renewal

CHANGES TO RULE:

333-333-3035
Psilocybin Training Program Curriculum ~~Rea~~Approval Renewal
(1) A training program that ~~wish~~applies for ~~its~~renewal of curriculum ~~to be reapproved upon expiration of its initial approval term~~approval must submit a complete~~d~~ re~~approv~~newal application, including proof that the program has received and continues to hold any approvals required from the Higher Education Coordinating Commission in accordance with applicable law governing the type of school or institution and a non-refundable US$500 ~~reapproval fee.¶~~
~~(2) The Oregon Health Authority (Authority) must receive the reapproval application and fee at least 30 days prior to the date that the training program's approval is set to expire~~application fee. The renewal application is not complete until payment of the application fee has cleared.¶
(2) A renewal application will be considered timely if a complete renewal application is received by the Oregon Health Authority (Authority) at least 60 calendar days before the date the curriculum approval expires. Applications received less than 60 days before the date the curriculum approval expires will be considered untimely.¶
(3) ~~If a~~A training program ~~files a reapproval application and fee at least 30 days prior to the date that the training program's approval is set to expire, the training program's curriculum approval remains valid while~~that submits a complete timely renewal application may continue to offer training using the previously approved curriculum after the stated curriculum approval expiration date, pending a decision by the Authority ~~con~~siders ~~the~~ir re~~approv~~newal application.¶
(4) A training program ~~must use its previously approved curriculum until the reapproval application is approved.¶~~
~~(4) If a training program does not file a reapproval application and fee at least 30 days prior to the date that the training program's approval is set to expire, the training program's~~who submits an untimely or incomplete renewal application or who does not submit a renewal application shall not continue to offer training using the previously approved curriculum when the curriculum approval ~~will~~ expire~~, and the training program must submit~~s.¶
(5) If the Authority approves a renewal application.¶
~~(5) If the Authority approves re~~ for curriculum approval, the ~~re~~curriculum approval is valid for one year from the date of approval.¶
(6) The Authority may deny ~~the~~an application for re~~approv~~newal if:¶
(a) The training program has not complied with these rules; or¶
(b) The training program instructors, staff or representatives have made false or misleading statements to the Authority, students or the public.¶
(7) If the Authority denies ~~reapproval~~a renewal application, the Authority will provide notice of the denial and the program has a right to a hearing under ORS chapter 183.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-3085

RULE SUMMARY: 333-333-3085: Adopt rule allowing students to transfer hours in the event of training program closure

CHANGES TO RULE:

333-333-3085
Transfer of Training Hours Due to Training Program Closure
(1) Training programs may accept transfer core training hours for students who were previously enrolled in another approved training program that on or after January 1, 2026:¶
(a) Effectively surrendered its curriculum approval pursuant to OAR 333-333-4280.¶
(b) Notified the Oregon Health Authority (Authority) that it has permanently ceased operations or permanently ceased offering instruction to enrolled students pursuant to OAR 333-333-3010. ¶
(c) Has had its curriculum approval revoked by the Authority.¶
(2) Training programs that choose to accept transfer hours under this rule are responsible for verifying the content and quantity of the hours transferred and for ensuring program completion pursuant to OAR 333-333-3090. ¶
(3) Transfer hours under this rule are independent from accelerated training hours described in OAR 333-333-3080. Training programs that choose to accept transfer hours are not required to accept accelerated training hours. ¶
(4) Training programs may not accept transfer hours for practicum.¶
(5) Training programs are not required to accept transfer hours. A training program's decision regarding acceptance of training hours may not be appealed to the Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3300

RULE SUMMARY: 333-333-3300: Clarify requirements for reporting continuing education

CHANGES TO RULE:

333-333-3300
Continuing Facilitator Education
(1) For renewal applications received on or after January 1, 2026, facilitator licensees must have completed four hours of continuing facilitator education during their annual license period in order to be eligible for license renewal.¶
(2) Continuing facilitator education must consist of skills and knowledge that are relevant to the core curriculum described in OAR 333-333-3050 and OAR 333-333-3060.¶
(3) The Oregon Health Authority (Authority) will consider continuing education hours to be valid if they meet the requirement in section (2) of this rule, and the education was offered by:¶
(a) Training programs with curricula approved by the Authority.¶
(b) Organizations or conferences that have been approved to offer continuing education for other types of professional licenses or certifications.¶
(4) Facilitator licensees must record and report continuing facilitator education hours in a form and manner prescribed by the Authority~~, including~~.¶
(5) For continuing facilitator education hours received from training programs with curricula approved by the Authority, documentation must include:¶
(a) Date of continuing facilitator education.¶
(b) Name of training program that offered the continuing facilitator education.¶
(c) A description of how the continuing facilitator education is relevant to the provision of psilocybin services under ORS chapter 475A.¶
(6) For continuing facilitator education hours received from an organization or conference, documentation must include:¶
(a) Date of continuing facilitator education.¶
(b) Name ~~of~~and contact information for the program, organization or conference offering the continuing facilitator education.¶
(c) Name of the organization that approved the continuing education for other types of professional licenses or certifications.¶
(~~c~~d) A description of how the continuing facilitator education is relevant to the provision of psilocybin services under ORS chapter 475A.¶
(~~5~~7) Training programs that offer continuing facilitator education must notify the Authority in form and manner prescribed by the Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-4000

RULE SUMMARY: 333-333-4000: Align application requirements with Oregon Laws 2025, Chapter 236 (SB 907) on verification of property ownership

CHANGES TO RULE:

333-333-4000
Application Process
(1) Applications must be submitted to the Oregon Health Authority (Authority) in the form and manner prescribed by the Authority.¶
(2) The application fee specified in OAR 333-333-4060(1) must be submitted at the time of application in the form and manner prescribed by the Authority.¶
(3) An application must include the following:¶
(a) The names and required information for all individuals and legal entities who are applicants as required by OAR 333-333-4030.¶
(b) An address to receive mail from the Authority at an established physical location within the United States of America or U.S Territories or the freely associated states Republic of Marshall Islands, Palau, and the Federated States of Micronesia.¶
(c) Any forms and information required by the Authority to evaluate the license application.¶
(d) A social equity plan as required by OAR 333-333-4020.¶
(e) Information regarding race, ethnicity, preferred spoken and written language, sexual orientation and gender identity of each individual applicant recorded in a form and manner prescribed by the Authority. ¶
(f) For manufacturer, service center and laboratory license applicants, a map and diagram of the proposed license premises, including the boundaries of the licensed premises relative to its location, identification of any unlicensed areas within the building where the licensed premises is located including suite numbers if applicable, identification of any residence or other unlicensed structures located on the same tax lot as the premises proposed to be licensed, a scaled floor plan identifying all points of ingress and egress, camera locations, limited access areas, client administration areas and areas where psilocybin products will be stored within the licensed premises as required by OAR 333-333-4510. The Authority may request additional documents or information related to the proposed licensed premises, including but not limited to photographs of the premises.¶
(g) If the applicant for an initial or renewal manufacturer license is not the owner of the real property proposed to be licensed, a written statement signed by the property owner ~~that~~witnessed by a notary public that confirms ownership of the real property and shows that the owner consents to manufacturing of psilocybin products on the property for at least one annual license term. This requirement must be satisfied by using the designated form published by the Authority on its website. ¶
(h) For service center applicants, a service center emergency plan as described in OAR 333-333-4460.¶
(i) For service center applicants whose proposed licensed premises includes outdoor administration areas, a detailed description of the outdoor administration areas including their location and verification that the area is free from hazards as required by OAR 333-333-5210.¶
(j) For service center and manufacturer applicants, a statement that every individual person and legal entity who holds a financial interest in the entity proposed to be licensed complies with the requirements of ORS 475A.280.¶
(k) For facilitator applicants, documentation that the applicant has completed training at a training program with curriculum that has~~d~~ been approved by the Authority at the time the applicant received and completed the training and that me~~ets~~t the requirements of OAR 333-333-3010 to OAR 333-333-3090 at the time of approval.¶
(l) For facilitator applicants, documentation that the applicant has passed the exam required by ORS 475A.325.¶
(m) For laboratory applicants, documentation that the applicant has received accreditation as described in ORS 475A.606.¶
(4) In addition to submitting an application form and the items described in section (3) of this rule, the Authority may require:¶
(a) Information or fingerprints required to perform a criminal ~~background~~records check in accordance with OAR 333-333-4100.¶
(b) Any additional information that is reasonably required to determine the merits of the license application.¶
(5) The Authority must review an application to determine if it is complete. An application may be considered incomplete if the form is not complete, the application or license fee has not been paid or payment has not cleared, or additional information or documentation required under this rule has not been submitted, included but not limited to:¶
(a) Documentation that an applicant for a facilitator license has completed the training required by ORS 475A.325.¶
(b) Documentation that an applicant for a facilitator license has passed the exam required by ORS 475A.325.¶

(c) Results of required criminal ~~background~~records checks completed pursuant to OAR 333-333-4100.¶
(d) A land use compatibility statement from the city or county that identifies an applicant name listed on the license application and authorizes land use in the city or county where the premises of a manufacturer or service center proposed to be licensed is located.¶
(e) Other required forms and documents identified in the training, licensing and compliance system.¶
(f) A complete owner consent form as required by subsection (3)(g) of this rule.¶
(6) The Authority will notify an applicant in writing if their application is determined to be incomplete. The applicant will have30 days from the date the notice is issued to submit a complete application. If the applicant does not complete their application within 30 days, the Authority will close the application. If the Authority closes an application, the applicant may submit a new application, including a non-refundable application fee, at any time.¶
(7) An applicant may submit a written request for reconsideration of an application that is closed as incomplete. Such a request must be received by the Authority within 10 calendar days of the date the closure notice was mailed to the applicant. The Authority will notify the applicant of the results of their request following receipt of the request for reconsideration.
Statutory/Other Authority: ORS 475A.235, ORS 475A.245, ORS 475A.255, ORS 475A.374, ORS 413.161, Oregon Laws 2025, chapter 236
Statutes/Other Implemented: ORS 475A.235, ORS 475A.245, ORS 475A.255, ORS 475A.594, ORS 475A.374, Oregon Laws 2025, chapter 236

AMEND: 333-333-4060

RULE SUMMARY: 333-333-4060: Clarify that certain fees are nonrefundable

CHANGES TO RULE:

333-333-4060
License Fees
(1) At the time of initial license application:¶
(a) An applicant for a service center, manufacturer or laboratory license must pay a US$500 non-refundable application fee.¶
(b) An applicant for a facilitator license must pay a US$150 non-refundable application fee.¶
(2) If the Oregon Health Authority (Authority) approves an initial license application or renewal and grants an annual license, the following non-refundable fees must be paid, except as provided in sections (3) and (4) of this rule:¶
(a) Manufacturer US$10,000.¶
(b) Service Center US$10,000.¶
(c) Facilitator US$2,000.¶
(d) Laboratory US$10,000.¶
(3) Notwithstanding section (2) of this rule, if the Authority approves an initial license application or renewal and grants an annual license to a non-profit entity the following non-refundable fees must be paid:¶
(a) Manufacturer US$5,000.¶
(b) Service Center US$5,000.¶
(4) Notwithstanding section (2) of this rule, if the Authority approves an initial license application or renewal and grants an annual license the following non-refundable fees must be paid, if every individual applicant identified in the application satisfies one or more of the requirements of section (5) of this rule:¶
(a) Manufacturer US$5,000.¶
(b) Service Center US$5,000.¶
(c) Facilitator US$1,000.¶
(5) In order to qualify for the reduced fees identified in section (4) of this rule, an individual applicant must qualify under one of the following circumstances:¶
(a) Have received Supplemental Security Income benefits within the 12 months prior to the application date. To qualify for the reduced fee, the applicant must submit at the time of application a copy of a current monthly Supplemental Security Income benefit statement showing dates of coverage. The Authority may require additional information to verify eligibility upon request.¶
(b) Be enrolled in or have qualified for the Oregon Health Plan within the 12 months prior to the application date. To qualify for the reduced fee the applicant must submit a copy of the applicant's recent eligibility statement or card including a date that shows they were eligible for or received benefits within the 12 months prior to the application date. The Authority may require additional information to verify eligibility upon request. ¶
(c) Have received food benefits through the Oregon Supplemental Nutrition Assistance Program within the 12 months prior to the application date. To qualify for the reduced fee the applicant must submit proof of receiving food benefits within the 12 months prior to the application date. The Authority may require additional information to verify eligibility upon request.¶
(d) Has served in the Armed Forces of the United States. To qualify for the reduced fee, the applicant must provide proof of having served in the Armed Forces, such as but not limited to, submitting a Veteran's Administration form DD-214.¶
(6) The Authority will charge a nonrefundable change fee of US$250 per applicant for any change to a previously approved license that ~~results in~~proposes the addition of an applicant. This change fee applies regardless of whether the licensee requests the change at renewal or during the term of their license.¶
(7) The Authority will charge a nonrefundable change fee of US$250 per inspection for any change to a previously approved license that requires an inspection of the licensed premises, or any inspection of a premises proposed to be licensed that takes place pursuant to OAR 333-333-4210(2). This change fee applies regardless of whether the licensee requests the change at renewal or during the term of their license.
Statutory/Other Authority: ORS 475A.235, ORS 475A.290, ORS 475A.305, ORS 475A.325, ORS 475A.594
Statutes/Other Implemented: ORS 475A.235, ORS 475A.290, ORS 475A.305, ORS 475A.325, ORS 475A.594

AMEND: 333-333-4070

RULE SUMMARY: 333-333-4070: Clarify requirements for worker permit applications and renewals

CHANGES TO RULE:

333-333-4070
Worker Permit Term and Fees
(1) An individual who is a licensee representative must have a valid worker permit if the individual participates in:¶
(a) The provision of psilocybin services at a licensed premises.¶
(b) The possession, manufacturing, securing or selling of psilocybin products at a licensed premises.¶
(c) The recording of the possession, manufacturing, securing or selling of psilocybin products at a licensed premises.¶
(d) The verification of any document described in ORS 475A.445.¶
(2) Initial and renewal applications for a worker permit must include documents and information required by the Oregon Health Authority (Authority) to be complete. ¶
(3) The Authority shall deny an initial or renewal application for a worker permit if:¶
(a) The applicant does not have an approved criminal records check under ORS 181A.195. ¶
(b) The applicant has not paid a civil penalty imposed under a final order issued by the Authority under ORS chapter 183 or payment has not cleared within the time frame specified in the order.¶
(4) The Authority may deny an initial or renewal application for a worker permit if:¶
(a) The applicant has violated any provision of ORS 475A.210 to 475A.722 or these rules. ¶
(b) The applicant has made a false statement to the Authority. ¶
(5) An individual person who holds a manufacturer, service center or laboratory license due to their ownership or control of a licensed legal entity, must have a valid worker permit if they perform any of the activities listed in subsections (1)(a) through (d) of this rule.¶
(~~3~~6) If the ~~Oregon Health Authority (Authority)~~Authority approves an initial or renewal application and grants a worker permit ~~prior to January 1, 2025,~~ the permit shall have a term of ~~fiv~~one years~~.~~¶
(47) ~~If~~Once the Authority ~~approves an initial or renewal~~has made a determination to issue a permit the individual must pay a US$25 fee to receive the permit.¶
(8) If an applica~~tion and grants a worker permit on or after January 1, 2025, the permit shall have a term of one year.¶~~
~~(5) Once~~nt for an initial worker permit fails to pay the fee or payment fails to clear within 180 calendar days of receiving notice of the Authority's determination to grant an application, the application will be considered incomplete.¶
(9) If an applicant for a renewal worker permit fails to pay the fee or payment fails to clear within 30 calendar days of receiving notice of the Authority ~~has made a~~'s determination to grant an application ~~as described in section (3) of this rule, the individual must pay a US$25 fee to receive the permit.¶~~
~~(6) If an applicant for a worker permit fails to pay the fee within 180 calendar days of receiving notice of the Authority's determination to grant an application, the application will be considered incomplete~~, the application will be considered incomplete.¶
(10) A renewal worker permit application will be considered timely if a complete renewal application is received by the Authority at least 60 calendar days before the date the permit expires. Applications received less than 60 days before the date the permit expires will be considered untimely.¶
(11) A permittee who submits a complete timely renewal application may continue to exercise the privileges of the permit after the stated permit expiration date, pending a decision by the Authority on the renewal application.¶
(12) A permittee who submits an untimely or incomplete renewal application or who does not submit a renewal application must cease engaging in activity that requires a worker permit when the permit expires.
Statutory/Other Authority: ORS 475A.235, ORS 475A.483, ORS 475A.480, ORS 475A.250, Oregon Laws 2025, chapter 147
Statutes/Other Implemented: ORS 475A.235, ORS 475A.483, ORS 475A.480, ORS 475A.250, Oregon Laws 2025, chapter 147

AMEND: 333-333-4100

RULE SUMMARY: 333-333-4100: Adjust language for Criminal Records Checks

CHANGES TO RULE:

333-333-4100
~~Background~~Criminal Records Checks
(1) The ~~Authority~~Oregon Health Authority (Authority) may require any individual person identified as a licensee, a worker permit holder or applicant on a worker permit or license application to undergo a criminal ~~background~~records check and fitness determination.¶
(2) Any person identified as an applicant on an initial worker permit or license application is required to undergo a criminal ~~background~~records check and fitness determination.¶
(3) Any person identified as an applicant on a renewal license application may be required to undergo a criminal ~~background~~records check and fitness determination at regular intervals determined by the Authority.¶
(4) Any person identified as an applicant on a renewal worker permit application is required to undergo a criminal ~~background~~records check and fitness determination.¶
(5) An applicant for a worker permit is not required to undergo a criminal ~~background~~records check and fitness determination if that person has completed a criminal ~~background~~records check and fitness determination in connection with a license application within 12 months of their worker permit application.¶
(6) An individual person identified as a license applicant is not required to undergo a criminal ~~background~~records check and fitness determination if that person has completed a criminal ~~background~~records check and fitness determination in connection with another license application within 30 days of their current license application.¶
(7) The Authority will require a licensee or worker permit holder to undergo a criminal ~~background~~records check if the Authority learns that the individual has been convicted of a crime after their license or permit has been issued.¶
(8) When the Authority requires an individual to undergo a criminal ~~background check, background~~records check, criminal records checks must be submitted to the Authority for a fitness determination in accordance with OAR 407-007-0200 to 407-007-0250, 407-007-0281, 407-007-0300 and 943-007-0001 to 943-007-0501. Individuals are not subject to a check for potentially disqualifying abuse, as described by OAR 407-007-0250(5).¶
(9) When the Authority requires an individual to undergo a criminal ~~background~~records check, the individual must provide:¶
(a) A criminal ~~background~~records check request form, prescribed by the Authority that includes but is not limited to:¶
(A) First, middle and last name;¶
(B) Any aliases;¶
(C) Date of birth; and¶
(D) Address and recent residency information.¶
(b) Fingerprints in accordance with the instructions on the Authority's webpage.¶
(10) The Authority may request an applicant to disclose their Social Security Number if notice is provided that:¶
(a) Indicates the disclosure of the Social Security Number is voluntary.¶
(b) The Authority requests the Social Security Number for the purpose of positively identifying the applicant during the criminal records check process.¶
(11) Pursuant to ORS 475A.250, the Authority may not consider the prior conviction of a subject individual for:¶
(a) The manufacture of psilocybin or the manufacture of a marijuana item, as defined in ORS 475C.009, if:¶
(A) The date of the conviction is two or more years before the date of the application; and¶
(B) The person has not been convicted more than once for the manufacture of psilocybin or a marijuana item; or¶
(b) The possession of a controlled substance, as defined in ORS 475.005, or a marijuana item, as defined in ORS 475C.009, if:¶
(A) The date of the conviction is two or more years before the date of the application; or¶
(B) The person has not been convicted more than once for the possession of a controlled substance or a marijuana item.¶
(12) The fitness determination described in section (8) of this rule will determine whether the applicant is ineligible to be licensed.¶
(13) ~~R~~For licensees and permittees refusal to participate in a ~~background~~criminal records check required by this rule is a violation.¶
(14) The Authority shall deny an application for a license or worker permit if the applicant does not have an approved criminal records check under ORS 181A.195¶
(14~~5~~) If an applicant is denied due to the fitness determination, the applicant has hearings rights to challenge the fitness determination under OAR 943-007-0501.

Statutory/Other Authority: ORS 475A.235, ORS 475A.255, ORS 475A.486, ORS 475A.598, ORS 475A.250, Oregon Laws 2025, chapter 147
Statutes/Other Implemented: ORS 475A.235, ORS 475A.255, ORS 475A.486, ORS 475A.598, ORS 475A.250, Oregon Laws 2025, chapter 147

AMEND: 333-333-4120

RULE SUMMARY: 333-333-4120: Clarify requirements for payment of license fees

CHANGES TO RULE:

333-333-4120
Approval and Issuance
(1) If upon review of an application the Oregon Health Authority (Authority) determines the application meets all licensing requirements, the Authority will notify the applicant in writing that the application is pending approval and will request license fee payment. An applicant may not exercise any license privileges until they receive proof of licensure issued under section (4) of this rule. ¶
(2) If an applicant for a manufacturer, service center or laboratory license fails to pay the license fee or payment fails to clear within 60 calendar days of the notice described in section (1) of this rule, the Authority may require re-inspection of the premises proposed to be licensed. Any re-inspections that take place pursuant to this rule will be subject to the change fee described in OAR 333-333-4060(7).¶
(3) If an applicant for any license type fails to pay the license fee or payment fails to clear within 180 calendar days of the notice described in section (1) of this rule, the application will be considered incomplete.¶
(4) The Authority will not approve the license until it has confirmed that payment of the license fee has cleared and processing the application is complete. When the license is approved, the Authority will notify the applicant in writing and will provide the applicant proof of licensure, that includes a unique license number, the licensee name(s), the operational name, the effective date of the license, and address of the licensed premises. Licenses issued under ORS chapter 475A may be held by multiple licensees. ¶
(5) A licensee may not exercise license privileges until the effective date of licensure identified on the proof of licensure issued under section (4) of this rule.¶
(6) Manufacturer, service center and laboratory licensees must display a proof of licensure in a prominent place on the licensed premises.¶
(7) Facilitator licensees must be able to provide proof of licensure when performing preparation, administration or integration sessions.¶
(8) Manufacturer, service center and laboratory licenses are only valid for the licensed premises and are only issued to the individuals or entities listed on the application or subsequently approved by the Authority.¶
(9) Facilitator licenses are only issued to the individual listed on the application.¶
(10) A license may not be transferred except as provided in OAR 333-333-4270.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4130

RULE SUMMARY: 333-333-4130: Amend denial criteria for unpaid civil penalties and failure to receive approved criminal records check

CHANGES TO RULE:

333-333-4130
Application Denial
(1) The Oregon Health Authority (Authority) shall deny an application if:¶
(a) An applicant is under the age of 21.¶
(b) The applicant for a facilitator license is not an individual person.¶
(c) The applicant's land use compatibility statement shows that the proposed land use is prohibited if a land use compatibility statement is required by these rules.¶
(d) The proposed licensed premises is located on state or federal land.¶
(e) If required, the applicant does not have an approved fitness determination in accordance with OAR 333-333-4100.¶
(f) The application identifies more than one licensed premises.¶
(g) The application identifies a licensed premises that fails to comply with the requirements of OAR 333-333-4300.¶
(h) The application identifies an applicant who has not paid a civil penalty imposed under a final order issued by the Authority under ORS chapter 183, or payment has not cleared within the time frame specified in the order.¶
(i) An individual identified as an applicant does not have an approved criminal records check under ORS 181A.195.¶
(2)(a) An applicant for a service center is ineligible for a license and the Authority shall deny an application if any portion of the proposed licensed premises for a service center applicant is located, except as provided in ORS 475A.310, within 1,000 feet of:¶
(A) A public elementary or secondary school for which attendance is compulsory under ORS 339.020; or¶
(B) A private or parochial elementary or secondary school, teaching children as described in ORS 339.030(1)(a).¶
(b) For purposes of determining the distance between a service center and a school, "within 1,000 feet" means a straight-line measurement in a radius extending for 1,000 feet or less in any direction from the closest point anywhere on the boundary line of the real property comprising a school to the closest point of the licensed premises of a service center.¶
(c) In order for the Authority to determine whether there is a physical or geographical barrier that qualifies for the exception under ORS 475A.310, the applicant must demonstrate, in a form and manner prescribed by the Authority, that a physical or geographic barrier exists, and the barrier is capable of preventing children from traversing to a proposed licensed premises. Examples of physical barriers include prisons or interstate highways. Examples of geographic barriers include rivers and mountains. Private properties, shallow streams, locked doors or property fences do not qualify for a school exclusion exception request.¶
(3) The Authority may deny an application when a person with a financial interest meets any license denial criteria that apply to applicants.¶
(4) The Authority may revoke a license for any reason it may deny an application.¶
(5) The Authority may deny an application for any reason identified in ORS 475A.250.
Statutory/Other Authority: ORS 475A.235, ORS 475A.250
Statutes/Other Implemented: ORS 475A.235, ORS 475A.250, ORS 475A.290, ORS 475A.305, ORS 475A.325, ORS 475A.310

AMEND: 333-333-4200

RULE SUMMARY: 333-333-4200: Clarify requirements for notification of changes

CHANGES TO RULE:

333-333-4200
Notification of Changes
(1) An applicant or licensee must notify the Oregon Health Authority (Authority) in writing in a form and manner prescribed by the Authority ~~within 10 business days of any of~~and receive written approval from the Authority prior to the following:¶
(a) Adding or removing an individual or legal entity who qualifies as an applicant under OAR 333-333-1010 or OAR 333-333-4030.¶
~~(b) A change in contact information for any person listed as an applicant or licensee~~ Individuals who qualify as applicants must submit information regarding race, ethnicity, preferred spoken and written language, sexual orientation and gender identity of each individual applicant recorded in a form and manner prescribed by the Authority.¶
(~~c~~b) A change in licensee's operational name.¶
(~~d~~2) An applicant or licensee must notify the Authority in writing in a form and manner prescribed by the Authority within 10 business days of any of the following:¶
(a) A change in contact information for any person listed as an applicant or licensee.¶
(b) Any closure of the licensed premises lasting more than 30 days.¶
(~~e~~c) Any conviction for any misdemeanor or felony committed by an individual listed as an applicant or licensee.¶
(~~f~~d) Any arrest for conduct that occurred on the licensed premises.¶
(~~g~~e) Any theft of psilocybin products or cash from the licensed premises.¶
(~~2~~3) If after receipt of information required under subsection (1)(a) of this rule the Authority determines that the addition of an individual or legal entity applicant could result in an initial or renewal application denial under OAR 333-333-4130 or serve as the basis of a license suspension or revocation, the Authority:¶
(a) Will notify the licensee of its determination.¶
(b) Will give the licensee 30 calendar days to take actions to ensure the individual or entity does not qualify as an applicant and provide documentation to the Authority that demonstrates such actions have been taken.¶
(c) May propose license suspension or revocation under OAR 333-333-4130 if the licensee does not comply with subsection (b) of this section.¶
(~~3~~4) If applicable, the licensee must pay the change fee specified in OAR 333-333-4060 and payment must clear prior to making changes to their licensed premises or approved licensees that require inspections or additional applicants.¶
(4~~5~~) A licensee who wishes to change the location of the licensed premises must submit a change of location request including required forms and documents and the license application fee specified in OAR 333-333-4060(1).¶
(a) A licensee that submits a change of location request is not required to pay an additional annual license fee.¶
(b) A change of location request submitted under this rule must be submitted in a form and manner prescribed by the Authority and must include:¶
(A) For changes to manufacturer or service center license location, a land use compatibility statement from the city or county that authorizes land use in the city or county where the new licensed premises will be located.¶
(B) For manufacturer, service center and laboratory license applicants, a map or diagram of the new location's licensed premises including the boundaries of the licensed premises relative to its location, identification of any residence or other structures located on the same tax lot as the premises proposed to be licensed that will not be included in the licensed premises, and a scaled floor plan identifying all limited access areas and client administration areas. The Authority may request additional documents or information related to the new locations, including but not limited to photographs of the premises to be licensed.¶
(C) For a manufacturer license, if the licensee is not the owner of the real property where the new location will be located, a written statement on a form prescribed by the Authority and signed by the property owner that shows that the owner consents to manufacturing of psilocybin products on the property. The form will be published by the Authority on its website.¶
(~~5~~6) The Authority may require a licensee to submit a new application including all required forms and documents and the fee specified in OAR 333-333-4060 for a change in ownership structure that is 51 percent or greater. For the purposes of this rule, a change is considered to be 51 percent or greater if natural persons who did not hold a direct or indirect interest in the entity at the start of the license year will collectively hold a direct or indirect interest of 51 percent or greater. The Authority may require licensees to submit additional information to determine whether a new application must be submitted.¶

(~~6~~7) The Authority may require a licensee to submit a new application including all required forms and documents and the fee specified in OAR 333-333-4060 for a change in ownership structure if the change in ownership structure results in changing the licensee's status from a non-profit entity to another type of entity.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4250

RULE SUMMARY: 333-333-4250: Clarify requirements for license renewal process

CHANGES TO RULE:

333-333-4250
License Renewal
(1) Renewal Applications:¶
(a) A renewal application must ~~include documents, an~~be submitted in a form~~ation requir~~ and manner prescribed by the Oregon Health Authority (Authority) and must include documents, and information required by the Authority to be complete.¶
(b) For facilitator applicants, a renewal application received on or after January 1, 2026 must include documentation that the applicant has completed the continuing education requirements described in OAR 333-333-3300.¶
(c) A renewal application will be considered timely if a complete renewal application is received by the Authority at least 60 calendar days before the date the license expires. Applications received less than 60 days before the date the license expires will be considered untimely.¶
(d) A licensee who submits a complete timely renewal application may continue to operate after the stated license expiration date, pending a decision by the Authority on the renewal application.¶
(e) A licensee who submits an untimely or incomplete renewal application or who does not submit a renewal application must cease engaging in the licensed activity when the license expires.¶
(f) A person who, while not actively licensed, engages in any activity that would require a license may be subject to administrative and criminal sanctions regardless of their prior licensure status.¶
(2) The Authority may require a licensee with a pending renewal application to submit forms, documents and information described in OAR 333-333-4000, including but not limited to information regarding race, ethnicity, preferred spoken and written language, sexual orientation and gender identity of each individual applicant, in order to complete an evaluation of a renewal application. Failure to submit forms, documents or information requested by the Authority under this section within a time period prescribed by the Authority may result in the renewal application being considered incomplete.¶
(3) The Authority may require an inspection of the premises proposed to be licensed prior to renewing a license after providing reasonable notice as described in OAR 333-333-6150(3). There is no fee for inspections performed under this section.¶
(4) If the Authority determines that the licensee is not in compliance with these rules following an inspection described in section (3) of this rule, the Authority ~~will provide a notice of the failed inspection identifying the requirements that have not been met.¶~~
~~(5) An applicant that fails an inspection described in section (3) of this rule will have 30 calendar days from the date the notice was sent to submit a written response that demonstrates the noted deficiencies have been corrected.¶~~
~~(6) If the applicant's response under section (5) of this rule appears to correct the noted deficiencies, the Authority may schedule another inspection.¶~~
~~(7) If the applicant fails a second inspection, the Authority may deny the application unless the applicant shows good cause for the Authority to perform additional inspections.¶~~
~~(8~~may issue a notice of violation.¶
(5) If upon review of an application the Authority determines the renewal application meets all licensing requirements, the Authority will notify the applicant in writing that the renewal application is pending approval and will request license fee payment.¶
(~~9~~6) If an applicant for any license type fails to pay the license renewal fee or payment fails to clear within 30 calendar days of the notice described in section (~~8~~5) of this rule, the renewal application will be considered incomplete.¶
(~~10~~7) The Authority will not renew the license until it has confirmed that payment of the license renewal fee has cleared and processing the renewal application is complete. When the license is renewed, the Authority will notify the applicant and provide the applicant updated proof of licensure that includes a unique license number, the licensee name(s), the operational name, the effective date of the license, and address of the licensed premises.
Statutory/Other Authority: ORS 475A.235, ORS 475A.483
Statutes/Other Implemented: ORS 475A.235, ORS 475A.483

AMEND: 333-333-4480

RULE SUMMARY: 333-333-4480: Require service centers to maintain a list of facilitators

CHANGES TO RULE:

333-333-4480
Service Center Privileges and Prohibitions
(1) A service center may:¶
(a) Between the hours of 6:00 AM and 11:59 PM local time, sell psilocybin products and provide psilocybin services to clients 21 years of age or older.¶
(b) Purchase, possess or receive psilocybin products from a manufacturer or service center.¶
(c) Transfer psilocybin products to a manufacturer or service center, subject to product quantity limits in OAR 333-333-2200.¶
(2) A service center must begin every administration session at a time that allows the minimum duration of that session described in OAR 333-333-5250 to elapse prior to 11:59 PM local time.¶
(3) A service center must collect tax on all psilocybin products sold to clients and document the sale of all products and services in the manner required by OAR 333-333-5180.¶
(4) A service center must create and maintain policies and procedures for possession and storage of firearms and other weapons on the licensed premises.¶
(5) A service center may not:¶
(a) Discount a psilocybin product or offer a psilocybin product for free. ¶
(b) Permit a client to bring psilocybin products onto the licensed premises or take any psilocybin product from the licensed premises.¶
(c) Sell or offer for sale any psilocybin product that does not comply with the requirements of ORS chapter 475A or these rules.¶
(6) A licensee representative of a service center may not assist a client with any of the activities required to be performed by a client support person pursuant to OAR 333-333-5070(5)(d), (f), (g) or (m).¶
(7) Service centers may permit clients to bring any food item and non-alcoholic beverage onto the licensed premises for consumption subject to the requirements of OAR 333-333-5170 and 333-333-4400. Service centers must store food items that require refrigeration at a temperature of 41 degrees Fahrenheit or less.¶
(8) Service centers may provide packaged food and beverages to clients and food that was prepared offsite at a restaurant or other facility licensed under ORS chapter 624. If food will be provided during an administration session, service centers must discuss client's dietary needs, restrictions and preferences prior to beginning the administration session.¶
(9) Service centers may not provide food items or beverages to clients that were prepared on the licensed premises. This rule does not prevent a service center from providing heated or unheated water to clients.¶
(10) Licensed service centers may not promote unregulated cultivation and processing of psilocybin products by offering for sale spores, mycelium or materials used to cultivate and process psilocybin products.¶
(11) In addition to the logs required by OAR 333-333-4400(3), service centers must:¶
(a) Create and maintain a list of all facilitators who have provided psilocybin services at the licensed premises in a form and manner prescribed by the Oregon Health Authority (Authority). ¶
(b) Provide the information described in subsection (a) of this section to the Authority upon request in a form and manner prescribed by the Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.305
Statutes/Other Implemented: ORS 475A.235, ORS 475A.305

AMEND: 333-333-4520

RULE SUMMARY: 333-333-4520: Amend Client Bill of Rights to remove obsolete reference

CHANGES TO RULE:

333-333-4520
Client Bill of Rights
(1) A service center must post the following "Client Bill of Rights" in a prominent location within the licensed premises and must provide every client with a copy during their preparation session:¶
"Clients receiving psilocybin services in Oregon have the following rights:¶
To be treated with dignity and respect while receiving psilocybin services.¶
To receive competent and equitable care consistent with values, policies, and practices that ensure all people, especially those who have been historically marginalized based on race, ethnicity, religion, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances are considered in the development of social pathways to health equity.¶
To be free from physical, sexual, psychological, and financial abuse before, during, and after receiving psilocybin services.¶
To make decisions without coercion or undue influence. To be informed of the known benefits and risks associated with psilocybin services.¶
To refuse psilocybin services prior to beginning an administration session.¶
To privacy and confidentiality regarding participation in psilocybin services.¶
To refuse to release any information to third parties, except as required by law. Information may be required to be released by law when a client initiates a complaint, when communications reveal an intent to cause harm to others or disclose that a minor may have been a victim of abuse, or when responding to an investigation by the Oregon Health Authority.¶
To full disclosure of any facilitator conflicts of interest.¶
To a full and accurate explanation of the costs associated with receiving psilocybin services before receiving those services.¶
To store personal belongings securely while receiving psilocybin services.¶
To access their client records after providing reasonable notice to a facilitator or service center and to correct information that is inaccurate.¶
To request a private space in which to receive psilocybin services.¶
To be monitored and supported by a licensed facilitator for the duration of psilocybin services until it is safe for the client to leave the service center.¶
To receive psilocybin services from a licensed facilitator for the duration of those services, except in cases of emergency.¶
To access service centers and psilocybin services that are welcoming and accessible to people with disabilities.¶
To have access to a clean, single occupancy restroom for the duration of psilocybin services.¶
To discuss this Bill of Rights with licensed facilitators and service center operators without facing discrimination or retaliation.¶
To report violations of this Bill of Rights to the Oregon Health Authority, or other appropriate governing body, without facing discrimination or retaliation.¶
To withdraw or alter my consent to receive psilocybin services at any time prior to beginning an administration session.¶
To withdraw or alter my consent to release information. ¶
To receive information regarding culturally and linguistically responsive services offered to support client safety. ¶
To receive services in a manner that considers my individual conditions, sensitivities and health concerns.¶
To be fully informed of a service center's policies on possession of firearms and other weapons on the licensed premises.¶
To make complaints to the Oregon Health Authority regarding psilocybin products and services.¶
~~To receive prior notice of any service center licensee representatives who may be present in the client administration area to assist with operations.¶~~
To choose their facilitator and request an opportunity to receive psilocybin services from an alternate facilitator. Facilitators and service centers may decline services to a client for any reason."¶
(2) The text of the Client Bill of Rights may not be altered and must be printed in an easily legible font.¶
(3) A facilitator or service center must provide the Client Bill of Rights in other languages or accessible formats upon a client's request.¶

(4) A facilitator or service center must provide the Client Bill of Rights to a client prior to a preparation session upon the client's request.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4620

RULE SUMMARY: 333-333-4620: Clarify security video requirements for recording equipment to differentiate between required and optional video recording

CHANGES TO RULE:

333-333-4620
Required Security Video Recording Equipment
(1) A licensed premises must have a fully operational video recording system.~~¶~~
~~(2) V~~ to ensure security of the licensed premises.¶
(2) Required video recording equipment must, at a minimum:¶
(a) Consist of:¶
(A) Digital or network video recorders.¶
(B) Cameras capable of meeting the requirements of OAR 333-333-4630 and this rule.¶
(C) Video monitors.¶
(D) Digital archiving devices.¶
(E) A minimum of one monitor on premises capable of viewing video.¶
(F) Interface devices, if required to adequately operate system or machinery such as a mouse and keyboard.¶
(b) Have the capability of producing a printable image from any camera image.¶
(c) Have sufficient battery backup to support a minimum of one hour of recording time in the event of a power outage.¶
(3) Except for mounted cameras and video monitors, all required video recording equipment and recordings ~~required by this rule~~, must be stored in a locked secure area that is accessible only to authorized licensee representatives, Oregon Health Authority (Authority) employees and contractors, and other state or local government officials that have jurisdiction over some aspect of the licensed premises or licensee. The requirements of this section do not apply to recordings that are stored on a cloud-based platform. ¶
(4) Video monitors that are placed outside of the secure area identified in section (3) of this rule must only be viewable by licensee representatives, facilitators, Authority employees and contractors, and other state or local government officials that have jurisdiction over some aspect of the licensed premises or licensee. ¶
(5) Video recording equipment may not record audio, unless authorized pursuant to OAR 333-333-4640.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4630

RULE SUMMARY: 333-333-4630: Clarify security video requirements for camera coverage to differentiate between required and optional video recording

CHANGES TO RULE:

333-333-4630
Required Security Camera Coverage and Camera Placement
(1) A licensed premises ~~must~~is required to have camera coverage, if applicable, for:¶
(a) All points of ingress and egress to and from indoor areas of the licensed premises, unless those points are located within a client administration area.¶
(b) All areas where psilocybin products are stored or produced.¶
(c) All areas where psilocybin waste is required to be stored, destroyed or rendered unusable as required by OAR 333-333-8000.¶
(2) A licensee must ensure that all required cameras are placed so that they capture clear and certain images of any individual and activity occurring:¶
(a) All points of ingress and egress to and from indoor areas of the licensed premises.¶
(b) In all locations on the licensed premises where psilocybin products are produced or stored.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4640

RULE SUMMARY: 333-333-4640: Clarify optional video recording requirements for optional recording of administration sessions.

CHANGES TO RULE:

333-333-4640
Video Recordings of Administration Sessions
(1) A service center licensee may not install video recording equipment in client administration areas. Service centers may make video and audio recordings of administration, preparation and integration sessions using portable equipment with the prior written consent provided in a form and manner prescribed by the Oregon Health Authority (Authority) of every client, facilitator and client support person who will be recorded. Service center licensees and facilitators may not permit clients to record administration, preparation and integration sessions using their own recording equipment. No person, including clients, facilitators, licensee representatives or clients support persons, may record an administration, preparation or integration session without obtaining prior written consent as required by this rule.¶
(2) Service centers must make recordings made under this rule available to the clients and facilitators who were recorded to view upon request at the service center's licensed premises. Service centers must create and maintain records that documents when and to whom recordings are made available. Service centers are prohibited from charging a fee to view recordings.¶
(3) Service centers must securely store recordings made under this rule and may not publish, share or otherwise distribute, to any person, including persons recorded, without the obtaining the prior written consent of every person recorded using the form described in OAR 333-333-4810(3) or as otherwise allowed under ORS 475A.450.¶
(4) Licensee representatives of a service center may only access recordings made under this rule under the following circumstances:¶
(a) To provide access to clients and facilitators who have been recorded.¶
(b) With prior written consent described in section (3) of this rule.¶
(c) To provide access to the ~~Oregon Health Authority (Authority)~~Authority or law enforcement when required by ORS 475A.450 or these rules.¶
(5) Service centers must retain recordings made under this rule for a period of five years. If a service center license is revoked, surrendered or expired the Authority may address in an order the manner and condition under which recordings held by the licensee must be maintained, destroyed or transferred to other licensees.¶
(6) Clients, facilitators and client support persons may withdraw their written consent described in section (1) of this rule at any time prior to beginning an administration session.¶
(7) Clients, facilitators and client support persons may withdraw their written consent described in section (3) of this rule at any time.¶
(8) Recordings made under this rule are not subject to OAR 333-333-4620 and OAR 333-333-4630, except that any video recordings of administration sessions in the licensee's possession must be provided to the Authority upon request.
Statutory/Other Authority: ORS 475A.235, ORS 475A.305
Statutes/Other Implemented: ORS 475A.235, ORS 475A.305

AMEND: 333-333-4650

RULE SUMMARY: 333-333-4650: Clarify security video requirements for recording at licensed premises to differentiate between required and optional video recording

CHANGES TO RULE:

333-333-4650
Security Video Recording Requirements for Licensed Facilities
(1) ~~A~~To ensure security of the licensed premises, a service center, manufacturer or laboratory licensee ~~must~~is required to have cameras that continuously record, 24 hours a day:¶
(a) In all areas where psilocybin products are produced or stored on the licensed premises.¶
(b) In all areas where psilocybin waste may be present on the licensed premises.¶
(c) All points of ingress and egress to and from: ¶
(A) Indoor areas of the licensed premises.¶
(B) Areas where psilocybin products are produced or stored.¶
(C) Areas where psilocybin waste may be present.¶
(2) A service center, manufacturer or laboratory licensee must:¶
(a) In all areas where camera coverage is required, use cameras that record at a minimum resolution of 1280 x 720 px and record at 10 fps (frames per second).¶
(b) Use cameras that are capable of recording in all lighting conditions.¶
(c) Retain video recordings for a minimum of 30 calendar days.¶
(d) Maintain video recordings in a format approved by the Oregon Health Authority (Authority) that can be easily accessed for viewing and easily reproduced.¶
(e) Upon request of the Authority, keep video recordings for periods exceeding the retention period specified in subsection (2)(c) of this rule.¶
(f) Have the date and time embedded on all video recordings without significantly obscuring the picture.¶
(g) Archive video recordings in a format that ensures authentication of the recording and guarantees that no alteration of the recorded image has taken place.¶
(h) Make video recordings available immediately upon request to the Authority in a format specified by the Authority for the purpose of ensuring compliance with ORS chapter 475A and these rules regardless of whether the recordings are stored on the licensed premises or on a cloud-based platform.¶
(i) Ensure that only authorized licensee representatives, Authority employees and contractors, and other state or local government officials that have jurisdiction over some aspect of the licensed premises or licensee have access to video recordings. ¶
(3) Notwithstanding the requirements in section (1) of this rule a service center, manufacturer or laboratory licensee may stop recording in areas where psilocybin products are not present due to seasonal closures or periods of inactivity.¶
(a) At least 24 hours before stopping recording, a licensee must submit written notice to the Authority by electronic mail using a designated form as published by the Authority on its website and the notice must include:¶
(A) A description of the total number and location of cameras that will be deactivated.¶
(B) The date and time recording will stop.¶
(C) An explanation for why recording will be stopped.¶
(D) The date and time recording will resume.¶
(b) A licensee must resume all required recording no later than the date and time specified in the notice submitted under subsection (a) of this section.¶
(c) A licensee may not engage in any licensed privileges in any areas where recording was stopped under this section.¶
(4) Recordings made under this rule are not subject to OAR 333-333-4640.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4660

RULE SUMMARY: 333-333-4660: Clarify security video requirements for location and maintenance of equipment to differentiate between required and optional video recording

CHANGES TO RULE:

333-333-4660
Location and Maintenance of Required Security Video Equipment
(1) Except as provided in OAR 333-333 4620(3), a service center, manufacturer or laboratory licensee must house the required recording equipment in a designated, locked, and secured room or other enclosure within the licensed premises with access limited to:¶
(a) The licensee, licensee representatives, and authorized personnel.¶
(b) Employees of the Oregon Health Authority (Authority).¶
(c) Service personnel or contractors.¶
(2) A service center, manufacturer or laboratory licensee must keep a current list of all authorized employees and service personnel who have access to the required video recording system and room on the licensed premises.¶
(3) Service center, manufacturer or laboratory licensees must keep a video recording equipment maintenance activity log on the licensed premises to record all service activity for the required video equipment including the identity of any individual performing the service, the service date and time and the reason for service to the video recording system.¶
(4) Service center, manufacturer or laboratory licensees must keep a video recording equipment outage log on the licensed premises to record all camera outages lasting more than 30 minutes for the required video equipment. The log must identify the cameras affected and record time and duration of the outage.¶
(5) Off-site monitoring of the licensed premises by a licensee or an independent third-party is authorized if standards exercised at the remote location meet or exceed all standards for on-site monitoring. Off-site monitoring may not be used to satisfy the requirements of OAR 333-333-5200(4).
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4820

RULE SUMMARY: 333-333-4820: Clarify requirements for client records that are not described in rule

CHANGES TO RULE:

333-333-4820
Record Retention
(1) Licensees shall store, maintain and destroy records, including client records, in a manner that prevents unauthorized access, protects client confidentiality and prevents alteration of client records.¶
(a) All client records and copies of client records, including records created by facilitators, must be stored at the service center where the client participates or intends to participate in an administration session. No client records, nor copies of client records may be stored at a location other than the service center where the client participates or intends to participate in an administration session except for client records that are transferred due to license surrender pursuant to the requirements of OAR 333-333-4280. ¶
(b) Service centers may store electronic records on cloud-based platforms that use security measures to effectively prevent unauthorized access and protect client confidentiality. Electronic records must be accessible at the licensed premises. Electronic records stored pursuant to this subsection are considered to be stored at the service center.¶
(c) If additional documentation regarding client participation in preparation, administration and integration sessions that is not required by these rules is created, it must be promptly incorporated into the client records. ¶
(2) Unless otherwise specified in these rules, licensees must retain required records for a period of five years. For example, licensees must retain security video required by OAR 333-333-4650 for a period of 30 calendar days.¶
(3) Facilitators must inform clients of the service center location which receives and stores the clients' records. Service centers must allow current and former clients to access and examine their own client records and request an addendum to those records. Following the retention period described in section (2) of this rule a service center must destroy client records upon the client's request.¶
(4) Service centers must allow facilitators who will provide or have provided psilocybin services at the service center to access and examine client records related to those services. Facilitators may not access the records of other clients without the client's prior written consent and may not alter the records.¶
(5) Licensee representatives of a service center may not access client records, without the client's prior written consent, unless doing so is necessary to support operations of the service center where the client has received or will receive psilocybin services.¶
(6) Service centers must create and retain a confidentiality plan that describes practices and procedures for storing and maintaining records on the licensed premises in a manner that prevents unauthorized access, protects client confidentiality and prevents alteration of client records. This plan must be provided to the Oregon Health Authority (Authority) upon request.¶
(7) If a service center license is revoked, surrendered or expired the Authority may address in an order the manner and condition under which client records held by the licensee must be destroyed or transferred to other licensees.¶
(8) If a service center requests to surrender its license the Authority may grant permission in writing for the service center to destroy client records or transfer the records to another service center after completing client consent forms described in OAR 333-333-4810(2).
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4910

RULE SUMMARY: 333-333-4910: Require reporting of number of clients who opt out of data submission; clarify requirements for expired licenses to report.

CHANGES TO RULE:

333-333-4910
Required Reporting of Data
(1) ~~Beginning March 31, 2025, a~~All data required to be submitted under this rule must be submitted in a form and manner prescribed by the Oregon Health Authority (Authority) on a quarterly basis no later than the 25th calendar day following the last day of the quarter. The last days of each quarter are March 31, June 30, September 30 and December 31 of every calendar year. Reporting for these periods must be made no later than April 25, July 25, October 25 and January 25 of every calendar year. Data required to be submitted under this rule must be reported by service center licensees and licensee representatives who have been designated in a form and manner prescribed by the Authority. ¶
(a) The reporting obligation by service centers applies to each quarter of reporting that the service center was licensed. If a service center's license expires, the center is responsible for reporting data in accordance with this rule for each quarter in which the license was valid. ¶
(b) For a service center that has not submitted a renewal application and whose license will expire, the Authority will provide an opportunity for the service center to access the reporting system for purposes of reporting data required by this rule before the license expires. ¶
(2) A service center must aggregate and submit the following aggregated 303 client data that pertains to the previous quarter for clients who participated in an administration session at the licensed premises, except for clients who have requested that their data be withheld from being submitted to the Authority:¶
(a) The race, ethnicity, preferred spoken and written languages, disability status, sexual orientation, gender identity, income, age, veteran status and if applicable the county of residence.¶
(b) The reasons, or reasons, for which clients requested psilocybin services.¶
(3) A service center must aggregate and submit the following aggregated 303 service center data that pertains to the previous quarter for psilocybin services provided at the licensed premises.¶
(a) The number of clients served by participating in an administration session.¶
(b) The number of individual administration sessions provided.¶
(c) The number of group administration sessions provided.¶
(d) The number of individuals to whom the psilocybin service center or a facilitator denied psilocybin services by declining to allow the individual to participate in an administration session following completion of a preparation session and the reasons for which psilocybin services were denied.¶
(e) The number of clients who requested that their 303 client data be withheld from data submitted to the Authority.¶
(4) A service center must compute and submit the following averaged 303 service center data that pertains to the previous quarter for psilocybin services provided at the licensed premises.¶
(a) The average number of times per client that a client participated in an administration session.¶
(b) The average number of clients participating in each group administration session.¶
(c) The average dose of psilocybin per client per administration session measured in milligrams of psilocybin analyte.¶
(5) A service center must compile records of adverse reactions required by OAR 333-333-5100(1)(g) and aggregate and submit the following aggregated data that pertains to the previous quarter:¶
(a) The number of severe adverse behavioral reactions experienced by clients who participated in an administration session at the licensed premises.¶
(b) The number of adverse behavioral reactions experienced by clients who participated in an administration session at the licensed premises.¶
(c) The number of severe adverse medical reactions experienced by clients who participated in an administration session at the licensed premises.¶
(d) The number of adverse medical reactions experienced by clients who participated in an administration session at the licensed premises.¶
(6) A service center must compile records of post-session reactions, aggregate the information, and submit the aggregated number of post-session reactions that pertain to the previous quarter.¶
(7) Service centers must report data in a manner that prevents unauthorized access and protects client confidentiality. Data may only be reported to the Authority and may not be shared except for licensee representatives of the service center that collect and maintain the data. ¶
(8) Failure to comply with this rule is a category V violation as described in OAR 333-333-6200.

Statutory/Other Authority: ORS 475A.372, Oregon Laws 2025, chapter 147
Statutes/Other Implemented: ORS 475A.372, Oregon Laws 2025, chapter 147

AMEND: 333-333-5000

RULE SUMMARY: 333-333-5000: Remove requirement to meet other clients and employees prior to client consuming psilocybin.

CHANGES TO RULE:

333-333-5000
Preparation Session Requirements
(1) A facilitator must complete a preparation session with every client who will participate in an administration session at least 24 hours but no more than 90 days prior to the commencement of the client's first administration session with the facilitator. All required forms and prior written consent described in this rule must be signed and completed prior to a client participating in an administration session. If different facilitators will conduct a client's preparation session, administration session or integration session, the client must provide written consent as described in subsection (9)(g) of this rule. A client must have an opportunity to approve and meet any facilitator who will provide psilocybin services prior to receiving services from that facilitator. Any facilitator who was not present for a client's preparation session must review the forms and documents required by this rule before providing psilocybin services to a client.¶
(2) Preparation sessions required under this rule must be conducted privately with each individual client to allow clients to share personal information.¶
(3) For every client who will participate in an administration session, a facilitator must receive a completed client information form as described in OAR 333-333-5050.¶
(4) On or after January 1, 2025, for every client who will participate in an administration session, a service center must receive written confirmation, in a form and manner prescribed by the Oregon Health Authority (Authority), that the client has had an opportunity to request that 303 data related to their receipt of psilocybin services be withheld from data submitted to the Authority.¶
(5) For every client who will participate in an administration session, a facilitator must complete a transportation plan as described in OAR 333-333-5150 in coordination with the client. The transportation plan may not approve a client to operate a motor vehicle, bicycle, or other form of self-operated transportation following the administration session.¶
(6) For every client who will participate in an administration session, a facilitator must coordinate with the client to complete a safety and support plan as described in OAR 333-333-5080.¶
(7) For every client who will participate in an administration session, a facilitator must inquire whether the client requests any culturally and linguistically responsive services. Upon a client's request a facilitator must provide a description of culturally and linguistically responsive services offered by the facilitator and the service center where the client intends to participate in an administration session. If culturally and linguistically responsive services are requested, the facilitator must include a description of culturally and linguistically responsive services that will be provided in the client's safety and support plan described OAR 333-333-5080. ¶
(8) A facilitator must review each of the following documents with a client during a preparation session:¶
(a) Informed consent document as described in OAR 333-333-5040.¶
(b) Client Bill of Rights as described in OAR 333-333-4520.¶
(c) Product information document as described in OAR 333-333-2410 for any products that may be consumed during an administration session, except as provided in OAR 333-333-2410(2).¶
(d) Documentation of the fees charged for provision of psilocybin services prepared in coordination with the service center. This documentation must indicate whether fees for services will be paid to the service center or directly to the facilitator. This documentation must describe applicable refund policies for psilocybin services and any additional fees, including but not limited to cancellation fees, that could be charged to the client. Documentation required by this subsection must be provided to a client prior to collecting any money from the client for psilocybin services.¶
(e) Documentation of the price charged for sale of psilocybin products prepared in coordination with the service center. This documentation must list product prices separately from taxes as required by OAR 333-333-5180. Documentation required by this subsection must be provided to a client prior to collecting any money from a client for psilocybin products.¶
(f) Applicable sections of the service center emergency plan required by OAR 333-333-4460.¶
(g) The service center's policy on possession of firearms and weapons required by OAR 333-333-4480(4).¶
(9) In addition to the documents required by sections (3), (4), (5), (6) and (8) of this rule, a facilitator must obtain prior written consent from a client for the following activities and circumstances:¶
(a) Participation in a group administration session, including the opportunity to meet ~~other clients and~~ facilitators participating in the group session as described in OAR 333-333-5020.¶
(b) Use of supportive touch during an administration session, if any, as described in OAR 333-333-5120(~~7~~8).¶

(c) Participation in a training practicum, including information regarding training program students and instructors who will be present during the client's administration session. The client must have an opportunity to meet any students or instructors who will be present during their administration session prior to the commencement of an administration session.¶
(d) Video or audio recording of an administration session pursuant to requirements of OAR 333-333-4640.¶
(e) Presence of an interpreter or client support person allowed by OAR 333-333-5070, in the administration area during an administration session.¶
(f) Sharing of identifiable client data as described in OAR 333-333-4810(2).¶
(g) The use of different facilitators to conduct a client's preparation, administration sessions or integration session.¶
(h) Consuming secondary doses of psilocybin products after the administration session has begun, including the maximum amount of psilocybin analyte that a client has agreed to consume, not to exceed 50 mg of psilocybin analyte.¶
(i) ~~Participating in an administration session where licensee representatives of a service center will be present pursuant to OAR 333-333-5200(9).¶~~
~~(j)~~ Disclosure form for de-identified client data required by OAR 333-333-4810(5).¶
(10) If a facilitator or service center intends to share de-identified data related to the client's receipt of psilocybin product or services, a facilitator or service center must provide a disclosure form required by OAR 333-333-4810(5) during the client's preparation session.¶
(11) During a preparation session, facilitators must provide clients an opportunity to discuss internal and external factors that could impact a psilocybin experience including but not limited to the client's intention and expectations. If the client will participate in an outdoor administration session, the facilitator must provide an opportunity to discuss the client's specific concerns that may be relevant to participating in an outdoor administration session, including but not limited to allergies and sensitivity to sun exposure.¶
(12) Preparation sessions may be completed in person or virtually using video conferencing technology.¶
(13) The requirements of this rule may be satisfied by conducting multiple preparation sessions.¶
(14) A facilitator must complete an initial preparation session with every client before conducting an administration session with that client for the first time. After a client completes an initial preparation session at a service center, the client is not required to complete additional preparation sessions prior to participating in an administration session at the same service center for a period of 12 months.¶
(15) If a facilitator does not complete additional preparation sessions as allowed by section (14) of this rule, the facilitator must confirm that the information contained in the client's previously completed client information form remains accurate prior to conducting an administration session. If the previously completed client information form is no longer accurate on the date of the client's proposed administration session, a facilitator must conduct an additional preparation session to complete an updated client information prior to conducting administration sessions.¶
(16) A facilitator must discuss the process for verification of license status and process for making complaints to the Authority during a preparation session.¶
(17) The documents described in sections (8), (9) and (10) of this rule must be provided to a client prior to a preparation session upon the client's request.¶
(18) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.¶
(19) If different facilitators will conduct preparation and administration sessions, the facilitator conducting the administration session must receive and review all forms and documents required to be completed during a preparation session prior to beginning the administration session.¶
(20) Except for practicum site supervisors, lead educators and students participating in a practicum with the client's prior written consent, only the client, and any facilitators and client support persons who will be present during the client's administration session may be present during a preparation session.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340, ORS 475A.372

AMEND: 333-333-5020

RULE SUMMARY: 333-333-5020: Remove requirement to meet other clients prior to consuming psilocybin.

CHANGES TO RULE:

333-333-5020
Group Preparation Sessions
(1) In addition to the requirements of OAR 333-333-5000 facilitators must inform clients who will participate in a group session of additional considerations for participating in group administration sessions including:¶
(a) Safety considerations related to adverse reactions from other clients in the group, appropriate boundaries, using a consent model when interacting with other clients and appropriate touch between clients as described in OAR 333-333-5230(5).¶
(b) Considerations for groups participating in outdoor administration sessions including an understanding that outdoor groups may be required to stay outdoors regardless of individual client preference.¶
(c) The expectation that clients maintain the confidentiality of other clients participating in group sessions. ¶
(2) ~~Clients who will participate in a group administration session must have the opportunity to meet and interact with other clients and any interpreters or client support persons who will participate in the group administration session prior to the session commencing.¶~~
~~(3)~~ Clients who will participate in a group administration session must have an opportunity to meet every facilitator who will participate in the group administration session prior to the session commencing.¶
(4<u>3</u>) The requirement~~s~~ of section~~s~~ (2) ~~and (3)~~ of this rule may be satisfied at any time prior to commencement of the group administration session, including the day of the administration session. Clients must have the opportunity to reschedule their administration session with alternate ~~groups or~~ facilitators after the meetings described in section~~s~~ (2) ~~and (3)~~ of this rule.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

AMEND: 333-333-5120

RULE SUMMARY: 333-333-5120: Amend notice requirements to align with Oregon Laws 2025, Chapter 147 (HB 2387) for facilitators that hold other license types

CHANGES TO RULE:

333-333-5120
Facilitator Conduct
(1) Facilitators have a duty to put clients' interest above their own and to use a standard of care that other reasonable facilitators would use under similar circumstances.¶
(2) A facilitator shall not make any misrepresentations to clients regarding psilocybin products or services, the requirements of ORS 475A.210 to 475A.722 and these rules, or the facilitator's qualifications and experience.¶
(3) A facilitator must use a nondirective facilitation approach to providing psilocybin services to clients during preparation, administration and integration sessions.~~¶~~
~~(~~4, except that a facilitator who has notified the Oregon Health Authority (Authority) of their license status as required by OAR 333-333-5130 is not required to use a nondirective facilitation approach when providing health care or behavioral health care services during preparation and integration sessions.¶
(4) A facilitator who has notified the Authority of their license status as required by OAR 333-333-5130 must provide prior notice of this license status to clients and inform clients whether they will be providing health care or behavioral health care services during preparation and integration sessions.¶
(5) A facilitator shall utilize their training to distinguish between typical side effects of consuming psilocybin and medical emergencies. In the event of a medical emergency, a facilitator must contact emergency responders or other appropriate medical professionals immediately.¶
(~~5~~6) A facilitator shall determine whether they are able to provide psilocybin services to a client. If a facilitator determines that they are unable to provide services to a client for any reason, the facilitator may refer the client to another facilitator.¶
(~~6~~7) If a facilitator has supervisory, evaluative, or other authority over a client, the facilitator shall provide the client an opportunity to receive psilocybin services from another facilitator.¶
(~~7~~8) Facilitators may provide supportive touch during administration sessions when requested by the client and with the client's prior written consent in a form and manner prescribed by the Oregon Health Authority.¶
(a) Supportive touch is limited to hugs or placing hands on a client's hands, feet or shoulders. A facilitator shall not use any other forms of touch, nor permit another person to use any other form of touch during an administration session, except for client support persons who perform activities identified in a written support person plan pursuant to OAR 333-333-5070.¶
(b) Clients participating in a group administration session may provide prior written consent to authorize supportive touch from other clients participating in the administration session. Supportive touch is limited to hugs or placing hands on a client's hands, feet or shoulders.¶
(~~8~~9) A facilitator shall not assist a client with any of the activities required to be performed by a client support person pursuant to OAR 333-333-5070(5)(d), (f), (g) or (m).¶
(~~9~~10) A facilitator shall not engage in any romantic relationship, sexual contact, or sexual intimacy with a client during the provision of psilocybin services including preparatory, administration, and integration sessions.¶
(1~~0~~1) A facilitator shall not engage in any romantic relationships, sexual contact, or sexual intimacy with clients, or clients' partners or immediate family members, for a period of one year following the last date that the facilitator provided psilocybin services to the client.¶
(1~~1~~2) A facilitator may not engage in any financial transactions with clients or the client's partners or immediate family members that violate a facilitator's duty to place client's interests above their own as required by section (1) of this rule.¶
(1~~2~~3) If a facilitator is a mandatory reporter of abuse under Oregon law, the facilitator must disclose their status and obligations to a client at the beginning of the client's first preparation session.¶
(1~~3~~4) A facilitator may not supervise individuals experiencing the effect of consuming psilocybin products at any location other than a service center except as allowed by section (14~~5~~) of this rule.¶
(14~~5~~) These rules do not prevent a facilitator from:¶
(a) Participating in harm reduction activities at festivals and events, via telephone hotlines and mobile applications, or in other situations when unforeseen circumstances arise that require harm reduction support. ¶
(b) Supervising individuals experiencing the effect of consuming psilocybin products during federally approved research and clinical trials.¶
(c) Supervising individuals experiencing the effect of consuming psilocybin products at locations outside of Oregon if they hold the necessary license or authorization or it is otherwise lawful to do so in that location.¶
(15~~6~~) The requirements of th~~is~~ese rules apply to all facilitators, regardless of whether a facilitator is also a licensee

representative of a service center.¶
(17) The requirements of these rules apply to all facilitators, regardless of whether multiple facilitators provide services to the same client, or whether a lead or primary facilitator has been designated.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340, Oregon Laws 2025, chapter 147
Statutes/Other Implemented: ORS 475A.340, Oregon Laws 2025, chapter 147

AMEND: 333-333-5130

RULE SUMMARY: 333-333-5130: Amend scope of practice to align with Oregon Laws 2025, Chapter 147 (HB 2387) for facilitators that hold other license types

CHANGES TO RULE:

333-333-5130
Facilitator Scope of Practice
(1) A facilitator shall not engage in any conduct that requires additional professional licensure while providing psilocybin services to clients, including but not limited to diagnosing and treating physical or mental health conditions.¶
(2) A facilitator is prohibited from transferring, selling or otherwise handling any psilocybin product while they are facilitating a preparation, administration or integration session, regardless of whether the facilitator is also a licensee representative of a service center.¶
(3) If a facilitator holds a professional license in another field, the facilitator shall not exercise the privileges of that license while providing psilocybin services to clients during preparation, administration or integration sessions.¶
(4) A facilitator may only conduct administration sessions at a licensed psilocybin service center~~, except as otherwise permitted in OAR 333-333-5120(14)~~. .(5) A facilitator who holds a license issued by the following boards must notify the Oregon Health Authority (Authority) in a form and manner prescribed by the Authority:¶
(a) The Oregon Board of Licensed Professional Counselors and Therapists.¶
(b) The Oregon Board of Naturopathic Medicine.¶
(c) The Oregon Board of Psychology. ¶
(d) The Oregon Medical Board. ¶
(e) The Oregon State Board of Nursing. ¶
(f) The State Board of Licensed Social Workers.¶
(g) The State Board of Pharmacy.¶
(6) Notwithstanding section (1) and (3) of this rule, a facilitator who has notified the Authority of their license status as required by section (5) may provide health care or behavioral health care services during preparation and integration sessions as long as the facilitator also notifies the client prior to providing health care or behavioral health care services. ¶
(~~5~~7) A facilitator is prohibited from providing psilocybin services in a manner that violates these rules.¶
(~~6~~8) A facilitator is prohibited from providing psilocybin services in a manner that violates any provision of ORS chapter 475A.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340, Oregon Laws 2025, chapter 147
Statutes/Other Implemented: ORS 475A.340, Oregon Laws 2025, chapter 147

AMEND: 333-333-5150

RULE SUMMARY: 333-333-5150: Clarify that licensee representatives may perform required activities described in rule.

CHANGES TO RULE:

333-333-5150
Transportation Plans
(1) A facilitator must create and record a transportation plan in a form and manner prescribed by the Oregon Health Authority for every client who will participate in an administration session.¶
(2) Transportation plans must be signed by the client and describe how the client will access safe transportation away from the service center at the conclusion of an administration session.¶
(3) Transportation plans shall advise a client not to operate a motor vehicle directly following an administration session. Facilitators shall make reasonable efforts to prevent clients from operating a motor vehicle at the conclusion of an administration session. If a client's failure to follow their transportation plan creates a danger to the client's safety or the safety of others, a facilitator must make reasonable efforts to resolve the safety issue.¶
(4) If facilitators are unable to resolve safety issues caused by client's failure to follow their transportation plan after making reasonable efforts required by section (3) of this rule, a facilitator~~s~~ or licensee representative must contact appropriate emergency services.¶
(5) If a client is unable to follow their transportation plan, a facilitator or licensee representative must make reasonable efforts to arrange for alternative transportation.¶
(6) A facilitator must document in writing and retain documentation for all instances in which a client does not follow their transportation plan.¶
(7) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

AMEND: 333-333-5200

RULE SUMMARY: 333-333-5200: Require planning and coordination for client access to multiple days of lower dose administration sessions of 2.5mg or less of psilocybin analyte

CHANGES TO RULE:

333-333-5200
Administration Session Requirements
(1) Administration sessions must be conducted by a facilitator and may only take place within a service center's designated administration area.¶
(2) The requirements of OAR 333-333-5000 and OAR 333-333-5020, if applicable, must be satisfied prior to any client participating in an administration session in an administration area.¶
(3) For clients who intend to consume doses of less than 2.5 mg of psilocybin analyte during administration sessions that occur over the course of multiple days, facilitators shall create a plan with the individual client and coordinate with service centers to ensure the client may access planned administration sessions. This plan must be stored with the client records and made available to the Oregon Health Authority (Authority) upon request. ¶
(4) A facilitator must always be present during administration sessions and shall continuously monitor any client participating in the administration session. Continuous monitoring means that a facilitator must maintain visual and audio contact with clients and monitor clients for signs of physical or emotional distress. Video monitoring or other equipment may not be used to satisfy the requirement to continuously monitor clients.¶
(45) The requirements of section (34) of this rule do not apply to client restroom breaks.¶
(56) A facilitator may take restroom breaks of approximately five minutes or less during an administration session if the facilitator remains on the licensed premises and a service center licensee representative is available to monitor clients.¶
(67) A facilitator or service center may provide recorded music or other recorded audio or visual materials during an administration session as long as the client consents to the use of these materials prior to beginning an administration session. Audio or visual media may not contain images or references to violence or harm to self or others. Facilitators and service centers must exercise reasonable judgement to avoid materials that are likely to cause distress for clients. Facilitators and service centers may only provide audio and visual materials that are non-directive. A client may decline the use of these materials at any time, including during the administration session. ¶
(78) In addition to a facilitator conducting the administration session, at least one licensee representative of a service center license must be present on the licensed premises at all times when an administration session is taking place at a service center. The licensee representative required by this rule may take restroom breaks of approximately five minutes or less during an administration session as long as they remain on the licensed premises and adequate measures to prevent unauthorized access to the licensed premises are in place as required by OAR 333-333-4550. Licensee representatives may traverse through client administration areas to access restrooms as long as they do not interfere with client administration sessions. If the licensee representative required by this rule holds a facilitator licensee, they are prohibited from transferring, selling or otherwise handling any psilocybin product while they are facilitating a preparation, administration or integration session.¶
(89) Except for individuals described in OAR 333-333-5070 and service centers acting as practicum sites, only clients, facilitators and licensee representatives of a service center may be present during an administration session.¶
(910) Licensee representatives of a service center who are present during an administration session:¶
(a) May not provide psilocybin services.¶
(b) May only be present to assist with operations and must leave the administration area after assisting with operations. ¶
(c) Shall not interfere with or otherwise participate in the administration session.¶
(d) May not share or disclose any information regarding clients' participation in psilocybin services without the client's prior written consent.¶
(101) A service center may not host administrative sessions for more than 100 clients at any given time regardless of whether the clients are participating in separate individual or group administration sessions.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.340

AMEND: 333-333-5230

RULE SUMMARY: 333-333-5230: Update cross references

CHANGES TO RULE:

333-333-5230
Group Administration Sessions
(1) Group administration sessions may be conducted pursuant to the requirements of OAR 333-333-5020 and this rule. ¶
(2) Client to Facilitator Ratio. The minimum facilitator to client ratio depends on the amount of psilocybin product clients participating in the group administration session will individually consume, including any secondary doses. If the clients consume different amounts of psilocybin, the largest amount consumed will dictate the required facilitator to client ratio. ¶
(a) For clients consuming less than 5 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 25.¶
(b) For clients consuming equal or greater than 5 mg and less than 10 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 15.¶
(c) For clients consuming equal or greater than 10 mg and less than 15 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 8¶
(d) For clients consuming equal or greater than 15 mg and less than 25 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 6. ¶
(e) For clients consuming equal or greater than 25 mg and less than 35 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 4¶
(f) For clients consuming equal or greater than 35 mg and up to 50 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 2.¶
(3) Group administration sessions may not exceed a total of 25 clients, or the service center's maximum occupancy for the administration area where the session takes place whichever is smaller, regardless of the number of facilitators present. ¶
(4) Client administration areas where group sessions take place, must provide an appropriate setting for the group sessions that:¶
(a) Provide sufficient space for clients and facilitators to participate in the session without touching or coming into close physical contact with other clients. Client administration areas where group administration sessions will take place must contain at least twenty-five square feet of area for every person who will be present during the session. ¶
(b) Allows a facilitator to monitor clients as required by OAR 333-333-5200(~~3~~4).¶
(5) Clients participating in a group administration session are prohibited from touching one another except for supportive touch as described in OAR 333-333-5120(~~6~~8). If supportive touch will be used during an administrative session, each participating client must provide prior written consent as described in OAR 333-333-5000(5)(b). ¶
(6) Every client participating in a group session must be provided with an opportunity to request individual support from a facilitator. ¶
(7) If a client becomes disruptive during a group administration session, a facilitator must make reasonable efforts to move that client to a separate area within the administration area that mitigates disruption to the other clients in the group. ¶
(8) Every client participating in a group administration session must be present at the beginning of the session. ¶
(9) Unless explicitly stated in this rule, all requirements of OAR 333-333-5200 apply to group administration sessions.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.340

AMEND: 333-333-6150

RULE SUMMARY: 333-333-6150: Clarify requirements for inspections.

CHANGES TO RULE:

333-333-6150
Inspections
(1) The ~~Authority~~Oregon Health Authority (Authority) may conduct:¶
(a) An inspection of a licensed premises at any time to ensure that a licensee or permittee is in compliance with ORS 475A.210 to 475A.722. and these rules.¶
(b) Compliance transactions in order to determine whether a licensee or permittee is complying with ORS 475A.210 to 475A.722.and these rules.¶
(2) The Authority will provide reasonable notice when inspecting a licensed premises except when unannounced inspections are necessary to ensure compliance with ORS 475A.210 to 475A.722 or these rules. ¶
(3) A licensee or licensee representative shall make their premises available for inspection after receiving notice as described in section (2) of this rule and must comply with the requirements of OAR 333-333-6000(5) to provide authorized Authority representatives access to the licensed premises in a timely manner.¶
(4) A licensee, licensee representative, or permittee must cooperate with authorized Authority representative's reasonable requests during an inspection.¶
(~~4~~5) Authorized Authority representatives will not inspect client administration areas when administration sessions are taking place unless necessary to prevent a serious danger to public health or safety. ¶
(~~5~~6) If a licensee, licensee representative or permittee fails to permit the Authority to conduct an inspection the Authority may issue an investigative subpoena to inspect the licensed premises and gather books, payrolls, accounts, papers, documents or records.
Statutory/Other Authority: ORS 475A.235, ORS 475A.385
Statutes/Other Implemented: ORS 475A.235, ORS 475A.385

AMEND: 333-333-6200

RULE SUMMARY: 333-333-6200: Remove violation for failure to pay civil penalty

CHANGES TO RULE:

333-333-6200
Suspension, Cancellation, Civil Penalties, Sanction Schedule
(1) The Oregon Health Authority (Authority) may suspend or revoke:¶
(a) A license issued under ORS chapter 475A for violation of a provision of ORS chapter 475A or these rules, in accordance with section (4) of this rule.¶
(b) A permit issued under ORS 475A.480 for violation of a provision of ORS chapter 475A or these rules, in accordance with section (4) of this rule.¶
(2) Civil Penalties.¶
~~(a)~~ The Authority may impose a civil penalty under ORS 475A.513, ORS 475A.618, or ORS 475A.654 for violation of a provision of ORS chapter 475A or these rules, in accordance with section (4) of this rule.¶
~~(b) Failure to pay a civil penalty imposed by final order of the Authority is a violation.¶~~
(3) The Authority uses the following violation categories for licensees licensed under ORS chapter 475A:¶
(a) Category I - Violations that pose the highest risk to public health and safety or make a licensee ineligible for a license.¶
(b) Category II - Violations that create a threat or substantial likelihood of a threat to public health or safety.¶
(c) Category III - Violations that create an increased risk to public health or safety.¶
(d) Category IV - Violations that are technical in nature and are inconsistent with the orderly regulation of the testing, sale or manufacture of psilocybin products and the provision of psilocybin services.¶
(e) Category V - Violations of OAR 333-333-4910.¶
(4) Violation sanctions.¶
(a) The Authority may sanction a licensee or permittee in accordance with the guidelines set forth in Exhibit 1, incorporated by reference.¶
(b) Exhibit 1 lists the proposed sanctions for single or repeat violations that occur within a two-year period for each category described in section (3) of this rule. The Authority may allege multiple violations in a single notice and may count violations alleged in notices issued within the previous two-year period toward the total number of violations. In calculating the total number of violations, the Authority may consider a proposed violation for which the Authority has not yet issued a final order.¶
(c) The proposed sanctions in Exhibit 1 are guidelines. If the Authority finds one or more mitigating or aggravating circumstances, it may assess a lesser or greater sanction, up to and including revocation. Mitigating circumstances may decrease the sanction but will not result in dismissal of the violation. The Authority may decrease or increase a sanction to prevent inequity or to take account of particular circumstances in the case.¶
(d) Mitigating circumstances include, but are not limited to:¶
(A) Making a good faith effort to prevent a violation.¶
(B) Extraordinary cooperation in the violation investigation demonstrating the licensee or permittee accepts responsibility.¶
(e) Aggravating circumstances include, but are not limited to:¶
(A) Receiving a prior warning about one or more compliance problems.¶
(B) Repeated failure to comply with laws.¶
(C) Efforts to conceal a violation.¶
(D) Intentionally committing a violation.¶
(E) A violation involving more than one client or employee.¶
(F) A violation involving unwanted or inappropriate touching of a client.¶
(G) A violation involving injury or death.¶
(H) A violation involving the transfer of psilocybin products to anyone other than a client during an administration session.¶
(I) A violation that resulted in a monetary benefit for the licensee or conduct that intended to create a monetary benefit for the licensee.¶
(J) Three or more violations within a two-year-period, regardless of the category, where the number of violations indicate a disregard for the law or failure to control the licensed premises.¶
(5) A licensee may not avoid the sanction for a violation or the application of the provision for successive violations by changing their corporate structure for example, by adding or dropping a partner or converting to another form of legal entity when the individuals who own, operate, or control the licensed entity are substantially similar.
Statutory/Other Authority: ORS 475A.235, ORS 475A.420, ORS 475A.425, ORS 475A.513
Statutes/Other Implemented: ORS 475A.235, ORS 475A.420, ORS 475A.425, ORS 475A.513

RULE ATTACHMENTS MAY NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

333-333-6200
Suspension, Cancellation, Civil Penalties, Sanction Schedule

Exhibit 1

Licensees:

Category	First violation in a 2-year period	Second violation in a 2-year period	Third violation in a 2-year period	Fourth violation in a 2-year period	Fifth violation in a 2-year period
I	Revoke				
II	30-day suspension	Revoke			
III	$2500 civil penalty	$5000 civil penalty	30-day suspension	Revoke	
IV	$500 civil penalty	$2500 civil penalty	$5000 civil penalty	30-day suspension	Revoke
V	$500 civil penalty	$1000 civil penalty	$2500 civil penalty	$5000 civil penalty	30-day suspension

Worker Permits:

Category	First violation in a 2-year period	Second violation in a 2-year period	Third violation in a 2-year period	Fourth violation in a 2-year period	Fifth violation in a 2-year period
I	Revoke				
II	30-day suspension	Revoke			
III	$1250 civil penalty	$2500 civil penalty	30-day suspension	Revoke	
IV	$250 civil penalty	$1250 civil penalty	$2500 civil penalty	30-day suspension	Revoke

AMEND: 333-333-8000

RULE SUMMARY: 333-333-8000: Allow testing laboratories to dispose of waste via compost. Clarify requirements for recording waste.

CHANGES TO RULE:

333-333-8000
Waste Management
(1) A manufacturer, service center or laboratory licensee must store, manage and dispose of solid and liquid wastes generated during production and processing of psilocybin products in accordance with applicable state and local laws and regulations which may include but are not limited to:¶
(a) Solid waste requirements in ORS chapter 459 and OAR chapter 340, divisions 93 to 96.¶
(b) Hazardous waste requirements in ORS chapter 466 and OAR chapter 340, divisions 100 to 106.¶
(c) Wastewater requirements in ORS chapter 468B and OAR chapter 340, divisions 41 to 42, 44 to 45, 53, 55 and 73.¶
(2) Psilocybin waste consisting of psilocybin products that have not been rendered unfit for human consumption must be securely stored and disposed of on the licensed premises or transferred to another licensee for disposal. Licensees must store psilocybin waste in either a limited access area or a locked waste receptacle located on the licensed premises until it is disposed.¶
(3) Psilocybin waste consisting of psilocybin products that have been rendered unfit for consumption may be stored prior to final disposal in a locked dumpster or other locked receptable outside of the licensed premises or may be stored pursuant to section (2) of this rule. Psilocybin products may be rendered unusable by composting, mixing with inactive ingredients, or any other method which renders the product unfit for consumption but does not pose a safety risk for accidental consumption.¶
(4) Manufacturers may dispose of waste, including psilocybin waste, that is a byproduct of cultivation or processing by composting that waste in a secured area on the licensed premises subject to the requirements of OAR 333-333-2010.¶
(5) Laboratories may dispose of psilocybin waste consisting of whole fungi or homogenized fungi that is a byproduct of testing by composting that waste in a secured area on the licensed premises subject to the requirements of OAR 333-333-2010.¶
(6) If a licensee generates psilocybin waste after a harvest or process lot has been recorded, or if psilocybin waste was previously designated as a finished psilocybin product, the licensee must document:¶
(a) A reason ~~for~~that the psilocybin product was recorded as waste in the product tracking system.¶
(b) The exact time and method of destruction or disposal in the product tracking system.¶
(~~6~~7) All psilocybin waste must be disposed of in a manner that effectively prevents spontaneous growth of fruiting bodies or mycelium containing psilocybin. For example, through a controlled composting process or by placing waste in a sealed container.¶
(~~7~~8) ~~Material~~Psilocybin waste that has been d~~esignated as psilocybin waste~~isposed of or destroyed must be ~~disposed of pursuant to this rule within 15 calendar days of such designation and~~recorded as waste in the product tracking system by 11:59 AM on the next calendar day. ¶
(9) Psilocybin waste may not be used for any purpose, including but not limited to the production of psilocybin products.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-8200

RULE SUMMARY: 333-333-8200: Clarify requirements for updating product tracking system data.

CHANGES TO RULE:

333-333-8200
Product Tracking - General Requirements
(1) A service center, manufacturer or laboratory licensee must use the product tracking system as an inventory and recordkeeping system to record and maintain an accurate inventory of psilocybin products as specified in OAR 333-333-8210(1)(b).¶
(2) Each individual service center, manufacturer and laboratory licensee will have access to the product tracking system. A licensee may authorize additional licensee representatives to use the product tracking system for their licensed premises in a form and manner prescribed by the Oregon Health Authority (Authority).¶
(3) Each service center, manufacturer and laboratory licensee must:¶
(a) Maintain an accurate and complete list of all product tracking system users for each licensed premises and must update the list in a form and manner prescribed by the Authority when a new product tracking system user is added or removed.¶
(b) Train and authorize any new product tracking system users before those users are permitted to access the product tracking system or input, modify, or delete any information in the product tracking system.¶
(c) Remove access for any product tracking system user from an associated product tracking system account if that individual is no longer a licensee representative.¶
(d) Correct any data that is entered into the product tracking system in error.¶
(4) Each service center, manufacturer and laboratory licensee is responsible for all actions licensee representatives take while logged into the product tracking system or while otherwise conducting inventory tracking activities.¶
(5) Nothing in this rule prohibits a service center, manufacturer or laboratory licensee from using secondary separate software applications to collect information to be used in its operation including secondary inventory tracking or point of sale systems.¶
(6) If at any point a service center, manufacturer or laboratory licensee loses access to the product tracking system for any reason, the licensee must keep and maintain comprehensive records detailing all tracking inventory activities that were conducted during the loss of access.¶
(a) Once access is restored, all inventory tracking activities that occurred during the loss of access must be entered into the product tracking system.¶
(b) A licensee must document when access to the system was lost and when it was restored.¶
(c) A licensee may not transport any psilocybin product to another licensed premises until such time as access is restored and all information is recorded into the product tracking system unless the Authority has provided written authorization to do so.¶
(7) The Authority may issue a temporary waiver of any requirements of these rules if the product tracking system is unable to perform required functions. Any temporary waiver issued under this section will be published on the Authority's website and will identify the specific rule sections affected and the duration of the waiver.
Statutory/Other Authority: ORS 475A.235, ORS 475A.400
Statutes/Other Implemented: ORS 475A.235, ORS 475A.400