

This draft is being provided to a Rules Advisory Committee for discussion of proposed changes related to Products and Premises. These proposed rules will be considered by the Rules Advisory Committee on July 7 and 9, 2026, and will be published for a public comment period on September 1, 2026, before the final versions are adopted later in 2026. The drafts will continue to evolve throughout the process. Current rules may be found [here](#).

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 ~~a facilitator name or the trade-operational name of a licensee-service center, manufacturer, or laboratory~~ 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;

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- (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.

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(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 and includes practicum observation and consultation.

(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

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(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.

(XX) “Individual applicant” means an individual who is identified on a license application submitted to the Authority and meets the definition of applicant, either in their individual capacity or due to their role in a legal entity applicant.

(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.

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(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.

(XX) “Legal entity applicant” means a legal entity, such as a corporation or partnership, that is identified as an applicant on a license application submitted to the Authority and meets the definition of applicant.

(XX) “Low dose administration session” means an administration session in which a client consumes a total of 2.50 mg or less of psilocybin analyte consisting entirely of psilocybin products that have been designated by a manufacturer for low dose administration sessions as required by OAR 333-333-2320.

(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.

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(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 or curriculum approval of a training program that the licensee(s) or training program will use for purposes of advertising and doing business with the public and, if applicable, includes a registered Assumed Business Name (ABN) that is used as an operational name.

(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.

(xx) “Primary point of contact” means a person designated by an applicant or licensee pursuant to OAR 333-333-4010 who is responsible for ensuring all persons identified as

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licensees or applicants are aware of relevant communications from the Authority, during the license application process and after the license is issued, including but not limited to notices issued under ORS chapter 183.

(68) “Process lot” means homogenized fungi, psilocybin 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.

(xx) “Psilocin analyte” has the meaning described in OAR 333-064-0025. As used in these rules, psilocin analyte refers to content of psilocin analyte as measured by potency tests required by OAR 333-333-7040.

(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.

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(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:

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(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.

(xx) “Total Psilocybin Equivalent” means the sum of psilocybin analyte concentration and 1.4 times the psilocin analyte concentration. This number is the maximum theoretical concentration of psilocybin in the sample.

(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 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” or “UIN” means the most recent unique number generated and assigned by the product tracking system for a psilocybin product and may include cultivation batches, harvest lots, harvest batches, process lots and products in client packaging.

(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 **333-333-**

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333-333-2010

Psilocybin Production

(1) A manufacturer is prohibited from:

- (a) Using manure in cultivation or production of psilocybin products.
- (b) Using wood chips as a growing medium in cultivation or production of psilocybin products.
- (c) Producing psilocybin by using genetically modified organisms such as bacteria.
- (d) Producing psilocybin by chemical synthesis.
- (e) Promoting unregulated cultivation and processing of psilocybin products by providing information or instruction related to home cultivation, or offering for sale spores, mycelium or materials used to cultivate and process psilocybin products, except for sales to other licensed parties as allowed by ORS chapter 475A and these rules.
- (f) Promoting unregulated consumption of psilocybin products, including recommending consumption of psilocybin products at any location other than a service center.

(2) Manufacturers who produce their own compost in cultivation must comply with the following requirements:

- (a) Compost shall not exceed the maximum acceptable pathogen concentrations described in subsection (2)(b) of this rule. Compost that contains any pathogens in amounts that exceed these pathogen reduction requirements shall be designated for additional processing, disposal, or other use as approved by local or state agencies having appropriate jurisdiction.
- (b) Manufacturers that produce their own compost shall ensure that:
 - (A) The density of fecal coliform in compost, that is or has at one time been active compost, shall be less than 1,000 Most Probable Number per gram of total solids (dry weight basis), and the density of Salmonella sp. bacteria in compost shall be less than three Most Probable Number per four grams of total solids (dry weight basis).
 - (B) If using a vessel composting process, active compost is maintained at a temperature of 55 degrees Celsius or higher for a pathogen reduction period of three days.
 - (C) If using a windrow composting process, active compost is maintained under aerobic conditions at a temperature of 55 degrees Celsius higher for a pathogen reduction period of 15 days or longer. During the period when the compost is maintained at 55 degrees Celsius or higher, there shall be a minimum of five turnings of the windrow.
 - (D) If using an aerated static pile composting process, all active compost is covered with 6 to 12 inches thickness of insulating material, and the active compost shall be maintained at a temperature of 55 degrees Celsius or higher for a pathogen reduction period of three days.
- (c) Manufacturers that utilize a windrow composting process or an aerated static pile composting process shall monitor as follows to ensure that the standards in subsection (2)(b) of this rule are met:

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(A) Each day during the pathogen reduction period, at least one temperature reading shall be taken per every 150 feet of windrow, or fraction thereof, or for every 200 cubic yards of active compost, or fraction thereof.

(B) Temperature measurements for pathogen reduction are measured as follows:

(i) Windrow composting processes and agitated bays shall be monitored 12 to 24 inches below the pile surface.

(ii) Aerated static pile composting processes shall be monitored 12 to 18 inches from the point where the insulation cover meets the active compost.

(d) Alternative methods of compliance to meet the pathogen reduction requirements of this section may be approved by the Oregon Health Authority (Authority) if the Authority determines that the alternative method will provide equivalent pathogen reduction.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.290

333-333-2320

Products for Low Dose Administration Session

(1) Psilocybin products designated for consumption by clients during low dose administration sessions must have a ratio of psilocybin analyte to psilocin analyte present in the product which equals or exceeds four parts of psilocybin analyte to one part of psilocin analyte. The ratio as calculated in OAR 333-064-0140 must be greater than or equal to 4.00.

(2) Psilocybin products for low dose administration sessions must contain less than 2.50 mg of psilocybin analyte per package.

(3) Whole fungi may not be consumed during a low dose administration session.

(4) All psilocybin products transferred from manufacturers to service centers must be designated on client packaging using one of the following classifications:

(a) "This product **MAY** be used for low dose administration sessions," or

(b) "This product **MAY NOT** be used for low dose administration sessions."

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

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:

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(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 operational~~ 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) The total psilocybin equivalent measured by the quantity of analyte contained in the product, expressed in milligrams per package, and calculated using laboratory test results required by OAR 333-333-7040.~~

~~(g) A designation for low dose administration sessions using the required text listed in OAR 333-333-2320.~~

~~(hf)~~ A unique identification number as defined in OAR 333-333-1010.

~~(ig)~~ The "best by" date indicating the time that the manufacturer has determined that their product will retain its original quality.

~~(jh)~~ A statement that "Activation times for psilocybin products are variable and cannot be accurately predicted."

~~(ki)~~ 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 must include on a label any other values regarding available, potential or equivalent psilocin or psilocybin that are identified by the laboratory performing tests required by OAR 333-333-7040, including total potential psilocin as defined in OAR 333-064-0025. 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~~

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~~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~~

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 operational~~ name and license number.
 - (b) The ~~business or trade operational~~ 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, ~~including the designation required by OAR 333-333-2320 including information required by OAR 333-333-2400(5).~~
 - (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).

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(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.

(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

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\$~~1000500~~ non-refundable application fee.

(b) An applicant for a facilitator license must pay a US\$~~200150~~ 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~~20,000.

(b) Service Center US\$~~10,000~~20,000.

(c) Facilitator US\$~~2,000~~4,000.

(d) For initial and renewal laboratory license applications received prior to January 1, 2029, Laboratory_ US\$10,000_-

(e) For initial and renewal laboratory license applications received on or after January 1, 2029, US\$20,000

~~(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:~~

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~~(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.~~

~~(36)~~ The Authority will charge a nonrefundable change fee of US\$~~250-500~~ per applicant for any change to a previously approved license that 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.

~~(47)~~ The Authority will charge a nonrefundable change fee of US\$~~250~~1,000 per inspection for any change to a previously approved license that requires an inspection of the licensed premises, ~~or including~~ any inspection of a premises proposed to be licensed that takes place pursuant to OAR 333-333-4210(2) and any inspection for a change of location pursuant to OAR 333-333-4200. 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

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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) An applicant or permittee must notify the Authority in writing using the form published on the Authority's website within 10 business days of any conviction for any felony or any offense under ORS 475A.210 to 475A.722 committed by the applicant or permittee.

~~(43)~~ 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.

~~(54)~~ 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.

~~(65)~~ 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.

(7) An individual designated as a practicum site supervisor must hold a worker permit.

~~(86)~~ If the Authority approves an initial or renewal application and grants a worker permit the permit shall have a term of one year.

~~(97)~~ Once the Authority has made a determination to issue a permit the individual must pay a US\$~~25200~~ fee to receive the permit.

~~(108)~~ If an applicant for an initial worker permit fails to pay the fee or payment fails to clear within ~~180~~ 90 calendar days of receiving notice of the Authority's determination to grant an application, the application will be ~~considered incomplete~~ closed as incomplete.

~~(119)~~ 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's determination to grant an application, the application will be ~~considered incomplete~~ closed as incomplete.

~~(120)~~ 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

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expires. Applications received less than 60 days before the date the permit expires will be considered untimely.

(1~~31~~) 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.

(1~~42~~) 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~~ [ORS 475A.377](#)

Statutes/Other Implemented: ORS 475A.235, ORS 475A.483, ORS 475A.480, ORS 475A.250 & ~~Oregon Laws 2025, chapter 147~~ [ORS 475A.377](#)

333-333-4280

Surrender

(1) A licensee may request to surrender a license ~~in a form and manner prescribed by the by submitting the form published on~~ Oregon Health Authority's (Authority's) [website](#). Each individual ~~person~~ identified as a licensee must submit a separate request, including a product plan and client record plan if applicable. The license remains in effect until the Authority accepts the surrender. The Authority may request additional information and require additional site inspections prior to accepting the surrender.

(2) A service center, manufacturer or laboratory license that requests to surrender its license must submit a products plan, ~~in a form and manner prescribed by the Authority using the form published on the Authority's website~~, in order to complete its surrender request. An identical products plan must be signed by every individual ~~person~~ identified as a licensee and must describe the licensees' plan to dispose of psilocybin products in inventory by destroying the products or transferring psilocybin products to another license in compliance with these rules. All psilocybin products designated as waste or transferred to another license must be recorded in the product tracking system.

(3) A service center that requests to surrender its license must submit a client records plan, ~~using the form published on the Authority's website in a form and manner prescribed by the Authority~~, for approval in order to complete its surrender request. An identical client records plan must be signed by every individual licensee affiliated with the licensed premises and must describe the service center's plan to:

(a) Destroy client records; or

(b) Obtain client's written consent as described in OAR 333-333-4810 and transfer client records to another service center.

(4) The Authority will review product plans and client record plans and may require revisions to plans prior to accepting a surrender request. If the Authority accepts a

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surrender request, the Authority will notify the licensee in writing of the date of acceptance. The licensee must cease all license privileges on this date through the remainder of the licensing period. The licensee must receive a new license before engaging in any licensed activities.

(5) A training program may request to surrender approval of its curriculum using the form published on the Authority's website. in a form and manner prescribed by the Authority. The training program's curriculum approval remains in effect until the Authority accepts the surrender. If the Authority accepts the surrender, the Authority will notify the training programs in writing of the date of acceptance. On or before the date of their surrender, the training program must notify any enrolled students that their curriculum is no longer approved by the Authority.

(6) A permittee may request to surrender their worker permit using the form published on the Authority's website. A worker permit remains in effect until the Authority accepts the surrender. If the Authority accepts the surrender, the Authority will notify the permittee in writing of the date of acceptance.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

333-333-4300

Licensed Premises Location Requirements

(1) A licensed premises may not be located on state or federally owned land.

(2) The interior and exterior areas of a licensed premises may not overlap with:

(a) An area that is licensed or certified or otherwise approved by the Oregon Liquor and Cannabis Commission, under ORS 475C.065, ORS 475C.085, ORS 475C.093 or ORS 475C.097, a licensed premises under ORS chapter 471 or a retail liquor store appointed as an agent.

(b) A medical marijuana grow site registered under ORS 475C.792.

(c) A medical marijuana processing site registered under ORS 475C.815.

(d) A medical marijuana dispensary registered under ORS 475C.833.

(e) An area used as an industrial hemp operation by an industrial hemp grower or handler licensed by the Oregon Department of Agriculture under ORS 571.281.

(f) A health care facility licensed under ORS chapter 441.

(g) An area that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited-service restaurant, single event temporary restaurant, commissary, mobile unit, bed and breakfast, or warehouse licensed under ORS chapter 624.

(h) A residence.

(i) An area that has been issued another license under ORS chapter 475A.

(3) The licensed premises of a service center may not be located:

(a) Except as provided in ORS 475A.310 and OAR 333-333-4130(4), within 1,000 feet of:

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(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.

(b) In an area that is zoned exclusively for residential use within city limits.

(4) A manufacturer with an edible psilocybin production endorsement may not:

(a) Engage in processing in an area that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited-service restaurant, single event temporary restaurant, commissary, mobile unit, bed and breakfast, or warehouse licensed under ORS chapter 624;

(b) Share a food establishment where psilocybin will be produced, with another person or entity; or

(c) Process food intended for commercial sale that does not contain psilocybin.

(5) A manufacturer, service center or laboratory license is prohibited from subletting any portion of the licensed premises.

~~(6) A service center may authorize the temporary use of the licensed premises for activities that are unrelated to the exercise of license privileges. Activities related to the regular operation of the licensed business, such as staff meetings, are not temporary uses.~~

~~(a) The requirements of these rules and ORS 475A.210 to 475A.722 remain in effect during authorized temporary uses and licensees are responsible for any violation of these rules and ORS 475A.210 to 475A.722 that occurs on the licensed premises during an authorized temporary use. Requirements include but are not limited to prohibiting any person under 21 years of age from being present on the licensed premises, preventing access to limited access areas, ensuring that no alcoholic beverages or other intoxicants are consumed during the temporary use, complying with local time, place and manner regulations and following applicable rules on food service.~~

~~(b) A service center must provide advance written notice in the form and manner prescribed by the Oregon Health Authority (Authority) of temporary uses of the licensed premises for activities unrelated to the exercise of licensed privileges at least five business days prior to the authorized temporary uses in the form and manner prescribed by the Authority. Service centers may use a single written notice to provide advance notice of multiple and reoccurring events occurring within 180 days following the date of the notice.~~

~~(c) Psilocybin products may not be sold or transferred, and no psilocybin services may be provided, during an authorized temporary use.~~

~~(d) A licensee representative must be present at the licensed premises for the duration of the authorized temporary use.~~

~~(e) An authorized temporary use may only occur between the hours of 6:00 AM and 11:59 PM local time.~~

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~~(6) A service center may authorize the temporary use of the licensed premises for activities that are unrelated to the exercise of license privileges. Activities related to the regular operation of the licensed business, such as staff meetings, are not temporary uses.~~

~~(a) The requirements of these rules and ORS 475A.210 to 475A.722 remain in effect during authorized temporary uses and licensees are responsible for any violation of these rules and ORS 475A.210 to 475A.722 that occurs on the licensed premises during an authorized temporary use. Requirements include but are not limited to prohibiting any person under 21 years of age from being present on the licensed premises, preventing access to limited access areas, ensuring that no alcoholic beverages or other intoxicants are consumed during the temporary use, complying with local time, place and manner regulations and following applicable rules on food service.~~

~~(b) A service center must provide advance written notice in the form and manner prescribed by the Oregon Health Authority (Authority) of temporary uses of the licensed premises for activities unrelated to the exercise of licensed privileges at least five business days prior to the authorized temporary uses in the form and manner prescribed by the Authority. Service centers may use a single written notice to provide advance notice of multiple and reoccurring events occurring within 180 days following the date of the notice.~~

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.305 & ORS 475A.310

333-333-4310

Service Center Temporary Events

~~(1) A service center may conduct temporary uses of the licensed premises for activities that are unrelated to the exercise of license privileges subject to the requirements of these rules. Activities related to the regular operation of the licensed business, such as staff meetings, are not temporary uses.~~

~~(2) The requirements of these rules and ORS 475A.210 to 475A.722 remain in effect during temporary uses and licensees are responsible for any violation of these rules and ORS 475A.210 to 475A.722 that occurs on the licensed premises during a temporary use. Requirements include but are not limited to prohibiting any person under 21 years of age from being present on the licensed premises, preventing access to limited access areas, required video recording, use of visitor logs and ensuring that no alcoholic beverages or other intoxicants are consumed during the temporary use, complying with local time, place and manner regulations and following applicable rules on food service.~~

~~(3) Psilocybin products may not be sold or transferred, and no psilocybin services may be provided, during a temporary use.~~

~~(4) A licensee representative must be present at the licensed premises for the duration of a temporary use.~~

~~(5) A temporary use may only occur between the hours of 6:00 AM and 11:59 PM local time.~~

~~(6) A temporary use may not occur while a service center's license is suspended.~~

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(7) A service center must provide complete and adequate advance written notice using the form published on the Oregon Health Authority's (Authority's) website of temporary uses of the licensed premises for activities unrelated to the exercise of licensed privileges at least five business days prior to the temporary. Service centers may use a single written notice to provide advance notice of multiple and reoccurring events occurring prior to the expiration, revocation or surrender of the current active license.

(8) Adequate and complete advanced written notice must describe the event in detail and must demonstrate that the event meets the requirements of these rules and ORS 475A.210 to 475.722.

(9) The Authority will provide written confirmation to service centers of whether their advanced notice of temporary use is adequate and complete.

(10) Service centers may not conduct temporary uses of their licensed premises unless the Authority has provided written confirmation that the notice of temporary use is adequate and complete.

(11) A service center must provide complete and adequate advance written notice using the form published on the Authority's website of any proposed changes to recurring authorized temporary uses at least five business days prior to the change.

Statutory/Other Authority: ORS 475A.235 & ORS 475A.305

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.305

333-333-4400

Licensed Premises Operating Requirements

(1) A licensee or permittee may not permit:

(a) A person under 21 years of age to work or be present on a licensed premises except for persons temporarily at the premises to make a service, maintenance, or repair call or for other purposes independent of the premises operations.

(b) On-site sale or transfer of a psilocybin product except for sales and transfers to other licensed premises and retail sales by a service center in connection with an administration session.

(c) On-site consumption of a psilocybin product except for clients consuming psilocybin products at a service center in connection with an administration session.

(d) On-site consumption of any intoxicants by any individual, except for clients consuming psilocybin products during an administration session.

(2) A licensee must clearly identify all limited access areas in accordance with OAR 333-333-4000(3)(f) and OAR 333-333-4550(5).

(3) Log. A licensee must keep a daily log of all licensees, licensee representatives, employees, client support persons, students participating in practicum and permitted visitors who perform work on the licensed premises, except for Oregon Health Authority (Authority) employees and other state or local government officials acting in an official capacity who have jurisdiction over some aspect of the licensed premises or operation.

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The daily log must contain the license number and worker permit number, if applicable, for all individuals listed in the log.

(a) A licensee must record and retain the following information for each current employee and licensee representative and make the information available to the Authority upon request:

(A) For a licensee, employee or licensee representative required to have a worker permit, the permit number and name of the individual as they appear on the worker permit.

(B) For a licensee, employee or licensee representative not required to have a worker permit, the legal name and date of birth of the individual.

(b) All permitted visitors present on the licensed premises must wear or display an item issued by the licensee that visually identifies the individual as a permitted visitor.

(c) Upon client request, facilitators, permitted workers and licensee representatives present at a service center must make reasonable efforts to wear, display or carry an item provided by the licensee that identifies their role at the licensed premises.

(d) All permitted visitors must be supervised by a licensee representative when they are present in limited access areas or any areas where clients may be present.

(e) On the daily log, a licensee must record the name and date of birth as this information is displayed on valid government-issued ID for every contractor who performs work on the licensed premises.

(f) A licensee must maintain a copy of the daily log required by subsection (3)(e) of this rule for a period of at least two years.

(4) Permitted Visitors. The general public is not permitted in limited access areas on a licensed premises. In addition to licensee representatives, the following visitors are permitted to be present in limited access areas on a licensed premises, subject to the requirements of these rules:

(a) Laboratory personnel if the laboratory is licensed by the Authority.

(b) A contractor, vendor or individual or entity providing professional services to a licensee, including media authorized by a licensee representative to be on the licensed premises.

(c) Another licensee or that licensee's representative.

(5) Nothing in this rule is intended to prevent or prohibit Authority employees or contractors, or other state or local government officials that have jurisdiction over some aspect of the licensed premises or licensee from being on the licensed premises.

(6) In addition to the daily log required by section (3) of this rule, service centers must keep a log of all guests who visit the licensed premises, excluding clients, and including but not limited to media and friends and family. All guests who visit the licensed premises must be 21 years of age or older.

(7) A licensee may not sublet any portion of a licensed premises. A service center may authorize the temporary use of a licensed premises subject to OAR 333-333-43~~1000~~(6), excluding limited access areas, for activities that are unrelated to the exercise of license

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privileges. The requirements of these rules and ORS 475A.210 to 475A.722 remain in effect when such activities take place.

(8) A licensed premises may receive psilocybin products only from other licensed premises as allowed by these rules.

(9) A licensee may not allow animals to be present on the licensed premises, except for assistance animals as allowed under ORS 659A.143.

(10) If the licensed premises contains outdoor areas, the boundaries of the licensed outdoor areas must be clearly marked with visible signage or barriers.

(11) Licensees that are required to be registered with the Oregon Secretary of State must register prior to receiving a license and maintain registration, including registration of an Assumed Business Name (ABN) if applicable that is used as an operational name.

(12) Licensee representatives who are not licensees under ORS 475A are prohibited from exercising control over the license.

(13) Manufacturer, service center and laboratory licensees must ensure that conditions at their licensed premises are appropriate to provide safe environments for licensee representatives, clients and other individuals. This includes but is not limited to regularly cleaning the premises, properly addressing safety issues and constructing and maintaining floors, walls, ceilings, counters and surface areas within a licensed premises in a manner that reduces the potential development of microbials, molds and unintended fungi.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.460

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:

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- (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) Service centers may not remove psilocybin products from client packaging for repackaging or any other purpose.
- (11) Licensed service centers may not promote unregulated cultivation and processing of psilocybin products by providing information or instruction related to home cultivation, offering for sale spores, mycelium or materials used to cultivate and process psilocybin products.
- (12) Service centers may not promote unregulated consumption of psilocybin products, including scheduling clients to consume psilocybin at an unlicensed location or recommending that clients consume psilocybin products at any location other than a service center.
- (13) 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.
- (14) Service centers must take reasonable steps to ensure that areas the licensee controls that are adjacent to or outside the licensed premises do not present a safety risk for clients entering and exiting the licensed premises.

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(15) A service center may refuse to provide psilocybin products to a client or potential client for any reason. These rules do not excuse a service center from complying with applicable federal, state and local non-discrimination laws.

Statutory/Other Authority: ORS 475A.235, ~~&~~ ORS 475A.305 & ORS 475A.370

Statutes/Other Implemented: ORS 475A.235, ~~&~~ ORS 475A.305 & ORS 475A.370

333-333-4650

Security Video Recording Requirements for Licensed Facilities

- (1) To ensure security of the licensed premises, a service center, manufacturer or laboratory licensee 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.

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(a) At least 24 hours before stopping recording, a licensee must submit written notice to the Authority ~~by electronic mail~~ using ~~a designated~~the 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

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(34).

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

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333-333-4900

Collection and Maintenance of 303 Client Data

- (1) ~~On and after January 1, 2025, s~~Service centers must collect 303 client data in a manner prescribed by the Oregon Health Authority (Authority), consistent with OAR chapter 950, division 30, by using the form published by the Authority for the current reporting period, on its website prior to beginning an administration session for every client who will participate in an administration session at the licensed premises.
- (2) Service centers, including licensee representatives described in section (3) of this rule, must store, maintain and destroy 303 client data, including 303 client data that is not reported to the Authority pursuant to OAR 333-333-4910, in a manner that prevents unauthorized access and protects client confidentiality.
- (3) 303 client data may only be accessed by licensees and licensee representatives of a service center. Service centers may enter into agreements with individuals and organizations to act as licensee representatives for the purpose of collecting, reporting, storing, maintaining and destroying 303 client data.
- (4) If a service center enters an agreement described in section (3) of this rule, the service center must provide notice to clients, and 303 client data must be stored at the service center or on cloud-based platforms as described OAR 333-333-4820.
- (5) Prior to beginning an administration session, every client must provide written confirmation, ~~in a form and manner prescribed by the~~using the form published on the Authority's website, that the client has had an opportunity to request that 303 client data related to their receipt of psilocybin services be withheld from data submitted to the Authority.
- (6) A service center must collect 303 client data by using the form described in section (1) from every client, even if a client requests their information be withheld from data submitted to the Authority.
- (7) Licensee representatives and facilitators are prohibited from encouraging clients to request that their data be withheld from data submitted to the Authority or otherwise influencing a client's responses to the form described in section (1) of this rule.
- (8) Failure to comply with this rule is a violation.

Statutory/Other Authority: ORS 475A.372 & ORS 413.161

Statutes/Other Implemented: ORS 475A.372 & ORS 413.161

333-333-4910

Required Reporting of Data

- (1) 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

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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) **For doses higher than five milligrams of psilocybin analyte, the average dose of psilocybin per client per administration session measured in milligrams of psilocybin analyte.**

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(d) For doses of five milligrams or less of psilocybin analyte, 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~~ [Oregon Laws 2026, Chapter 109](#)

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

333-333-4930

Reporting of Licensee and Applicant Data

(1) Every individual licensee and applicant associated with a psilocybin license or [new license or renewal](#) application must provide information regarding their race, ethnicity, preferred spoken and written languages, sexual orientation and gender identity of each applicant and licensee in a form and manner prescribed by the Oregon Health Authority.

~~(2) Licensees and applicants who submitted a complete application for a psilocybin license prior to January 1, 2025, must provide the information described in section (1) of this rule on or before March 1, 2025. Failure to do so is a violation.~~

~~(23) Applicants who submit an application for a psilocybin license on or after January 1, 2025, must provide the information described in section (1) of this rule. Failure to submit the information may result in the application being closed as incomplete. in order for the application to be considered complete.~~

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Statutory/Other Authority: ORS 475A.235 & ORS 475A.374

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.374

333-333-5250

Duration of Administration Session

(1) The minimum duration of an administration session shall be dependent on the total amount of psilocybin analyte a client consumes during that session, including any secondary dose consumed.

(a) For clients consuming less than 2.50 mg of psilocybin analyte that designated for low dose administration sessions as described in OAR 333-333-2320, the minimum duration of the administration session shall be 30 minutes for the client's initial administration session at a service center. Except as described in section (2) of this rule, after completing an initial administration session at the service center, the minimum duration shall be 15 minutes when the client participates in any subsequent administration session at the same service center within a period of 12 months following the initial administration session.

(b) For clients consuming products that contain less than 2.50 mg of psilocybin analyte not designated for low dose administration sessions as described in OAR 333-333-2320, the minimum duration of the administration session shall be one hour.

~~(cb)~~ For clients consuming equal or greater than 2.50 mg and equal to or less than 5 mg of psilocybin analyte, the minimum duration of the administration session shall be one hour.

~~(de)~~ For clients consuming equal or greater than 5 mg and less than 10 mg of psilocybin analyte, the minimum duration of the administration session shall be two hours.

~~(ed)~~ For clients consuming equal or greater than 10 mg and less than 15 mg of psilocybin analyte, the minimum duration of the administration session shall be three hours.

~~(fe)~~ For clients consuming equal or greater than 15 mg and less than 25 mg of psilocybin analyte, the minimum duration of the administration session shall be four hours.

~~(gf)~~ For clients consuming equal or greater than 25 mg and less than 35 mg of psilocybin analyte, the minimum duration of the administration session shall be five hours.

~~(hg)~~ For clients consuming equal or greater than 35 mg and up to 50 mg of psilocybin analyte, the minimum duration of the administration session shall be six hours.

(2) Notwithstanding subsection (1)(a) of this rule, the minimum duration of an administration session shall be one hour for clients consuming whole fungi that contains less than 2.5 mg of psilocybin analyte.

~~(23)~~ Upon or after the conclusion of the minimum duration period described in sections (1) and (2) of this rule, a facilitator, in consultation with the client, shall determine whether the administration session should be concluded. If the facilitator and client determine that continuing the administration session is not required to ensure the safety of the client and the public, the administration session may be concluded.

~~(34)~~ If following the consultation described in section (3) of this rule, a facilitator determines that it is appropriate to continue the administration session beyond 11:59 PM

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local time, the service center where the client received services, in consultation with the facilitator, shall notify the Oregon Health Authority (Authority) ~~using the form published on the Authority's website in a form and manner prescribed by the Authority~~ no later than 4:00 PM local time the next calendar day. Notices required by this section must include:

- (a) Start and end time of the administration session.
- (b) Amount each client consumed during the administration session, including any secondary doses.
- (c) Minimum duration of the administration session required by OAR 333-333-5250.
- (d) Whether the administration session was a group session or an individual session.
- (e) For group sessions, the number of clients participating in the administration session.
- (f) The names and worker permit numbers, if applicable, of all facilitators, licensee representatives and other authorized individuals who were present at the licensed service center after 11:59 PM.

~~(45)~~ A facilitator shall record and retain the time and date that each administration session began and concluded ~~using the form published on the Authority's website in a form and manner prescribed by the Authority~~.

~~(56)~~ If a client leaves their administration session prior to the minimum duration described in sections (1) and (2) of this rule the facilitator must document the incident ~~using the form published on the Authority's website in a form and manner prescribed by the Authority~~.

~~(67)~~ A facilitator shall request that every client sign a release document at the conclusion of the administration session which states that the client agrees to end their administration session and follow the terms of their transportation agreement. If a client refuses to sign a release document the facilitator shall create and maintain records ~~in a form and manner prescribed by the Authority that to~~ document the client's refusal ~~using the form published on the Authority's website~~.

~~(78)~~ A facilitator shall attempt to contact every client within 72 hours of the conclusion of the administration session to offer the client information on integration sessions and other services, including but not limited to peer support groups and community resources, in support of a client's ongoing integration needs.

~~(89)~~ When a facilitator contacts clients under section ~~(78)~~ of this rule, the facilitator must inquire whether the client experienced any post-session reactions and, if applicable, document post session reactions ~~using the form published on the Authority's website in a form and manner prescribed by the Authority~~ and share that documentation with the service center where the client participated in an administration session.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.340

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333-333-6030

Laboratory Licensee Prohibited Conduct

(1) In addition to the prohibitions set forth in OAR 333-333-6000, a laboratory licensee may not:

(a) Perform any required psilocybin sampling or testing using any sampling or testing methods or equipment not permitted under the laboratory's accreditation through the Oregon Environmental Laboratory Accreditation Program.

(b) Perform any required psilocybin sampling or testing for any licensed psilocybin manufacturer in which the laboratory licensee has a financial interest.

(c) Receive, possess or perform sampling and testing of psilocybin products from any source other than a licensed premises as allowed by these rules.

(d) Engage in any activity that violates any provision of ORS chapter 475A, OAR chapter 333, division 64 as applicable, or these rules.

(e) Promote unregulated cultivation and processing of psilocybin products by providing information or instruction related to home cultivation, or offering for sale spores, mycelium or materials used to cultivate and process psilocybin products.

(2) Samples of psilocybin products received for tests required by OAR 333-333-7030, OAR 333-333-7040, OAR 333-333-7050, OAR 333-333-7060, OAR 333-333-7070, OAR 333-333-7080 may only be used to perform the compliance test that was ordered and for the purpose of establishing instrument calibration or validating laboratory processes necessary for testing required under ORS 475A.590.

(3) Notwithstanding section (2) of this rule, any unused portions of samples collected and retained for the purpose of performing compliance tests may be used to perform quality control tests pursuant to OAR 333-333-7150 upon a manufacturer's request.

(4) Nothing in these rules prohibits testing laboratory licensees from possessing *Psilocybe cubensis* for purposes of method validation.

(5) The Oregon Health Authority may suspend or revoke a laboratory license for any violation of ORS chapter 475A, OAR chapter 333, division 64, or these rules. The licensee has a right to a hearing under the procedures of ORS chapter 183.

Statutory/Other Authority: ORS 475A.235 & ORS 475A.594

Statutes/Other Implemented: ORS 475A.235

333-333-6100

Advertising Restrictions

(1) Advertising for psilocybin products and services may not:

(a) Contain statements that are deceptive, false, or misleading.

(b) Contain any content that can reasonably be considered to target individuals under the age of 21, including but not limited to images of minors, cartoons, toys, or similar images and items typically marketed towards minors, or references to products that are commonly associated with minors or marketed by minors.

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(c) Encourage activity that is illegal under state law.

(d) Assert that psilocybin products are safe because they are regulated by the Authority or have been tested by a certified laboratory or otherwise make claims that any government agency endorses or supports psilocybin.

(e) Make claims that psilocybin products and services have curative or therapeutic effects or make other health claims that are not supported by the totality of publicly available scientific evidence (including evidence from 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.

(2) A licensee may not make any deceptive, false, or misleading assertions or statements on any informational material, any sign, or any document provided to a consumer.

(3) A licensee commits a violation of this rule if the licensee directs or authorizes licensee representatives, employees, advertising companies, social media influencers, or any other individual or entity to engage in conduct on the licensee's behalf that is prohibited by this rule.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

333-333-6150

Inspections

(1) The 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) An individual named as 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 be present at the time of the inspection.

(4) A licensee 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.

~~(54)~~ A licensee, licensee representative, or permittee must cooperate with authorized Authority representative's reasonable requests during an inspection.

~~(65)~~ 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.

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(76) 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

333-333-6160

Investigations

(1) For purposes of this rule and OAR 333-333-6040, “evidence” includes but is not limited to, physical objects, documents, records, video recordings ~~and~~, interviews with an Oregon Health Authority (Authority) authorized representative, and information recorded in the product tracking system.

(2) An applicant, licensee or permittee must cooperate with the Authority during any investigation of compliance with ORS 475A.210 to 475A.722 and these rules and must promptly provide the Authority with evidence when requested to do so, in a manner specified by the Authority.

(3) The requirement to provide evidence promptly means:

(a) Producing evidence within 10 business days of the Authority’s request unless the Authority grants an extension.

(b) Participating in an interview within a reasonable timeframe identified by the Authority.

(4) As specified in OAR 333-333-6040(4), an applicant, licensee or permittee may not damage, alter or conceal evidence, including but not limited to redacting client records or other information that was unredacted at the time of the Authority’s request.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

333-333-7020

Ordering Tests

(1) A manufacturer must provide to a laboratory, prior to the laboratory taking samples, the following information:

(a) The manufacturer’s license number and endorsement type;

(b) The manufacturer’s name, address and contact information;

(c) Type of psilocybin product;

(d) Unique identification numbers assigned to products that will be sampled;

(e) Total mass or volume of each batch to be sampled; and

(f) Identification of tests requested pursuant to OAR 333-333-7030, OAR 333-333-7040, OAR 333-333-7050, OAR 333-333-7060, OAR 333-333-7070, OAR 333-333-7080 and OAR 333-333-7150.

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(2) If the manufacturer informs a laboratory that a psilocybin product is being re-sampled after a failed test, the manufacturer must provide the laboratory with documentation of the failed test.

(3) A manufacturer is responsible for ordering the compliance tests necessary to comply with OAR 333-333-7010 to OAR 333-333-7150.

(4) A manufacturer may not order more than one compliance test for the same harvest lot, process lot or psilocybin product except as allowed under OAR 333-333-7120.

(5) A manufacturer violates these rules if they:

(a) Fail to provide information required in these rules to a laboratory.

(b) Submit false or misleading information to a laboratory.

(6) Tests ordered under these rules expire after one year. If a test has expired, the psilocybin product must be ~~tested again before it can be sold to a client, transferred to another licensee, or converted to another product type~~ destroyed and designated as waste.

(7) Manufacturers may only order tests for the purposes described in OAR 333-333-7010 to OAR 333-333-7150.

Statutory/Other Authority: ORS 475A.235 & ORS 475A.590

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.590

333-333-7040

Potency Testing

(1) A manufacturer must order tests for every batch of finished psilocybin product from a harvest lot or process lot to determine the concentration (potency) of psilocybin and psilocin in the product.

(2) A laboratory that tests batches of psilocybin products for potency must designate whether the psilocybin product may be used for low dose administration sessions as described in OAR 333-333-2320.

~~(3)~~ A process lot of homogenized fungi, psilocybin extract or edible psilocybin product fails potency testing if the amount of psilocybin or psilocin between primary and duplicate samples taken from the batch exceeds 20.0 percent relative percent difference between samples.

~~(4)~~ In addition to the requirements of section (1) of this rule, a manufacturer must submit one or more batches from a harvest lot or process lot for potency testing upon written request by the Oregon Health Authority.

Statutory/Other Authority: ORS 475A.235 & ORS 475A.590

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.590

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333-333-7050

Solvent Testing

- (1) If methanol or acetic acid are used to manufacture psilocybin extract, a manufacturer must order tests for methanol or acetic acid for every process lot of psilocybin extract prior to selling or transferring the psilocybin extract or converting to another product type.
- (2) A batch fails solvent testing if a laboratory detects the presence of methanol above 3000.0 µg/g or acetic acid above 5000.0 µg/g in any sample.
- (3) If a sample from a batch fails solvent testing, the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.
- (4) A batch that is remediated in accordance with section (3) of this rule, must be re-sampled and re-tested for solvents in accordance with these rules.
- (5) In addition to the requirements of section (1) of this rule, a manufacturer must submit one or more batches from a process lot for solvent testing upon written request by the Authority.

Statutory/Other Authority: ORS 475A.235 & ORS 475A.590

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.590

333-333-7090

Psilocybin Batch Requirements

- (1) A manufacturer must separate each harvest lot of dried whole fungi into batches no larger than ~~one~~1.0 kilogram.
- (2) A process lot for psilocybin extracts, homogenized fungi or edible psilocybin products is considered a batch.
- (3) A manufacturer must associate each batch with a unique identification number and that unique identification number must be:
 - (a) Provided to the individual responsible for taking samples; and
 - (b) Included in the batch labels required by OAR 333-333-7110.

Statutory/Other Authority: ORS 475A.235 & ORS 475A.590

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.590

333-333-7120

Failed Test Samples

- (1) If a sample or a field duplicate sample (collectively referred to as "sample" for purposes of this rule) fails any initial test, the laboratory that did the testing may reanalyze the sample. The laboratory that did the initial test may not subcontract the reanalysis. If a primary sample or a field duplicate sample fails, both must be reanalyzed. If the sample passes, the Oregon Health Authority (Authority) may require another laboratory ~~must to~~ resample the batch and confirm that result for the batch to pass testing.

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(a) If a manufacturer wishes to have a sample reanalyzed, the manufacturer must request a reanalysis within seven calendar days from the date the laboratory sent notice of the failed test to the manufacturer. The reanalysis must be completed by the laboratory within 30 days from the date the reanalysis was requested.

~~(b) If a manufacturer has requested a reanalysis in accordance with subsection (1)(a) of this rule and the sample passes, the manufacturer has seven calendar days from the date the laboratory sent notice of the passed test to request that another laboratory resample the batch and confirm the passed test result. The retesting must be completed by the second laboratory within 30 days from the date the retesting was requested.~~

~~(b)~~ (b) A manufacturer must inform the Oregon Health Authority (Authority) immediately, of the following, in a manner prescribed by the Authority:

(A) A request for reanalysis of a sample;

(B) The testing results of the reanalysis;

(C) A request for retesting; and

(D) The results of retesting.

(2) If a sample fails a test or a reanalysis under section (1) of this rule the batch:

(a) May be remediated in accordance with these rules; or

(b) If it is not or cannot be remediated under this rule, must be destroyed in a manner specified by the Authority.

(3) If a manufacturer is permitted to remediate under this rule, the manufacturer must provide notice to the Authority of the registrant's intent to remediate.

(4) A psilocybin extract that is permitted to undergo remediation cannot be further processed into a psilocybin product during the remediation process.

(5) Failed microbiological contaminant testing. If a sample from a batch psilocybin product fails microbial contaminant testing the batch may not be remediated and must be destroyed as ordered by the Authority.

(6) Failed solvent testing.

(a) If a sample from a batch fails solvent testing the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.

(b) A batch that is remediated in accordance with subsection (a) of this section must be re-sampled and re-tested in accordance with these rules and must be tested if not otherwise required for that product under these rules for solvents.

(c) A batch that fails solvent testing that is not remediated or that if remediated fails testing must be destroyed in a manner specified by the Authority.

(7) Failed pesticide testing. If a sample from a batch of psilocybin product fails pesticide testing the batch may not be remediated and must be destroyed as ordered by the Authority

(8) Failed heavy metal testing. If a sample from a batch of psilocybin product fails heavy metal testing the batch may not be remediated and must be destroyed as ordered by the Authority

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(9) Failed potency testing. A psilocybin product that fails potency testing under OAR 333-333-7040 may be re-mixed in an effort to meet the standards in OAR 333-333-7040. A psilocybin product that is re-mixed must be re-sampled and re-tested in accordance with these rules.

(10) If a sample fails a test after undergoing remediation as permitted under this rule the batch must be destroyed in a manner approved by the Authority.

(11) A manufacturer must inform a laboratory prior to samples being taken that the batch has failed a test and is being retested after undergoing remediation.

(12) A manufacturer must document all sampling, testing, remediation and destruction that are a result of failing a test under these rules.

(13) If a batch fails a test under these rules a manufacturer:

(a) Must store and segregate the batch in a secure area and label the batch clearly to indicate it has failed a test and the label must include a test batch number.

(b) May not remove the batch from the registered premises without permission from the Authority.

Statutory/Other Authority: ORS 475A.235 & ORS 475A.590

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.590

333-333-8100

Product Transportation

(1) Psilocybin products transferred by licensees.

(a) Psilocybin products transferred between licensed premises may only be transported by a licensee or licensee representative of the originating or receiving licensee.

(b) Samples of psilocybin products obtained by a laboratory licensee pursuant to OAR 333-333-7100 may only be transported by the laboratory licensee or a laboratory licensee representative of the receiving laboratory.

(c) Every manufacturer, service center and laboratory licensee must maintain a list of licensee representatives authorized to transport product or travel in vehicles transporting product.

(d) Psilocybin products transferred between licensed premises must not exceed possession quantities described in OAR 333-333-2200.

(2) Physical transport requirements for licensees.

(a) A licensee representative of a manufacturer, service center or laboratory licensee who transports psilocybin products on behalf of a licensee must have a valid driver license.

(b) A manufacturer, service center or laboratory licensee must:

(A) Store psilocybin products in the delivery vehicle within a locked, secured area, shielded from view from the exterior of the vehicle.

(B) When transporting perishable psilocybin products, provide appropriate temperature control within the delivery vehicle.

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(C) Use a delivery vehicle that is equipped with an alarm system and is insured at or above the legal requirements in Oregon.

(D) Deliver psilocybin products to all destinations and return any remaining psilocybin products to the licensed premises of origin within 60 hours of initial departure and notify the Oregon Health Authority (Authority) immediately in the manner prescribed by the Authority if they are unable to satisfy this requirement due to inclement weather, mechanical failure, or other unforeseen circumstances.

(E) Document all overnight stops in the planned route of the manifest and include the address, estimated arrival time at, and estimated departure time from the location of each overnight stop.

(F) Package all psilocybin products for transport in shipping receptacles and assign and affix a unique identification number to all shipping receptacles containing psilocybin products. ~~as required by these rules.~~

(G) Provide a copy of the manifest to each location receiving the inventory described on the manifest but may prepare a separate product tracking system manifest for each receiving location in order to maintain transaction confidentiality.

(H) Contact the Authority as soon as possible under the circumstances ~~and in the form and manner prescribed by the Authority via phone or email~~, if a vehicle transporting psilocybin products is involved in any accident or other situation involving product loss.

(I) Travel directly from the originating location to the destination location described in the manifest route.

(J) Notify the Authority as soon as it is safe to do so of every stop at an unlicensed location that exceeds two hours in duration and is not already listed in the manifest route.

(K) Upon the Authority's request, make the vehicle and its contents available for inspection if the delivery vehicle is stopped at an unlicensed location.

(c) A licensee may not:

(A) Make any unnecessary stops in between the originating and destination locations except to other licensed premises receiving inventory as described on the manifest;

(B) Remove psilocybin products from the vehicle until they arrive at the destination recorded in the manifest. Licensees or laboratory licensees may not transfer psilocybin products to, nor store psilocybin products in or at any unlicensed premises;

(C) Void or change a manifest after departing the originating licensed premises; or

(D) Travel with any persons not listed on the manifest.

(d) Any vehicle that meets the requirements of this rule may be used as a delivery vehicle.

(3) Product tracking system manifest requirements.

(a) Prior to removing a psilocybin product from the originating licensed premises for the purposes of transport or delivery, the originating licensee must use the product tracking system to generate a printed transport manifest containing the following information:

(A) The originating location's license number and address as it appears in the product tracking system.

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(B) The destination location's license number and address as it appears in the product tracking system.

(C) The unique identification number, product type, and quantity of each psilocybin product.

(D) The actual date and estimated time of departure.

(E) Location, purpose, and duration of time for any overnight stop.

(F) The arrival date and estimated time of arrival or completion of delivery.

(G) The delivery vehicle make, model, and license plate number.

(H) The name, contact information, worker permit number and signature of any licensee representatives accompanying the transport.

(b) A physical, printed copy of the generated manifest must accompany every transport of psilocybin products.

(4) Product tracking system requirements when receiving psilocybin products. Upon receipt of a delivery of psilocybin products, the receiving licensee must:

(a) Record each applicable unique identification number as accepted and received or rejected in the product tracking system as applicable.

(b) Verify the psilocybin products received are as described on the manifest and record receipt of the psilocybin products in the product tracking system if accepted.

(c) Separately and for each unique identification number document any differences between the quantities specified on the manifest and the quantities received in the product tracking system.

Statutory/Other Authority: ORS 475A.235 & ORS 475A.400

Statutes/Other Implemented: ORS 475A.235

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.

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(c) Ensure that all product tracking system users complete product tracking system training and document completion in a form and manner prescribed by the Authority.

~~(de)~~ Remove access for any product tracking system user from an associated product tracking system account if that individual is no longer a licensee representative.

~~(ed)~~ 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

333-333-8210

Product Tracking - Reconciliation of Inventory

(1) Each service center, manufacturer and laboratory licensee must:

(a) Use the product tracking system for all inventory tracking activities, as required by these rules.

(b) By 11:59 AM local time of the next calendar day, reconcile all psilocybin product inventory in the product tracking system to reflect the prior day's activity.

(c) For psilocybin products that have completed potency testing, use the product tracking system to record the total amount of psilocybin analyte contained in psilocybin products by weight, measured in grams or milligrams.

(2) The requirements of subsection (1)(b) of this rule do not apply:

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(a) To psilocybin spores or mycelium that are in a preproduction process at a manufacturer's licensed premises.

(b) During the first 15 days following the harvest of fruiting bodies or mycelium, daily reconciliation by a manufacturer of the weight of moisture lost to evaporation is not required. The weight of moisture loss must be reconciled by a manufacturer prior to transferring, processing, selling, or packaging the fungi and no later than 15 days after the harvest, whichever comes first.

(c) To psilocybin products held by a laboratory licensee that are undergoing analytical testing required by these rules so long as the psilocybin products do not leave the laboratory's licensed premises and are reconciled on the same day that the analytical testing concludes.

(3) Notwithstanding section (1)(b) of this rule, a service center, manufacturer or laboratory must reconcile all psilocybin product inventory in the product tracking system prior to license expiration.

(43) In addition to the requirements in section (1) of this rule, service centers must record each individual sale or transfer of a psilocybin product to a client as a sales transaction and record the price before tax and amount of each individual item sold and the date of each transaction in the product tracking system for each individual transaction.

Statutory/Other Authority: ORS 475A.235 & ORS 475A.400

Statutes/Other Implemented: ORS 475A.235 & ORS 475A.400