(2)(a) OPS estimates that many licensed psilocybin businesses meet the definition of small businesses. As of August 25, 2026, there are 422 psilocybin businesses in Oregon, including psilocybin facilitators. The number of licensees has fluctuated, and at this time OPS cannot accurately predict how many licensed psilocybin businesses will operate in Oregon going forward.

(b) The rules contain some additional reporting and documentation requirements to support client and public safety, while other requirements have been streamlined. The new requirements create costs of compliance; however, these costs are offset to some degree by improved efficiency due to rule revisions. OPS cannot accurately predict the net cost of compliance.

(c) Some of the proposed rules could lead to increased costs for equipment, supplies, labor, and administration. For example, the rules require additional information to be printed on product labels. However, OPS cannot predict what portion of a business' overall costs will be impacted.

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

Small businesses participated in the rule advisory committee.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

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

AMEND: 333-333-1010

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

CHANGES TO RULE:

333-333-1010
Definitions
For purposes of chapter 333, division 333, in addition to the definitions in ORS 475A.220, the following definitions apply:¶
(1)(a) "Adulterant" means:¶
(A) Chemicals, drugs, plants or substances that alter the potency, intoxicating effect, duration of effect, toxicity or potential for excessive use when added to psilocybin products.¶
(B) Any additives that are intended to manipulate the ratio of any analyte or to manipulate the ratio of compound relative to another analyte or compound present in the fungi used in extraction or processing.¶
(b) Adulterant does not mean naturally occurring substances contained in food items such as, but not limited to chocolate.¶
(2) "Adverse reaction" means an adverse behavioral or medical reaction that occurred during an administration session and does not require transport to a hospital.¶
(3) "Adverse behavioral reaction" means a client's behavioral reaction that required contacting emergency services

or receiving care from a medical care provider that occurred during an administration session.¶
(4) "Adverse medical reaction" means a client's medical reaction that required contacting emergency services or receiving care from a medical care provider that occurred during an administration session.¶
(5) "Advertising" means publicizing ~~the trade~~a facilitator name or the 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;¶
(d) Images of minors; or¶
(e) Words that refer to products that are commonly associated with minors or marketed by minors.¶
(9) "Authority" means the Oregon Health Authority.¶
(10) "Authorized Authority representative" means an employee of the Authority who is authorized to conduct inspections or investigations and otherwise enforce ORS chapter 475A and any rules adopted thereunder.¶
(11) "Batch" means a quantity of whole fungi from a harvest lot, or a quantity of psilocybin product from a process lot.¶
(12) "Billboard" means a large outdoor advertising structure.¶
(13) "Capsule" means a small soluble pill, tablet or container that contains psilocybin extract or homogenized fungi and is intended for human consumption.¶
(14) "Cartoon" means any drawing or other depiction of an object, person, animal, creature or any similar caricature which may exhibit any of the following:¶
(a) The use of comically exaggerated features;¶
(b) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or¶
(c) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.¶
(15) "Chemical synthesis" means a method of producing psilocybin products using precursor ingredients rather than cultivation of fruiting bodies and mycelium, or a method of producing psilocybin products that results in psilocybin products that contain analytes or compounds that were not present in the source fruiting bodies, mycelium and other ingredients.¶
(16) "Client administration area" means any area within the licensed premises of a service center where:¶
(a) Psilocybin products may be transferred to a client.¶
(b) Psilocybin products may be consumed by a client.¶
(c) Administration sessions may take place.¶
(17) "Client" means an individual that is provided psilocybin services in this state.¶
(18) "Client information form" means the form required by ORS 475A.350.¶
(19) "Client packaging" means packaging containing psilocybin products intended to be sold to clients.¶
(20) "Client records" means information held or known by a service center or facilitator, including 303 client data, that may be used to identify a client or prospective client, including any communication made by a client or prospective client and any information related to providing psilocybin services or selling psilocybin products to a client.¶
(21) "Client support person" means a person who will be present during a client's administration session for any purposes described in OAR 333-333-5070.¶
(22) "Consultation" means feedback and discussion provided by an instructor, practicum site supervisor or lead educator to students regarding students' observation of clients receiving psilocybin services.¶
(23) "Control over the entity" includes but is not limited to the authority to bind the entity to contracts, obligations or debt and does not include a licensee representative acting under the direction of a licensee.¶
(24) "Cultivation batch" means a quantity of unharvested fruiting body or mycelium that is grown together under

the same conditions, that may contain fungi that originates from diverse spores or mycelial tissue of Psilocybe cubensis.¶
(25) "Cultural equity" means values, policies, and practices that ensure all people, especially those who have been historically marginalized based on race, ethnicity, religion, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances are considered in the development of social pathways to health equity.¶
(26) "Culturally and linguistically responsive services" for the purpose of ORS 475A.210 to 475A.722 and these rules means psilocybin services offered by service centers and facilitators that are responsive to diverse cultural beliefs and practices, preferred languages, literacy, and other communication needs of clients.¶
(27) "Curriculum" means the topics, subjects, and activities that make up courses taught by a training program 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¶
(b) Manufacturing psilocybin extracts.¶
(35) "Facilitator" means an individual that facilitates the provision of psilocybin services in this state.¶
(36) "Facilitation" means the provision of services to a client by a licensed facilitator before, during, and after the client's consumption of a psilocybin product during a preparation, administration, or integration session.¶
(37) "Financial interest":¶
(a) Means entitlement to receive a portion of revenue, proceeds or profits from a licensed entity or an entity proposed to be licensed; or¶
(b) A membership interest, partnership interest or other ownership interest in a licensed entity or an entity proposed to be licensed.¶
(c) Includes any individual ~~person~~ or legal entity that qualifies as an applicant under OAR 333-333-1010 or 333-333-4030.¶
(d) Does not include an investment interest that the investor does not control in nature, amount or timing.¶
(38) "Fruiting bodies" means the spore producing organs of the fungi Psilocybe cubensis.¶
(39) "Fungi" means the fruiting bodies or mycelium of the fungi Psilocybe cubensis.¶
(40) "Harvest" means the act of removing mycelium or fruiting bodies from a production environment for drying or processing.¶
(41) "Harvest lot" means a specifically identified quantity of fungi that is cultivated and dried under the same conditions and harvested within a seven calendar-day period at the same location within the licensed premises, that may be partially harvested~~,~~ and may use the substrate material for multiple harvests.¶
(42) "Health equity" means the opportunity for all people to reach their full health potential and well-being without being disadvantaged by their race, ethnicity, religion, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities or other socially determined circumstances.¶
(43) "Homogenized fungi" means dried fruiting bodies or mycelium that have been mixed by powdering or other techniques which uniformly distribute psilocybin throughout the product. Homogenized fungi may be packaged in capsules and may contain inactive ingredients such as binders, dilutants and carrying agents.¶
(44) "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. ¶

(45) "Instructor" means an individual identified by a training program in a form and manner prescribed by the Authority who provides instruction to students.~~-~~¶
(4~~5~~6) "Intervention" means taking proactive steps to respond to the client's behavior, experience, or condition during an administration session.¶
(4~~6~~7) "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.¶
(4~~7~~8) "Laboratory" means a laboratory licensed under ORS 475A.594.¶
(4~~8~~9) "Lead educator" means a person affiliated with a training program who is responsible for tracking the progress of students throughout the program.¶
(~~49~~50) "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.¶
(51) "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.¶
(5~~0~~2) "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.¶
(5~~1~~3) "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.¶
(5~~2~~4) "Limited access area" means any area of a licensed premises where psilocybin products or psilocybin waste are stored or produced.¶
(5~~3~~5) "Manufacturer" means a manufacturer licensed under ORS 475A.290.¶
(5~~4~~6) "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.¶
(5~~5~~7) "Marijuana" has the meaning given that term in ORS 475C.009.¶
(5~~6~~8) "Mycelium" means the fungal threads or hyphae of Psilocybe cubensis.¶
(5~~7~~9) "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~~60) "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~~61) "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.~~-~~¶
(6~~0~~2) "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.~~-~~¶
(6~~1~~3) "Operational name" means an individual, legal entity or business name listed on an application and license certificate of a service center, manufacturer~~ or~~, laboratory license ~~that the licensee(s) will use for purposes of advertising and doing business with the public~~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.¶

(6~~2~~4) "Oregon Psilocybin Services Act" means ORS 475A.210 to ORS 475A.722.¶
(6~~3~~5) "Pesticide" means any substance or mixture of substances included in ORS 634.006(8).¶
(6~~4~~6) "Permittee" means a person who holds a permit issued under ORS 475A.480.¶
(6~~5~~7) "Practicum site" means a licensed service center that provides practicum training.¶
(6~~6~~8) "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.¶
(6~~7~~9) "Preproduction process" means cultivation environments that are used to facilitate growth of mycelial tissue prior to that tissue being transferred to production growth medium. Examples include but are not limited to agar dishes and grain spawn.¶
(~~68~~70) "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 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.¶
(71) "Process lot" means homogenized fungi, psylocibin extract or edible psilocybin product of the same type that was processed at the same time using the same processing method, ingredients, and standard operating procedures.¶
(~~69~~72) "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.¶
(7~~0~~3) "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.¶
(74) "Psilocybin" has the meaning described in ORS 475A.220.¶
(7~~1~~5) "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.¶
(7~~2~~6) "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.¶
(7~~3~~7) "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.¶
(7~~4~~8) "Product tracking system" or "PTS" means the system for tracking psilocybin products required by ORS 475A.400.¶
(7~~5~~9) "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~~80) "Psilocybin waste" means:¶
(a) Waste material that is a byproduct of manufacturing psilocybin products that contains a detectable amount of psilocybin.¶
(b) Partially consumed psilocybin products, excluding client packaging.¶
(c) Psilocybin products that a manufacturer, service center or laboratory disposes.¶
(d) Any psilocybin product that is required to be designated as waste by these rules.¶
(~~77~~81) "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.¶
(~~7~~82) "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~~83) "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.¶
(8~~0~~4) "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.¶
(8~~1~~5) "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.¶
(8~~2~~6) "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.¶
(8~~3~~7) "Secondary school" means a learning institution containing any combination of grades 9 through 12 and includes junior high schools that have 9th grade.¶
(8~~4~~8) "Service center" means a premises licensed under ORS 475A.305.¶
(8~~5~~9) "Severe adverse reaction" means an adverse behavioral or medical reaction that requires a client to be transported to a hospital.¶
(~~86~~90) "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~~91) "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~~92) "Synchronous learning" means that students learn from their instructor at the same time as their fellow students.¶
(~~8~~93) "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.¶
(9~~0~~4) "These rules" means OAR 333-333-1010 through 333-333-8250.¶
(9~~1~~5) "Tincture" means a liquid containing psilocybin that consists of either:¶
(a) A non-potable solution of at least 25 percent non-denatured alcohol, that is exempt from the Liquor Control Act under ORS 471.035; or¶
(b) A non-potable solution comprised of glycerin, plant-based oil, syrup and other ingredients.¶
(9~~2~~6) "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.¶
(97) "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.¶
(9~~3~~8) "Training program" means a program with an approved curriculum that offers training to psilocybin facilitators as described in ORS 475A.380.¶
(9~~4~~9) "Training program applicant" means a program that has applied to offer training to psilocybin facilitators as described in ORS 475A.380.¶
(~~95~~100) "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~~101) "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~~102) "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~~103) "Whole fungi" means dried fruiting bodies of Psilocybe cubensis, or portions thereof, that have not been homogenized.¶
(~~99~~104) "Wood chips" mean substrates consisting primarily of wood products that have not been composted.¶
(10~~0~~5) "Worker permit" means a permit required by ORS 475A.480.¶
(10~~1~~6) "303 client data" means information that OAR 333-333-4900 requires service centers to collect from clients, store and maintain.¶
(10~~2~~7) "303 service center data" means information that OAR 333-333-4910(3) and (4) require service centers to compile, aggregate, compute and report to the Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.372, ORS 475A.374
Statutes/Other Implemented: ORS 475A.235, ORS 475A.372, ORS 475A.374

AMEND: 333-333-2010

RULE SUMMARY: Amend OAR 333-333-2010: Amend to clarify prohibition of promoting unregulated cultivation and consumption of psilocybin.

CHANGES TO RULE:

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 within Oregon where it is unlawful to do so. ¶
(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:¶
(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

AMEND: 333-333-2400

RULE SUMMARY: Amend OAR 333-333-2400: Amend label to include new value for total potential psilocybin that will be used to determine lowest dosing tier. Deletes unnecessary information regarding other potency formulas.

CHANGES TO RULE:

333-333-2400
Labeling for Sale to Client
(1) A label required by these rules must:¶
(a) Be printed or attached to client packaging containing psilocybin products.¶
(b) Contain all required information in a legible font at least eight points large.¶
(c) Be in English, though it may also be in other languages.¶
(d) Be unobstructed and clearly visible.¶
(2) A label may not:¶
(a) Display any untruthful or misleading statements including, but not limited to, a health claim that is not supported by the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims; or¶
(b) Be attractive to minors, as that is defined in OAR 333-333-1010.¶
(3) Required Information. All client packaging must display:¶
(a) The manufacturer's ~~business or trade~~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 unique identification number as defined in OAR 333-333-1010.¶
(~~g~~h) The "best by" date indicating the time that the manufacturer has determined that their product will retain its original quality.¶
(~~h~~i) A statement that "Activation times for psilocybin products are variable and cannot be accurately predicted."¶
(~~i~~j) 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 calculated, including any formulas and assumptions that were used to calculate the listed values.~~
Statutory/Other Authority: ORS 475A.235, ORS 475A.626~~, Oregon Laws 2025, chapter 147~~
Statutes/Other Implemented: ORS 475A.626~~, Oregon Laws 2025, chapter 147~~

AMEND: 333-333-2410

RULE SUMMARY: Amend OAR 333-333-2410: Amend the product information document requirements to align with label requirements. Amend for term consistency to align with definitions.

CHANGES TO RULE:

333-333-2410
Product Information Document
(1) Manufacturers must provide a product information document with all products transferred to a service center that lists the following information in English on a printed or electronic document in 12-point font or larger.¶
(a) The manufacturer's ~~business or trade~~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 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).¶
(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

AMEND: 333-333-3010

RULE SUMMARY: Amend OAR 333-333-3010: Increase fee for training program curriculum approval. Clarify requirement to cooperate with investigation.

CHANGES TO RULE:

333-333-3010
Psilocybin Training Program Curriculum Approval Process
(1) A training program applicant must submit the following to the Oregon Health Authority (Authority) to be considered for curriculum approval to train psilocybin facilitators:¶
(a) A completed application package, including a description of the proposed curriculum that shows the applicant meets the requirements of OAR 333-333-3050, OAR 333-333-3060, OAR 333-333-3070 and OAR 333-333-3090; and¶
(b) A US$~~5~~1,000 non-refundable application evaluation fee paid in ~~the~~a form and manner specified by the Authority.¶
(2) Following receipt of the items described in section (1) of this rule, the Authority will notify a training program applicant whether its application is complete or incomplete.¶
(a) If an application is incomplete, the training program applicant will have 30 days from the date the notice is issued to submit a complete application. If the training program applicant does not complete their application within 30 days, the Authority will refuse to process the application. If the Authority refuses to process an application, the applicant may submit a new application, including a non-refundable application evaluation fee, for the program to be considered for approval.¶
(b) If an application is complete, the Authority will evaluate the training program application to determine if the curriculum meets the standards in OAR 333-333-3010 to OAR 333-333-3090.¶
(3) The Authority will notify a training program applicant in writing if its complete application for curriculum approval is approved or denied. If the application is approved, the approval is effective on the date of notice. The Authority may not retroactively approve or pre-approve training program applications.¶
(4) A training program must, within 180 calendar days of receiving curriculum approval, provide documentation to the Authority~~, in the form and manner prescrib~~ of one of the following by using the form published ~~by~~on the Authority~~, one of the following~~'s website:¶
(a) Documentation demonstrating the program has applied for a license from the Higher Education Coordinating Commission in accordance with applicable laws in ORS chapter 345 or ORS chapter 348 and any applicable Higher Education Coordinating Commission rules adopted under those chapters and paid any required Higher Education Coordinating Commission application fees and the program's application is pending, and the Higher Education Coordinating Commission has not yet issued a final order of denial.¶
(b) Proof of current licensure from the Higher Education Coordinating Commission as a career school.¶
(c) Documentation from the Higher Education Coordinating Commission that the applicant is not required to be licensed as a career school.¶
(5) The Authority shall deny a training program application for curriculum approval and shall revoke approval of a previously approved training program curriculum if:¶
(a) The training program or training program application does not meet the requirements of OAR 333-333-3010 to OAR 333-333-3090~~;~~.¶
(b) The program instructors, staff or representatives have made false or misleading statements to the Authority, students or the public.¶
(c) A training program fails to comply with requirements of section (4) this rule.¶
(d) A training program fails to produce evidence within 10 business days of the Authority's request unless the Authority grants an extension or otherwise fails to cooperate with an investigation of violations of ORS 475A.210 to 475A.722 and these rules.¶
(e) The Higher Education Coordinating Commission denies a training program's application for licensure under applicable laws in ORS chapter 345 or ORS chapter 348, or any applicable Higher Education Coordinating Commission rules adopted under those chapters. ~~.~~¶
(~~e~~f) A training program fails to maintain its approval status with Higher Education Coordinating Commission in accordance with applicable law governing the type of school or institution.¶
(6) If the Authority denies an application or suspends or revokes a curriculum approval, the Authority will provide notice of the denial, suspension or revocation and the training program has a right to a hearing under ORS chapter 183.¶
(7) For applications approved prior to January 1, 2025, training program curriculum approval has a term of five years from the date of initial approval.¶

(8) Programs whose curricula approval has been denied or revoked by the Authority may not reapply for a period of one year from the date of the final order denying the application for curriculum approval or the date of the final order revoking the application for curriculum approval.¶
(9) For new or renewal applications approved on or after January 1, 2025, training program approval has a term of one year from the date of initial approval.¶
(10) If the requirements of OAR 333-333-3010 to OAR 333-333-3090 change substantively during the term, the Authority may require training programs to resubmit an application for approval.¶
(11) Training programs that cease enrolling students or cease offering instruction to enrolled students must provide written notice to the Authority in ~~the form and manner prescrib~~by using the form published ~~by~~on the Authority's website. Training programs may request to surrender their training program approval pursuant to the requirements of OAR 333-333-4280.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3020

RULE SUMMARY: Amend OAR 333-333-3020: Clarify training program requirements for describing practicum and cooperating during application process; failure to submit documents may result in application being closed.

CHANGES TO RULE:

333-333-3020
Psilocybin Training Program Application Requirements
(1) For curriculum to be approved, training program applicants must:¶
(~~1~~a) Demonstrate that its proposed course modules contain the content required by OAR 333-333-3060;¶
(~~2~~b) Demonstrate that its proposed hours of instruction meet the requirements of OAR 333-333-3050;¶
(~~3~~c) Demonstrate that its proposed practicum meets the requirements of OAR 333-333-3070 by identifying service centers acting as practicum sites and practicum site supervisors, and describing practicum observation and consultation;¶
(~~4~~d) Identify a training program director as defined in OAR 333-333-1010;~~-~~¶
(~~5~~e) Identify at least two lead educators, as defined in OAR 333-333-1010, and list lead educator qualifications to meet the lead educator requirements;¶
(~~6~~f) Identify all instructors as defined in OAR 333-333-1010 and list the instructors' qualifications to teach curriculum modules identified in these rules; and¶
(~~7~~g) Provide an address to receive mail from the Oregon Health Authority (Authority) at an established physical location within the United States of America or U.S Territories or the freely associated states Republic of Marshall Islands, Palau, and the Federated States of Micronesia.¶
(2) A training program must provide any additional information that the Authority requests to determine the merits of an application. ¶
(3) Failure to submit forms, documents or information requested by the Authority under this rule within 30 calendar days may result in the application being closed as incomplete.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3030

RULE SUMMARY: Amend OAR 333-333-3030: Establish new fee for material changes to training program curriculum. Define material change. Clarify timeframe for notice of other types of changes.

CHANGES TO RULE:

333-333-3030
Psilocybin Training Instructor Qualifications and Program Performance
(1) In order for curriculum to be approved or reapproved, a training program must demonstrate that each lead educator, instructor and person who trains instructors at a training program has sufficient experience, knowledge, skills and ability to competently train students in their assigned subject matter.¶
(2) Sufficient experience, knowledge, skills and ability can be demonstrated via education, certifications, professional experience, personal narratives and references.¶
(3) Training programs shall treat personal narratives and references as confidential unless an instructor has consented to their publication.¶
(4) Each lead educator and instructor at a training program must:¶
(a) Understand the objectives of the training program and be able to communicate effectively with students; and¶
(b) Demonstrate skill in instruction and student supervision.¶
(5) ~~Beginning September 1, 2025, a~~At least one instructor at a training program must hold a valid facilitator license in order for the training program to be approved or reapproved.~~.~~¶
(6) ~~Beginning January 1, 2026, t~~Training programs must register with the Oregon Secretary of State and maintain registration, including registration of an Assumed Business Name (ABN) if applicable that is used as an operational name, in order for the training program to be approved or reapproved.¶
(7) Training programs m~~ust notify the Oregon Health Authority (Authority) of any~~ay not make material changes to the curriculum listed in their application that affect the requirements of OAR 333-333-3010 to OAR 333-333-3090 ~~and any changes to the address required by OAR 333-333-3020(7), instructors, lead educators, training program director, registered agent or training program responsible party identified in the application in a form and manner prescribed by the Authority. A training program must use its previously approved curriculum and associated information until its request has been accepted~~without the Oregon Health Authority's (Authority's) prior written approval. A material change is a change that affects the minimum requirements for core training and practicum described in OAR 333-333-3050 and OAR 333-333-3070. Changes to practicum sites are not material changes. ¶
(a) Training programs must notify the Authority using the form published on the Authority's website to request material changes to their curriculum. ¶
(b) A non-refundable change fee of US$500 must be paid and cleared to modify previously approved curriculum. This change fee applies regardless of whether a training program requests the change at renewal or during the term of their approval.¶
(c) A training program must use its previously approved curriculum until the Authority provides written approval to make material changes to curriculum.¶
(8) Training programs must notify the Authority within 10 business days of any changes to the address required by OAR 333-333-3020, practicum sites, instructors, lead educators, training program director, registered agent or training program responsible party identified in the application using the form published on the Authority's website. The changes described in this section are not material changes to the curriculum.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3035

RULE SUMMARY: Amend OAR 333-333-3035: Increase fee for renewal of training program approval. Clarify requirements for providing information for training program renewal applications.

CHANGES TO RULE:

333-333-3035
Psilocybin Training Program Curriculum Approval Renewal
(1) A training program that applies for renewal of curriculum approval must submit a complete renewal application, including proof that the program has received and continues to hold any approvals required from the Higher Education Coordinating Commission in accordance with applicable law governing the type of school or institution and a non-refundable US$~~5~~1,000 application fee. The renewal application is not complete until payment of the application fee has cleared. ¶
(2) A ~~renewal application will be considered timely if a~~ training program must provide any additional information that the Oregon Health Authority (Authority) requests to determine the merits of a renewal application. ¶
(3) Failure to submit forms, documents or information requested by the Authority under this rule within 30 calendar days may result in the application being closed as incomplete.¶
(4) A renewal application ~~is received by th~~will be considered timely if a complete ~~O~~re~~gon Health Authority (~~newal application is received by the Authority~~)~~ at least 60 calendar days before the date the curriculum approval expires. Applications received less than 60 days before the date the curriculum approval expires will be considered untimely.¶
(~~3~~5) A training program that submits a complete timely renewal application may continue to offer training using the previously approved curriculum after the stated curriculum approval expiration date, pending a decision by the Authority on the renewal application.¶
(~~4~~6) A training program who submits an untimely or incomplete renewal application or who does not submit a renewal application shall not continue to offer training using the previously approved curriculum when the curriculum approval expires.¶
(~~5~~7) If the Authority approves a renewal application for curriculum approval, the curriculum approval is valid for one year~~ from the date of approval.~~¶
(~~6~~8) The Authority may deny an application for renewal if:¶
(a) The training program has not complied with these rules; or¶
(b) The training program instructors, staff or representatives have made false or misleading statements to the Authority, students or the public.¶
(~~7~~9) If the Authority denies a renewal application, the Authority will provide notice of the denial and the program has a right to a hearing under ORS chapter 183.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3040

RULE SUMMARY: Amend OAR 333-333-3040: Clarify training program record keeping requirements.

CHANGES TO RULE:

333-333-3040
Psilocybin Training Program Record Keeping
(1) Training programs ~~shall~~must maintain records for each class, including course syllabi, location, date, whether the class was online or in-person, and student attendance for every online and in-person class. These records must be maintained for five years. Training programs shall provide these records to current and former students upon request. Training programs shall provide these records to the Authority upon request.¶
(2) Training programs shall maintain enrollment records, including the name of each student enrolled, their date of completion and examination results. These records must be maintained for five years.¶
(3) Training programs shall provide records required to be maintained under this rule to the Authority upon request, and in the manner requested.¶
(4) Training programs ~~sha~~will make a summary of their approved curriculum, including practicum sites, available to prospective students prior to enrollment.¶
(5) Except as required by sections (1) and (3) of this rule, student records shall not be released without the student's written consent.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3050

RULE SUMMARY: Amend OAR 333-333-3050: Remove obsolete date reference.

CHANGES TO RULE:

333-333-3050
Psilocybin Training Program Core Requirements
(1) ~~For new applications and renewals received on or after January 1, 2025, t~~Training programs ~~shall~~must provide core training that consists of at least 128 hours of instruction.¶
(2) For training that is not conducted in person, at least 50 percent of the training shall be conveyed through online synchronous learning.¶
(3) ~~For new applications and renewals received on or after January 1, 2025, a~~Applicants for training program~~s~~, curriculum approval must demonstrate that their curriculum consists of the following minimum hours of instruction, in the following areas consistent with the requirements of OAR 333-333-3060:¶
(a) Historical, Traditional, and Contemporary Practices and Applications: 12 hours.¶
(b) Cultural Equity in relation to Psilocybin Services: 12 hours.¶
(c) Safety, Ethics and Responsibilities: 12 hours.¶
(d) Psilocybin Pharmacology, Neuroscience, and Clinical Research: 12 hours.¶
(e) Core Facilitation Skills: 16 hours.¶
(f) Preparation and Orientation: 16 hours.¶
(g) Administration: 20 hours.¶
(h) Integration; 12 hours.¶
(i) Group Facilitation: 16 hours.¶
(4) Training programs must comply with the requirements specified in these rules to maintain approved status.¶
(5) The requirements listed in these rules are minimum requirements. Nothing in these rules prevents a training program from offering additional modules or hours of instruction.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3070

RULE SUMMARY: Amend OAR 333-333-3070: Remove obsolete date reference; clarify process for changing practicum sites, clarify requirements for students observing psilocybin services for practicum.

CHANGES TO RULE:

333-333-3070
Psilocybin Facilitator Practicum Requirements
(1) Training programs must have curriculum that requires students to complete practicum training that provides an opportunity to observe the facilitation of non-ordinary states of consciousness.¶
(2) A~~fter January 1, 2026, a~~ll practicum must take place at a practicum site. Practicum training shall include placement at a practicum site where students can observe psilocybin services under the supervision of a practicum site supervisor.¶
(3) Any licensed service center can function as practicum site for training programs with curriculum approved by the Oregon Health Authority (Authority) subject to the requirements of OAR 333-333-4470. A training program with curriculum approved by the Authority ~~sha~~will notify the Authority in a form and manner prescribed by the Authority ~~when it is using a~~of practicum sites used to satisfy the requirements of this rule. The fee described in OAR 333-333-3030(7) does not apply to reporting changes to licensed service centers acting as practicum sites.¶
(4) Any licensed service center can function as a practicum site for training programs authorized to provide psilocybin training by another state within the United States of America or U.S. Territories or the freely associated states of the Republic of Marshall Islands, Palau, and the Federated States of Micronesia where provision of psilocybin services is allowed under state or territory law. If an out-of-state or outside the U.S. training program uses a practicum site in Oregon, the practicum site shall notify the Authority in a form and manner prescribed by the Authority.~~-~~¶
(5) A practicum site must obtain written client consent prior to allowing a client to be observed by practicum students and prior to sharing any client information with practicum students or a training program.¶
(6) The practicum site supervisor is responsible for developing students' practicum skills and evaluating students' practicum performance, related to psilocybin services.~~-~~¶
(7) ~~Until January 1, 2026, if a practicum site is not reasonably available or accessible to students, a training program may identify alternative practicum in its application for approval that reasonably approximates training at a practicum site. For alternative practicum, the lead educator or training program director is responsible for developing students' alternative practicum skills and evaluating students' alternative practicum performance, focusing on services with clients. Alternative practicum may not be used to satisfy the requirem~~Programs must provide students with a minimum of 40 hours of practicum training, including at least 30 hours of observation in which students directly observe clients receiving psilocybin services, and at least 10 hours of consultation relating to the student's o~~f this rule after January 1, 2026. ¶~~
~~(8) Alternative practicum may include but is not limited to observation of taped facilitation sessions that were recorded with participants' consent, participating in psychedelic peer support organization, role playing, and experience with altered states of consciousness that are not drug-induced, for example breath work, meditation or spiritual journeys.¶~~
~~(9) P~~bservation. A training program may provide students up to four hours of credit towards the observation requirement for participating in an administration session at a practicum site as a client.¶
(8) A training program~~s~~ must ~~provide students with a minimum of 40 hours of practicum training, including at least 30 hours of direct practice in which students directly observe clients receiving psilocybin services or directly participate in alternative~~conduct all practicum training, including observation and consultation in person or by observing preparation and integration sessions conducted via video while supervised by a practicum ~~activity as described in section (8), and at least 10 hours of consultation relating to the student's direct practice. A training program may provide students up to four hours of credit towards the direct practice requirement for participating in an administration session at a practicum site as a~~site supervisor.¶
(9) Observation is limited to observation of licensed facilitators who provide psilocybin services to clients. Practicum students may not provide psilocybin services to clients. ¶
(10) ~~A training program must conduct all practicum training, including direct practice, consultation and alternative practicum in person~~Practicum students and practicum site supervisors may not act as client support persons while participating in practicum.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380, ORS 475A.325

AMEND: 333-333-3300

RULE SUMMARY: Amend OAR 333-333-3300: Clarify language related to facilitator continuing education.

CHANGES TO RULE:

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

AMEND: 333-333-4000

RULE SUMMARY: Amend OAR 333-333-4000: Implement Oregon Laws 2026, Chapter 109 (HB 4040) by describing documentation that facilitator applicant has completed a training program in another state that meets or exceeds Oregon requirements.

CHANGES TO RULE:

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

limited to:¶
(a) Documentation that an applicant for a facilitator license has completed the training required by ORS 475A.325.¶
(b) Documentation that an applicant for a facilitator license has passed the exam required by ORS 475A.325.¶
(c) Results of required criminal records checks completed pursuant to OAR 333-333-4100.¶
(d) A land use compatibility statement from the city or county that identifies an applicant name listed on the license application and authorizes land use in the city or county where the premises of a manufacturer or service center proposed to be licensed is located.¶
(e) Other required forms and documents identified in the training, licensing and compliance system.¶
(f) A complete owner consent form as required by subsection (3)(g) of this rule.¶
(6) The Authority will notify an applicant in writing if their application is determined to be incomplete. The applicant will have 30 days from the date the notice is issued to submit a complete application. If the applicant does not complete their application within 30 days, the Authority will close the application. If the Authority closes an application, the applicant may submit a new application, including a non-refundable application fee, at any time.¶
(7) An applicant may submit a written request for reconsideration of an application that is closed as incomplete. Such a request must be received by the Authority within 10 calendar days of the date the closure notice was mailed to the applicant. The Authority will notify the applicant of the results of their request following receipt of the request for reconsideration.
Statutory/Other Authority: ORS 475A.235, ORS 475A.245, ORS 475A.255, ORS 475A.374, ORS 413.161, Oregon Laws 202~~5~~6, chapter ~~236~~109
Statutes/Other Implemented: ORS 475A.235, ORS 475A.245, ORS 475A.255, ORS 475A.594, ORS 475A.374, O~~regon Laws 2025, chapter 236~~RS 475A.290, ORS 475A.302

AMEND: 333-333-4010

RULE SUMMARY: Amend OAR 333-333-4010: Describes location of required forms.

CHANGES TO RULE:

333-333-4010
Communication with the Oregon Health Authority
(1) If an applicant or licensee is required to or elects to submit anything in writing to the Oregon Health Authority (Authority), unless otherwise prescribed by the Authority, the applicant or licensee may submit the writing to the Authority via:¶
(a) Mail; or¶
(b) Electronic mail.¶
(2) If a written notification must be submitted by a particular deadline it must be received, regardless of the method used to submit the writing, by 5:00 p.m. Pacific Time on the date specified in the notification.¶
(3) Applicants must designate an individual applicant in their license application who will serve as the primary point of contact for communication with the Authority. If a license is issued, the designated primary point of contact listed in the application continues to serve as primary point of contact unless the licensee provides written notice in the form and manner prescribed by the Authority.¶
(4) The primary point of contact identified in section (3) of this rule is responsible for ensuring all persons identified as 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.¶
(5) All forms published on the Authority's website described in these rules are published to [insert url].
Statutory/Other Authority: ORS 475A.235, ORS 475A.245
Statutes/Other Implemented: ORS 475A.235, ORS 475A.245

AMEND: 333-333-4060

RULE SUMMARY: Amend OAR 333-333-4060: Increase application fee, annual license fees, and applicable change fees for all license types. Eliminate reduced license fees.

CHANGES TO RULE:

333-333-4060
License Fees
(1) At the time of initial license application:¶
(a) An applicant for a service center, manufacturer or laboratory license must pay a US$~~5~~1,000 non-refundable application fee.¶
(b) An applicant for a facilitator license must pay a US$~~15~~200 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$~~1~~20,000.¶
(b) Service Center US$~~1~~20,000.¶
(c) Facilitator US$~~2~~4,000.¶
(d) ~~Laboratory US$10,000.¶~~
~~(3) Notwithstanding section (2) of this rule, if the Authority approves an initial license application or renewal and grants an annual license to a non-profit entity the following non-refundable fees must be paid:¶~~
~~(a) Manufacturer US$5,000.¶~~
~~(b) Service Center US$5,000.¶~~
~~(4) Notwithstanding section (2) of this rule, if the Authority approves an initial license application or renewal and grants an annual license the following non-refundable fees must be paid, if every individual applicant identified in the application satisfies one or more of the requirements of section (5) of this rule:¶~~
~~(a) Manufacturer US$5,000.¶~~
~~(b) Service Center US$5,000.¶~~
~~(c) Facilitator~~For initial and renewal laboratory license applications received prior to January 1, 2029, US$10,000.¶
(~~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~~e) For initial and renewal laboratory license applications received on or after January 1, 2029, US$20,000.¶
(~~6~~3) The Authority will charge a nonrefundable change fee of US$~~2~~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.¶
(~~7~~4) The Authority will charge a nonrefundable change fee of US$~~25~~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

AMEND: 333-333-4070

RULE SUMMARY: Amend OAR 333-333-4070: Increase annual fee for worker permit. Clarify requirements for holding worker permit. Require notice of felony conviction.

CHANGES TO RULE:

333-333-4070
Worker Permit Term and Fees
(1) An individual who is a licensee representative must have a valid worker permit if the individual participates in:¶
(a) The provision of psilocybin services at a licensed premises.¶
(b) The possession, manufacturing, securing or selling of psilocybin products at a licensed premises.¶
(c) The recording of the possession, manufacturing, securing or selling of psilocybin products at a licensed premises.¶
(d) The verification of any document described in ORS 475A.445.¶
(2) Initial and renewal applications for a worker permit must include documents and information required by the Oregon Health Authority (Authority) to be complete.~~.~~¶
(3) 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.¶
(4) The Authority shall deny an initial or renewal application for a worker permit if:¶
(a) The applicant does not have an approved criminal records check under ORS 181A.195.~~.~~¶
(b) The applicant has not paid a civil penalty imposed under a final order issued by the Authority under ORS chapter 183 or payment has not cleared within the time frame specified in the order.¶
(~~4~~5) The Authority may deny an initial or renewal application for a worker permit if:¶
(a) The applicant has violated any provision of ORS 475A.210 to 475A.722 or these rules.~~.~~¶
(b) The applicant has made a false statement to the Authority.~~.~~¶
(~~5~~6) 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.¶
(~~6~~7) An individual designated as a practicum site supervisor must hold a worker permit. ¶
(8) If the Authority approves an initial or renewal application and grants a worker permit the permit shall have a term of one year.¶
(~~7~~9) Once the Authority has made a determination to issue a permit the individual must pay a US$2~~5~~00 fee to receive the permit.¶
(~~8~~10) If an applicant for an initial worker permit fails to pay the fee or payment fails to clear within ~~18~~90 calendar days of receiving notice of the Authority's determination to grant an application, the application will be c~~onsidered~~losed as incomplete.¶
(~~9~~11) 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 c~~onsidered~~losed as incomplete.¶
(1~~0~~2) A renewal worker permit application will be considered timely if a complete renewal application is received by the Authority at least 60 calendar days before the date the permit expires. Applications received less than 60 days before the date the permit expires will be considered untimely.¶
(1~~1~~3) 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~~2~~4) 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, O~~regon Laws 2025, chapter 14~~RS 475A.377
Statutes/Other Implemented: ORS 475A.235, ORS 475A.483, ORS 475A.480, ORS 475A.250, O~~regon Laws 2025, chapter 14~~RS 475A.377

AMEND: 333-333-4100

RULE SUMMARY: Amend OAR 333-333-4100: Clarifies ambiguous language.

CHANGES TO RULE:

333-333-4100
Criminal Records Checks
(1) The Oregon Health Authority (Authority) may require any individual ~~person~~ identified as a licensee, a worker permit holder or applicant on a worker permit or license application to undergo a criminal records check and fitness determination.¶
(2) Any person identified as an applicant on an initial worker permit or license application is required to undergo a criminal records check and fitness determination.¶
(3) Any person identified as an applicant on a renewal license application may be required to undergo a criminal records check and fitness determination at regular intervals determined by the Authority.¶
(4) Any person identified as an applicant on a renewal worker permit application is required to undergo a criminal records check and fitness determination.¶
(5) An applicant for a worker permit is not required to undergo a criminal records check and fitness determination if that person has completed a criminal records check and fitness determination in connection with a license application within 12 months of their worker permit application.¶
(6) An individual ~~person~~ identified as a license applicant is not required to undergo a criminal records check and fitness determination if that person has completed a criminal records check and fitness determination in connection with another license application within 30 days of their current license application.¶
(7) The Authority will require a licensee or worker permit holder to undergo a criminal records check if the Authority learns that the individual has been convicted of a crime after their license or permit has been issued.¶
(8) When the Authority requires an individual to undergo a criminal records check, criminal records checks must be submitted to the Authority for a fitness determination in accordance with OAR 407-007-0200 to 407-007-0250, 407-007-0281, 407-007-0300 and 943-007-0001 to 943-007-0501. Individuals are not subject to a check for potentially disqualifying abuse, as described by OAR 407-007-0250(5).¶
(9) When the Authority requires an individual to undergo a criminal records check, the individual must provide:¶
(a) A criminal records check request form, prescribed by the Authority that includes but is not limited to:¶
(A) First, middle and last name;¶
(B) Any aliases;¶
(C) Date of birth; and¶
(D) Address and recent residency information.¶
(b) Fingerprints in a~~ccordance with the instructions on~~ form and manner prescribed by the Authority~~'s webpage~~.¶
(10) The Authority may request an applicant to disclose their Social Security Number if notice is provided that:¶
(a) Indicates the disclosure of the Social Security Number is voluntary.¶
(b) The Authority requests the Social Security Number for the purpose of positively identifying the applicant during the criminal records check process.¶
(11) Pursuant to ORS 475A.250, the Authority may not consider the prior conviction of a subject individual for:¶
(a) The manufacture of psilocybin or the manufacture of a marijuana item, as defined in ORS 475C.009, if:¶
(A) The date of the conviction is two or more years before the date of the application; and¶
(B) The person has not been convicted more than once for the manufacture of psilocybin or a marijuana item; or¶
(b) The possession of a controlled substance, as defined in ORS 475.005, or a marijuana item, as defined in ORS 475C.009, if:¶
(A) The date of the conviction is two or more years before the date of the application; or¶
(B) The person has not been convicted more than once for the possession of a controlled substance or a marijuana item.¶
(12) The fitness determination described in section (8) of this rule will determine whether the applicant is ineligible to be licensed.¶
(13) For licensees and permittees refusal to participate in a criminal records check required by this rule is a violation.¶
(14) The Authority shall deny an application for a license or worker permit if the applicant does not have an approved criminal records check under ORS 181A.195¶
(15) If an applicant is denied due to the fitness determination, the applicant has hearings rights to challenge the fitness determination under OAR 943-007-0501.
Statutory/Other Authority: ORS 475A.235, ORS 475A.255, ORS 475A.486, ORS 475A.598, ORS 475A.250, O~~regon Laws 2025, chapter 14~~RS 475A.377

Statutes/Other Implemented: ORS 475A.235, ORS 475A.255, ORS 475A.486, ORS 475A.598, ORS 475A.250, O~~regon Laws 2025, chapter 14~~RS 475A.377

AMEND: 333-333-4110

RULE SUMMARY: Amend OAR 333-333-4110: Requires an applicant to be present during inspections.

CHANGES TO RULE:

333-333-4110
Application Review
(1) Once the ~~Authority~~Oregon Health Authority (Authority) has determined that an application is complete, it must review the application to determine compliance with ORS chapter 475A and these rules.¶
(2) The Authority must receive a land use compatibility statement from the city or county that authorizes land use in the city or county where the premises proposed to be licensed is located prior to acting on an application for a new manufacturer or service center license.¶
(3) The Authority may verify any information submitted by the applicant, including but not limited to contacting any individual or legal entity identified in the application to request additional documents or information.~~-~~¶
(4) The Authority may require an inspection of the premises proposed to be licensed prior to issuing a license. An individual named as an applicant on the license application must be present at the time of the inspection. There is no fee for inspections performed under this section.~~-~~¶
(5) If the Authority determines that the applicant is not in compliance with these rules following an inspection described in section (4) of this rule, the Authority will provide a notice of the failed inspection identifying the requirements that have not been met.~~-~~¶
(6) An applicant that fails an inspection described in section (4) of this rule will have 90 calendar days from the date the notice was sent to submit a written response that demonstrates the noted deficiencies have been corrected.~~-~~¶
(7) If the applicant's response under section (6) of this rule appears to correct the noted deficiencies, the Authority may schedule another inspection.~~-~~¶
(8) If the applicant fails a second inspection, the Authority will deny the application unless the applicant shows good cause for the Authority to perform additional inspections.
Statutory/Other Authority: ORS 475A.235, ORS 475A.250, ORS 475A.290
Statutes/Other Implemented: ORS 475A.235, ORS 475A.250, ORS 475A.290

AMEND: 333-333-4120

RULE SUMMARY: Amend OAR 333-333-4120: Reduces payment window for licenses from 180 to 90 days.

CHANGES TO RULE:

333-333-4120
Approval and Issuance
(1) If upon review of an application the Oregon Health Authority (Authority) determines the application meets all licensing requirements, the Authority will notify the applicant in writing that the application is pending approval and will request license fee payment. An applicant may not exercise any license privileges until they receive proof of licensure issued under section (4) of this rule.¶
(2) If an applicant for a manufacturer, service center or laboratory license fails to pay the license fee or payment fails to clear within 60 calendar days of the notice described in section (1) of this rule, the Authority may require re-inspection of the premises proposed to be licensed. Any re-inspections that take place pursuant to this rule will be subject to the change fee described in OAR 333-333-4060(~~7~~4).¶
(3) If an applicant for any license type fails to pay the license fee or payment fails to clear within ~~18~~90 calendar days of the notice described in section (1) of this rule, the application will be c~~onsidered~~losed as incomplete.¶
(4) The Authority will not approve the license until it has confirmed that payment of the license fee has cleared and processing the application is complete. When the license is approved, the Authority will notify the applicant in writing and will provide the applicant proof of licensure, that includes a unique license number, the licensee name(s), the operational name, the effective date of the license, and address of the licensed premises. Licenses issued under ORS chapter 475A may be held by multiple licensees.¶
(5) A licensee may not exercise license privileges until the effective date of licensure identified on the proof of licensure issued under section (4) of this rule.¶
(6) Manufacturer, service center and laboratory licensees must display a proof of licensure in a prominent place on the licensed premises.¶
(7) Facilitator licensees must be able to provide proof of licensure when performing preparation, administration or integration sessions.¶
(8) Manufacturer, service center and laboratory licenses are only valid for the licensed premises and are only issued to the individuals or entities listed on the application or subsequently approved by the Authority.¶
(9) Facilitator licenses are only issued to the individual listed on the application.¶
(10) A license may not be transferred except as provided in OAR 333-333-4270.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4200

RULE SUMMARY: Amend OAR 333-333-4200: Clarifies required use of published forms, refines ambiguous language.

CHANGES TO RULE:

333-333-4200
Notification of Changes
(1) An applicant or licensee must notify the Oregon Health Authority (Authority) in writing ~~in a form and manner prescrib~~using forms published ~~by~~on the Authority's website and receive written approval from the Authority prior to the following:¶
(a) Adding or removing an individual or legal entity who qualifies as an applicant under OAR 333-333-1010 or OAR 333-333-4030. Individuals who qualify as applicants must submit information regarding race, ethnicity, preferred spoken and written language, sexual orientation and gender identity of each individual applicant recorded in a form and manner prescribed by the Authority as required by OAR 333-333-4930.¶
(b) A change in licensee's operational name.¶
(2) An applicant or licensee must notify the Authority in writing ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority's website within 10 business days of any of the following:¶
(a) A change in contact information for any person listed as an applicant or licensee.¶
(b) Any closure of ~~the~~a licensed premises lasting more than 30 days.¶
(c) Any conviction for any misdemeanor or felony committed by an individual listed as an applicant or licensee.¶
(d) Any arrest for conduct that occurred on ~~the~~a licensed premises.¶
(e) Any theft of psilocybin products or cash from ~~the~~a licensed premises.¶
(3) If after receipt of information required under subsection (1)(a) of this rule the Authority determines that the addition of an individual or legal entity applicant could result in an initial or renewal application denial under OAR 333-333-4130 or serve as the basis of a license suspension or revocation, the Authority:¶
(a) Will notify the licensee of its determination.¶
(b) Will give the licensee 30 calendar days to take action~~s~~ to ensure the individual or entity does not qualify as an applicant and provide documentation to the Authority that demonstrates such actions have been taken.¶
(c) May propose license suspension or revocation under OAR 333-333-4130 if the licensee does not comply with subsection (b) of this section.¶
(4) If applicable, the licensee must pay the change fee specified in OAR 333-333-4060 and payment must clear prior to making changes to their licensed premises or approved licensees that require inspections or additional applicants.¶
(5) A licensee who wishes to change the location of ~~the~~a licensed premises must submit a change of location request including required forms and documents and the ~~license applica~~site inspection fee specified in OAR 333-333-4060(~~1~~4).¶
(a) A licensee that submits a change of location request is not required to pay an additional annual license fee.¶
(b) A change of location request submitted under this rule must be submitted ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority's website and must include:¶
(A) For changes to manufacturer or service center license location, a land use compatibility statement from the city or county that authorizes land use in the city or county where the new licensed premises will be located.¶
(B) For manufacturer, service center and laboratory license applicants, a map or diagram of the new location's licensed premises including the boundaries of the licensed premises relative to its location, identification of any residence or other structures located on the same tax lot as the premises proposed to be licensed that will not be included in the licensed premises, and a scaled floor plan identifying all limited access areas and client administration areas. The Authority may request additional documents or information related to the new locations, including but not limited to photographs of the premises to be licensed.¶
(C) For a manufacturer license, if the licensee is not the owner of the real property where the new location will be located, a written statement ~~in the form and manner prescribed by the Authority~~ signed by the property owner and witnessed by a notary public that confirms ownership of the real property and shows that the owner consents to manufacturing of psilocybin products on the property for at least one annual license term. The written statement must be submitted using the form published on the Authority's website. ¶
(6) The Authority may require a licensee to submit a new application including all required forms and documents and the fee specified in OAR 333-333-4060 for a change in ownership structure that is 51 percent or greater. For the purposes of this rule, a change is considered to be 51 percent or greater if natural persons who did not hold a direct or indirect interest in the entity at the start of the license year will collectively hold a direct or indirect interest of 51 percent or greater. The Authority may require licensees to submit additional information to determine whether a new application must be submitted.¶

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

AMEND: 333-333-4250

RULE SUMMARY: Amend OAR 333-333-4250: Clarifies process for license renewal applications, allows Oregon Psilocybin Services (OPS) to close applications when applicants fail to provide documents or cure defects. Allows OPS to deny renewal application for unpaid civil penalties.

CHANGES TO RULE:

333-333-4250
License Renewal
(1) Renewal Applications:¶
(a) A renewal application must be submitted in a form and manner prescribed by the Oregon Health Authority (Authority) and must include documents, and information required by the Authority~~ to be complete.~~, including but not limited to completing forms required by OAR 333-333-4930. ¶
(b) For facilitator applicants, a renewal application ~~received on or after January 1, 2026~~ must include documentation that the applicant has completed the continuing education requirements described in OAR 333-333-3300.¶
(c) ~~A renewal application will be considered timely if a complete renewal application is received by the Authority~~For service center, manufacturer and laboratory applicants, a renewal application must include an attestation that every product tracking system user for the licensed premises has completed training required by the Authority for the product tracking system. ¶
(d) Upon receipt of a renewal application, the Authority will perform an initial review to determine if the applicant has submitted a complete application including all required documents. A renewal application will be considered timely if an applicant has submitted all required documents at least 60 calendar days before the date the license expires. Applications received less than 60 days before the date the license expires will be considered untimely. An application's submission date is the date the Authority receives a completed application, including all required documents.¶
(~~d~~e) A licensee who submits a ~~complete~~ timely renewal application may continue to operate after the stated license expiration date, pending a decision by the Authority on the renewal application.¶
(~~e~~f) A licensee who submits an untimely ~~or incomplete~~ renewal application or who does not submit a renewal application must cease engaging in the licensed activity when the license expires.¶
(~~f~~g) A person who, while not actively licensed, engages in any activity that would require a license may be subject to administrative and criminal sanctions regardless of their prior licensure status.¶
(2) ~~T~~After performing an initial review, the Authority may require a licensee with a pending renewal application to submit additional forms, documents and information described in OAR 333-333-4000~~, including but not limited to information regarding race, ethnicity, preferred spoken and written language, sexual orientation and gender identity of each individual applicant, in order to complete an evaluation of a renewal application. Failure to submit forms, documents or information requested by the Authority under this section within a time period prescribed by the Authority may result in the renewal application being considered incomplete.~~ ¶
(3) The Authority may require an inspection of the premises proposed to be licensed prior to renewing a license after providing reasonable notice as described in OAR 333-333-6150(~~3~~2). An individual named as an applicant on the renewal application must be present at the time of the inspection. There is no fee for inspections performed under this section.¶
(4) If the Authority determines that the licensee is not in compliance with these rules following an inspection described in section (3) of this rule, the Authority may issue a notice of violation~~.~~ or provide applicants an opportunity to modify their licensed premises to achieve compliance. The Authority will identify required modifications in writing and applicants must address modifications within 30 calendar days. The Authority may deny a renewal application if the applicant does not address modifications within 30 calendar days¶
(5) If upon review of an application the Authority determines the renewal application meets all licensing requirements, the Authority will notify the applicant in writing that the renewal application is pending approval and will request license fee payment.¶
(6) If an applicant for any license type fails to pay the license renewal fee or payment fails to clear within 30 calendar days of the notice described in section (5) of this rule, the renewal application will be c~~onsidered~~losed as incomplete.¶
(7) The Authority will not renew the license until it has confirmed that payment of the license renewal fee has cleared and processing of the renewal application is complete. When the license is renewed, the Authority will notify the applicant and provide the applicant with updated proof of licensure that includes a unique license number, the licensee name(s), the operational name, the effective date of the license, and address of the licensed premises.¶

(8) Failure to submit forms, documents or information requested by the Authority under this rule within 30 calendar days may result in the renewal application being closed as incomplete.¶
(9) The Authority shall deny a renewal application if the application identifies an applicant who has not paid a civil penalty imposed under a final order issued by the Authority under ORS chapter 183, or payment has not cleared within the time frame specified in the order.
Statutory/Other Authority: ORS 475A.235, ORS 475A.483
Statutes/Other Implemented: ORS 475A.235, ORS 475A.483, ORS 475A.374

AMEND: 333-333-4280

RULE SUMMARY: Amend OAR 333-333-4280: Clarifies form requirements; allows worker permits to request surrender of their permit.

CHANGES TO RULE:

333-333-4280
Surrender
(1) A licensee may request to surrender a license ~~in a form and manner prescrib~~by submitting the form published ~~by~~on the 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 prescrib~~using the form published ~~by~~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, ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority's website, 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 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 ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority's website. 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

AMEND: 333-333-4300

RULE SUMMARY: Amend OAR 333-333-4300: Removes provisions that are now contained in OAR 333-333-4310 pertaining to requirements for authorized temporary uses.

CHANGES TO RULE:

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:¶
(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 475.722 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.~~
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.305, ORS 475A.310

ADOPT: 333-333-4310

RULE SUMMARY: Adopt OAR 333-333-4310: Existing requirements for authorized temporary uses were moved into this new rule from OAR 333-333-4300 and description of complete and adequate notice was added.

CHANGES TO RULE:

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 475.722 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. ¶
(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 proposed temporary use. 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

AMEND: 333-333-4400

RULE SUMMARY: Amend OAR 333-333-4400: Adjusts cross reference.

CHANGES TO RULE:

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. 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 333-333-43100~~0(6)~~, excluding limited access areas, for activities that are unrelated to the exercise of license 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 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

AMEND: 333-333-4480

RULE SUMMARY: Amend OAR 333-333-4480: Clarifies that service centers may not remove psilocybin products from packaging. Clarifies prohibition on promoting consumption at unlicensed locations.

CHANGES TO RULE:

333-333-4480
Service Center Privileges and Prohibitions
(1) A service center may:¶
(a) Between the hours of 6:00 AM and 11:59 PM local time, sell psilocybin products and provide psilocybin services to clients 21 years of age or older.¶
(b) Purchase, possess or receive psilocybin products from a manufacturer or service center.¶
(c) Transfer psilocybin products to a manufacturer or service center, subject to product quantity limits in OAR 333-333-2200.¶
(2) A service center must begin every administration session at a time that allows the minimum duration of that session described in OAR 333-333-5250 to elapse prior to 11:59 PM local time.¶
(3) A service center must collect tax on all psilocybin products sold to clients and document the sale of all products and services in the manner required by OAR 333-333-5180.¶
(4) A service center must create and maintain policies and procedures for possession and storage of firearms and other weapons on the licensed premises.¶
(5) A service center may not:¶
(a) Discount a psilocybin product or offer a psilocybin product for free.¶
(b) Permit a client to bring psilocybin products onto the licensed premises or take any psilocybin product from the licensed premises.¶
(c) Sell or offer for sale any psilocybin product that does not comply with the requirements of ORS chapter 475A or these rules.¶
(6) A licensee representative of a service center may not assist a client with any of the activities required to be performed by a client support person pursuant to OAR 333-333-5070(5)(d), (f), (g) or (m).¶
(7) Service centers may permit clients to bring any food item and non-alcoholic beverage onto the licensed premises for consumption subject to the requirements of OAR 333-333-5170 and 333-333-4400. Service centers must store food items that require refrigeration at a temperature of 41 degrees Fahrenheit or less.¶
(8) Service centers may provide packaged food and beverages to clients and food that was prepared offsite at a restaurant or other facility licensed under ORS chapter 624. If food will be provided during an administration session, service centers must discuss client's' dietary needs, restrictions and preferences prior to beginning the administration session.¶
(9) Service centers may not provide food items or beverages to clients that were prepared on the licensed premises. This rule does not prevent a service center from providing heated or unheated water to clients.¶
(10) Service centers may not remove psilocybin products from client packaging for repackaging or any other purpose, except for psilocybin products that will be destroyed and designated as waste in the product tracking system.¶
(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.¶
(1~~1~~2) 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 within Oregon where it is unlawful to do so. ¶
(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.¶
(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

AMEND: 333-333-4520

RULE SUMMARY: Amend OAR 333-333-4520: Describes expectations for client conduct and renames “Client Bill of Rights” as “Client Rights and Responsibilities.”

CHANGES TO RULE:

333-333-4520
Client ~~Bill of Right~~Rights and Responsibilities
(1) A service center must post the ~~following "Client Bill of Right~~attached "Client Rights and Responsibilities" in a prominent location within the licensed premises and must provide every client with a copy during their preparation session:¶
~~"Clients receiving psilocybin services in Oregon have the following rights:¶~~
~~To be treated with dignity and respect while receiving psilocybin services.¶~~
~~To receive competent and equitable care consistent with values, policies, and practices that ensure all people, especially those who have been historically marginalized based on race, ethnicity, religion, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances are considered in the development of social pathways to health equity.¶~~
~~To be free from physical, sexual, psychological, and financial abuse before, during, and after receiving psilocybin services.¶~~
~~To make decisions without coercion or undue influence. To be informed of the known benefits and risks associated with psilocybin services.¶~~
~~To refuse psilocybin services prior to beginning an administration session.¶~~
~~To privacy and confidentiality regarding participation in psilocybin services.¶~~
~~To refuse to release any information to third parties, except as required by law. Information may be required to be released by law when a client initiates a complaint, when communications reveal an intent to cause harm to others or disclose that a minor may have been a victim of abuse, or when responding to an investigation by the Oregon Health Authority.¶~~
~~To full disclosure of any facilitator conflicts of interest.¶~~
~~To a full and accurate explanation of the costs associated with receiving psilocybin services before receiving those services.¶~~
~~To store personal belongings securely while receiving psilocybin services.¶~~
~~To access their client records after providing reasonable notice to a facilitator or service center and to correct information that is inaccurate.¶~~
~~To request a private space in which to receive psilocybin services.¶~~
~~To be monitored and supported by a licensed~~(2) The text of the Client Rights and Responsibilities may not be altered and must be printed in an easily legible font.¶
(3) A facilitator ~~for the duration of psilocybin services until it is safe for the client to leave the service center.¶~~
~~To receive psilocybin services from a licensed facilitator for the duration of those services, except in cases of emergency.¶~~
~~To access service centers and psilocybin services that are welcoming and accessible to people with disabilities.¶~~
~~To have access to a clean, single occupancy restroom for the duration of psilocybin services.¶~~
~~To discuss this Bill of Rights with licensed facilitators and service center operators without facing discrimination or retaliation.¶~~
~~To report violations of this Bill of Rights to the Oregon Health Authority, or other appropriate governing body, without facing discrimination or reta~~service center must provide the Client Rights and Responsibili~~ati~~~~on.¶~~
~~To withdraw or alter my consent to receive psilocybin services at any time prior to beginning an administration session.¶~~
~~To withdraw or alter my consent to release information. ¶~~
~~To receive information regarding culturally and linguistically responsive services offered to support client safety. ¶~~
~~To receive services in a manner that considers my individual conditions, sensitivities and health concerns.¶~~
~~To be fully informed of a service center's policies on possession of firearms and other weapons on the licensed premises.¶~~
~~To make complaints to the Oregon Health Authority regarding psilocybin products and services.¶~~
~~To choose their facilitator and request an opportunity to receive psilocybin services from an alternate facilitator. Facilitators and service centers may decline services to a client for any reason."¶~~
~~(2) The text of the Client Bill of Rights may not be altered and must be printed in an easily legible fon~~es in other languages or accessible formats upon a client's request.¶
(~~3~~4) A facilitator or service center must provide the Client ~~Bill of Rights in other languages or accessible formats~~

~~upon a client's request.¶~~
~~(4) A facilitator or service center must provide the Client Bill of Right~~Rights and Responsibilities to a client prior to a preparation session upon the client's request.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.370

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

NOTE: Attachments referenced are attached to this document. You may view the attachment 333-333-4520.pdf from the Attachments panel. Alternately, you may view the attachments at the following link: https://secure.sos.state.or.us/oard/viewAttachment.action?ruleVrsnRsn=339170

AMEND: 333-333-4650

RULE SUMMARY: Amend OAR 333-333-4650: Clarifies required form for providing notice of video stoppage.

CHANGES TO RULE:

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

AMEND: 333-333-4660

RULE SUMMARY: Amend OAR 333-333-4660: Adjusts cross reference.

CHANGES TO RULE:

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

AMEND: 333-333-4810

RULE SUMMARY: Amend OAR 333-333-4810: Clarifies forms required for client consent to release information.

CHANGES TO RULE:

333-333-4810
Client Confidentiality
(1) A service center or facilitator may not disclose any information that may be used to identify a client, or disclose any communication made by a client related to psilocybin services or selling psilocybin products to a client to any person including other clients, except with a client's consent or otherwise as allowed by ORS 475A.450. Service centers may allow facilitators to access records related to services a facilitator provided to clients at the service center without the client's consent. A licensed facilitator may only access client records for clients to whom they have provided preparation, administration, or integration sessions. A licensed facilitator may not access the client records of any other client unless the client has provided prior written consent and the facilitator accesses the records for the purpose of providing services to the client.¶
(2) A service center must have a completed client consent form to disclose identifiable client information that contains the following:¶
(a) A specific description of the client's identifiable information to be used or disclosed.¶
(b) The name or specific identification of the person(s) or class of person(s) the client's information will be disclosed to.¶
(c) The specific purpose for which the information will be used or disclosed.¶
(d) The date and signature of the client.¶
(e) An expiration date when the consent to use or disclose is withdrawn.¶
(3) A service center or facilitator must use the client written consent form provided by the Oregon Health Authority (Authority) to meet the requirements of section (2) of this rule. The consent form is available on the Authority's website.¶
(4) If a client consents to disclose their identifiable client information the client consent form described in section (2) of this rule must be completed at least 24 hours prior to the client's administration session or at least 72 hours after the conclusion of the client's administration session. If a client chooses to withdraw their consent form described in section (2), they may do so by providing written notice to the service center or facilitator ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority~~.~~'s website. ¶
(5) A service center or facilitator must provide a client with a disclosure form during or prior to a preparation session if the facilitator or service center intends to share de-identified data related to the client's receipt of psilocybin product or services.¶
(a) The disclosure form must contain:¶
(A) The name of the person or organization that will receive de-identified data.¶
(B) The specific purpose for which the de-identified data will be used or disclosed.¶
(C) The date the form was provided to the client and client signature acknowledging receipt.¶
(D) An option that allows the client to opt out of having their de-identified data disclosed to third parties.¶
(b) The disclosure form is not required when reporting required data to the Authority pursuant to OAR 333-333-4910 and may not be used for clients to request that their data be withheld from the Authority as described in OAR 333-333-4900(4).¶
(6) A service center or facilitator must use the disclosure form provided by the Authority to meet the requirements of section (5) of this rule. The disclosure form is available on the Authority's website.¶
(7) If a client chooses to withdraw their disclosure form described in section (5), they may do so by providing written notice to the service center or facilitator ~~in a form and manner prescrib~~. Service centers and facilitators must document clients' written notice using the form published ~~by~~on the Authority's website.¶
(8) Service centers are not required to complete consent forms for disclosure required by section (2) of this rule when releasing a client's own records to a client who received services. These records may not contain information that could identify other clients.~~-~~¶
(9) Service centers and facilitators are not required to complete disclosure forms required by section (5) of this rule when sharing de-identified data describing the total number of clients to whom the licensee has provided preparation, administration, and integration sessions.~~-~~¶
(10) Service centers and facilitators may not alter client records after the completion of preparation, administration or integration sessions. Service centers and facilitators may create an addendum to existing records.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.450, ORS 475A.372

AMEND: 333-333-4900

RULE SUMMARY: Amend OAR 333-333-4900: Clarifies forms required for opt-out of client data reporting.

CHANGES TO RULE:

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 prescrib~~using the form published ~~by~~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

AMEND: 333-333-4910

RULE SUMMARY: Amend OAR 333-333-4910: Adjusts average dose reporting requirements to align with Oregon Laws 2026, Chapter 109 (HB 4040).

CHANGES TO RULE:

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 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) ~~T~~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.¶
(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 202~~5~~6, chapter 1~~47~~09
Statutes/Other Implemented: ORS 475A.372~~, Oregon Laws 2025, chapter 147~~

AMEND: 333-333-4930

RULE SUMMARY: Amend OAR 333-333-4930: Removes obsolete date reference, clarifies language regarding incomplete applications.

CHANGES TO RULE:

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.¶~~
~~(3) 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 r~~Applicants must provide the information described in section (1) of this rule. Failure to submit the information may resul~~e~~t in ~~order for~~ the application ~~to be considered~~ being closed as incomplete.
Statutory/Other Authority: ORS 475A.235, ORS 475A.374
Statutes/Other Implemented: ORS 475A.235, ORS 475A.374

AMEND: 333-333-5000

RULE SUMMARY: Amend OAR 333-333-5000: Removes requirements that clients have a preparation session at least 24 hours before administration session. Adjusted for clarifying edits and cross references.

CHANGES TO RULE:

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

group session as described in OAR 333-333-5020.¶
(b) Use of supportive touch during an administration session, if any, as described in OAR 333-333-5120(~~8~~9).¶
(c) Participation in a training practicum, including information regarding training program students and instructors who will be present during the client's administration session. The client must have an opportunity to meet any students or instructors who will be present during their administration session prior to the commencement of an administration session.¶
(d) Video or audio recording of an administration session pursuant to requirements of OAR 333-333-4640.¶
(e) Presence of an interpreter or client support person allowed by OAR 333-333-5070, in the administration area during an administration session.¶
(f) Sharing of identifiable client data as described in OAR 333-333-4810(2).¶
(g) The use of different facilitators to conduct a client's preparation, administration sessions or integration session.¶
(h) Consuming secondary doses of psilocybin products after the administration session has begun, including the maximum amount of psilocybin analyte that a client has agreed to consume, not to exceed 50.0 mg of psilocybin analyte.¶
(i) Disclosure form for de-identified client data required by OAR 333-333-4810(5).¶
(10) If a facilitator or service center intends to share de-identified data related to the client's receipt of psilocybin product or services, a facilitator or service center must provide a disclosure form required by OAR 333-333-4810(5) during the client's preparation session.¶
(11) During a preparation session, facilitators must provide clients an opportunity to discuss internal and external factors that could impact a psilocybin experience including but not limited to the client's intention and expectations. If the client will participate in an outdoor administration session, the facilitator must provide an opportunity to discuss the client's specific concerns that may be relevant to participating in an outdoor administration session, including but not limited to allergies and sensitivity to sun exposure.¶
(12) Preparation sessions may be completed in person or virtually using video conferencing technology.¶
(13) The requirements of this rule may be satisfied by conducting multiple preparation sessions.¶
(14) A facilitator must complete an initial preparation session with every client before conducting an administration session with that client for the first time. After a client completes an initial preparation session at a service center, the client is not required to complete additional preparation sessions prior to participating in an administration session at the same service center for a period of 12 months.¶
(15) If a facilitator does not complete additional preparation sessions as allowed by section (14) of this rule, the facilitator must confirm that the information contained in the client's previously completed client information form remains accurate prior to conducting an administration session. If the previously completed client information form is no longer accurate on the date of the client's proposed administration session, a facilitator must conduct an additional preparation session to complete an updated client information prior to conducting administration sessions.¶
(16) A facilitator must discuss the process for verification of license status and process for making complaints to the Authority during a preparation session.¶
(17) The documents described in sections (8), (9) and (10) of this rule must be provided to a client prior to a preparation session upon the client's request.¶
(18) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.¶
(19) If different facilitators will conduct preparation and administration sessions, the facilitator conducting the administration session must receive and review all forms and documents required to be completed during a preparation session prior to beginning the administration session.¶
(20) Except for practicum site supervisors, lead educators and students participating in a practicum with the client's prior written consent, only the client, and any facilitators and client support persons who will be present during the client's administration session may be present during a preparation session.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340, ORS 475A.372

AMEND: 333-333-5040

RULE SUMMARY: Amend OAR 333-333-5040: Conforming edit for renamed Client Rights and Responsibilities.

CHANGES TO RULE:

333-333-5040
Informed Consent
(1) A facilitator or service center must provide every client a copy of the ~~following informed consent document during the client's preparation session or prior to the preparation session upon a client's request:¶~~
~~Introduction:¶~~
~~In the State of Oregon, psilocybin services include a preparation session, administration session, and integration session. You should receive this informed consent form prior to or during your preparation session. During the preparation session, your facilitator will review and discuss this form with you. Please make sure you read and understand every section because you must sign the form before the administration session begins. If you do not understand any part of this document, please ask your facilitator for clarification before signing.¶~~
~~I have been informed of and understand the following:¶~~
~~(Please initial each item below)¶~~
~~1. ____ I have reviewed the Psilocybin Services Client Bill of Rights, my facilitator has explained it to me, and I understand my rights as a client.¶~~
~~2. ____ I understand that psilocybin services do not require medical diagnosis or referral and that psilocybin services are not a medical or clinical treatment.¶~~
~~3. ____ I understand that psilocybin has not been approved by the Food and Drug Administration and the federal government currently classifies psilocybin as a Schedule I controlled substance under the Controlled Substances Act.¶~~
~~a. Federal law prohibits the manufacture, distribution, and possession of psilocybin even in cities and states that have adopted laws to allow its possession or use.¶~~
~~b. Despite its federal Schedule I status, research suggests that psilocybin is very unlikely to be addictive. Additionally, research and other information suggests that psilocybin may improve symptoms of depression, anxiety, end of life distress, various forms of trauma, and problematic substance use.¶~~
~~4. ____ I understand that the risks, benefits, and drug interactions of psilocybin are not fully understood, and individual results may vary.¶~~
~~5. ____ I understand that some people have found psilocybin administration sessions to be challenging or uncomfortable. Common potential side effects include nausea, mild headache, fatigue, anxiety, confusion, increased blood pressure, elevated heart rate, paranoia, perceptual changes, altered thought patterns, reduced inhibitions, recovery of repressed memories and past traumas, and altered perception of time and one's surroundings. If they occur, these side effects are usually mild and temporary but could include long-term distress, worsening psychiatric symptoms and cardiovascular effects. Because the potential risks and benefits of psilocybin administration are not fully understood, there may be unanticipated side effects.¶~~
~~6. ____ I understand that if I am taking prescription medications or have a medical condition or mental health condition, I should consider consulting with a medical or clinical provider before participating in an administration session.¶~~
~~7. ____ I understand that psilocybin is derived from fungi. If I have a known mushroom allergy, I should consult with a medical or clinical provider before participating in an administration session.¶~~
~~8. ____ I understand that the risks of consuming psilocybin while pregnant or feeding with breast milk are unknown.¶~~
~~9. ____ I understand that facilitators may not use touch while providing psilocybin services without my prior written consent. My facilitator and I have discussed acceptable types of supportive touch and the requirement to provide prior written consent prior to the start of my administration session.¶~~
~~10. ____ I understand that facilitators may be mandatory reporters of abuse. If my facilitator is a mandatory reporter, they have shared this information with me and explained their legal obligations to report abuse.¶~~
~~11. ___ I understand that licensees have a duty to report misconduct that harms or endangers a client to the Oregon Health Authority. If the misconduct presents an immediate risk to health and safety, service centers have a duty to contact emergency services.¶~~
~~12. ____ I agree to follow my agreed upon transportation plan. I understand that a facilitator may contact emergency services if failure to follow my transportation plan presents a risk to my safety or the safety of others.¶~~
~~13. ____ I understand that consuming psilocybin is completely voluntary, and I may decide not to consume psilocybin at any time.¶~~
~~14. ___ I understand that I have the right to update my client information form prior to beginning an administration~~

~~session and I have the right to receive a copy of my client information form upon request.¶~~
~~15. ___ I understand that if de-identified data collected by facilitators and service centers is shared with people and institutions outside of the facilitator or psilocybin service center, I must be provided with a disclosure form that describes who will receive the data and how it will be used, and that I have the opportunity to opt-out of having my de-identified data provided to third parties .¶~~
~~16. ___I understand data that may be used to identify me as a client will only be shared to the extent permitted or required by law. Specifically, ORS 475A.450 allows disclosure in the following circumstances:¶~~
~~(1) When the client or a person authorized to act on behalf of the client gives consent to the disclosure;¶~~
~~(2) When the client initiates legal action or makes a complaint against the psilocybin service center operator, the psilocybin service facilitator, or the employee;¶~~
~~(3) When the communication reveals the intent to commit a crime harmful to the client or others;¶~~
~~(4) When the communication reveals that a minor may have been a victim of a crime or physical, sexual or emotional abuse or neglect; or¶~~
~~(5) When responding to an inquiry by the Oregon Health Authority made during the course of an investigation into the conduct of the psilocybin service center operator, the psilocybin service facilitator, or the employee under ORS 475A.210 to 475A.722.¶~~
~~17. ___I understand that my facilitator may take short restroom breaks during my administration session.¶~~
~~18. ___ I understand that for my own safety, leaving a psilocybin service center during an administration session once it has begun is strongly discouraged. Doing so could lead to safety and legal risks.¶~~
~~19. ___ I understand and have been informed of the potential benefits, risks, and complications of psilocybin services with my facilitator to the extent that they are known.¶~~
~~20. ___My facilitator has shared information regarding verification of license status and process for making complaints to the Oregon Health Authority.¶~~
~~21. ___ I have had the opportunity to ask questions regarding anything I may not understand or that I believe should be made clear.¶~~
~~22. ___ If participating in a group administration session, I understand that I will be experiencing the effects of psilocybin in the presence of other clients who are also experiencing the effects of psilocybin and may be reacting to the experience in a different manner.¶~~
~~23.___I understand that activation times for psilocybin products are variable and cannot be accurately predicted.¶~~
~~24. ___I acknowledge that the risks and benefits of consuming doses greater than 35 mg of psilocybin analyte are unknown.¶~~
~~25. ___If consuming whole fungi during an administration session, I understand that psilocybin content can vary between individual fruiting bodies.¶~~
~~26. ___I understand that the risks and benefits of repeated psilocybin use are unknown.¶~~
~~27. ___I understand that a facilitator has a duty to call emergency services if required and a client assumes responsibility for costs of emergency services.¶~~
~~28. ___I understand that I will be required to identify an emergency contact and a facilitator or service center may contact this person in the event of a medical or other emergency.¶~~
~~29. ___ I understand that I may be charged a cancellation fee if I cancel a scheduled preparation, administration or integration session.¶~~
~~30. ___I understand that I have the right to choose my facilitator and if a facilitator has supervisory, evaluative, or other authority over me, I will be provided an opportunity to receive psilocybin services from another facilitator.¶~~
~~31.___I understand that service center licensee representatives may be present during my administration session to assist licensed facilitators with operations.¶~~
~~32.___I understand that if a service center license is surrendered or revoked that service center may transfer my records to another service center license with my prior written consent or destroy the record.¶~~
~~33. __I understand that service centers and facilitators are required to provide information regarding culturally and linguistically responsive services upon request. ¶~~
~~_____¶~~
~~Name (Print)¶~~
~~_____ _____¶~~
~~Signature Date~~attached informed consent document during the client's preparation session or prior to the preparation session upon a client's request:¶
(2) A facilitator must review the contents of the informed consent form with each client and receive a signed copy of each client's informed consent document prior to beginning an administration session.¶
(3) A facilitator or service center must provide the informed consent document in other languages or accessible formats upon a client's request. If a facilitator or service center is unable to provide a translated or accessible document upon a client's request, they may not conduct an administration session with the client.¶
(4) Informed consent documents may be delivered electronically as long as the facilitator receives a signed

informed consent document, in either paper or electronic format, prior to beginning an administration session.¶
(5) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

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

NOTE: Attachments referenced are attached to this document. You may view the attachment 333-333-5040.pdf from the Attachments panel. Alternately, you may view the attachments at the following link:
https://secure.sos.state.or.us/oard/viewAttachment.action?ruleVrsnRsn=339190

AMEND: 333-333-5050

RULE SUMMARY: Amend OAR 333-333-5050: Clarifies that required form is posted on program website.

CHANGES TO RULE:

333-333-5050
Client Information Form
(1) A client must review and complete a client information form in coordination with a facilitator prior to participating in an administration session. This requirement must be satisfied by using the designated form published by the Oregon Health Authority (Authority) on its website.¶
(2) A facilitator must provide a client information form in other languages or accessible formats upon a client's request. If a facilitator is unable to provide a translated or accessible client information form upon a client's request, they may not conduct an administration session with the client.¶
(3) The client information form must include the following questions, and a client must answer each question by indicating "yes" or "no":¶
(a) Have you taken the prescription drug Lithium in the last 30 days?¶
(b) Are you currently being treated by a medical, clinical or other healthcare provider for a medical, mental health, or behavioral health condition?¶
(c) Have you ever had an allergic reaction to consuming mushrooms or other fungi?¶
(d) Are you currently taking any prescription medications, non-prescription medication or nutritional supplements that might need to be consumed during an administration session?¶
(e) Will you require assistance from an interpreter during an administration session?¶
(f) Will you require assistance from a client support person for catheter, ostomy, or toileting assistance, ambulation or transfer mobility support, or medical device assistance during the administration session?¶
(g) Will you require assistance from a client support person for augmentative and alternative communication (AAC) device support or assistive listening device support during the administration session?¶
(h) Are you having thoughts of causing harm, or wanting to cause harm, to self or others?¶
(i) Do you have a history of causing harm, or wanting to cause harm, to self or others?¶
(j) Have you ever been diagnosed with active psychosis or treated for active psychosis?¶
(k) Are you pregnant or feeding with breast milk?¶
(l) Do you require any assistive mobility devices?¶
(m) Will you require assistance to consume psilocybin products?¶
(n) Would you like to share any other conditions, sensitivities or health concerns with your facilitator?¶
(4) The client information form must include the following questions, and a client may provide a narrative answer to these questions.¶
(a) Would you like to share anything about your medical history, including current prescription medications, non-prescription medication or nutritional supplements, that you feel would be helpful for an administration session?¶
(b) Would you like to share anything about your mental health history, including traumatic experiences that you feel would be helpful for an administration session?¶
(c) Would you like to share anything about specific behaviors, internal or external stimuli ("triggers") that could cause you to be uncomfortable during an administration session?¶
(d) Would you like to share anything about your history of substance use, including current substance use, that you feel would be helpful for an administration session?¶
(e) Would you like to share any past experiences with psychedelics or altered states of consciousness?¶
(f) Would you like to share any information about your relationships, your living situation, or your educational or work environment that may be affected by your administration session or may require additional safety or support planning?¶
(5) A facilitator must evaluate the answers to questions listed in section (3) of this rule to determine whether the client should participate in an administration session.¶
(a) If a client answers yes to question (3)(a), the client may not participate in an administration session.¶
(b) If a client answers yes to question (3)(b), a facilitator shall encourage the client to consult a medical, clinical or other healthcare provider regarding the risk of consuming psilocybin.¶
(c) If a client answers yes to question (3)(c), the client should be encouraged to consume an alternative psilocybin product rather than whole fungi or homogenized fungi during the administration session.¶
(d) If a client answers yes to question (3)(d), a facilitator should encourage the client to schedule their administration session at a time that allows them to participate without taking prescription medications, non-prescription medication or nutritional supplements. A facilitator should also encourage the client to consult with a pharmacist or medical, clinical or other healthcare provider regarding contraindications. If the client will take

prescription medications, non-prescription medication or nutritional supplements during an administration session, the client and facilitator must work together to identify whether the client will be able to administer the prescription medications, non-prescription medication or nutritional supplements themselves. If the client is unable to administer the prescription medications, non-prescription medication or nutritional supplements themselves, the client must identify a client support person who will be available to administer the prescription medications, non-prescription medication or nutritional supplements when required and complete a written medication plan ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority~~.~~'s website. ¶
(e) If a client answers yes to question (3)(e), the client and facilitator must work together to identify an appropriate interpreter who will be present in person or virtually during the client's administration session.¶
(f) If a client answers yes to question (3)(f), the client and facilitator must work together to create a written assistance and medical device plan ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority~~.~~'s website. ¶
(A) If the client requires a medical device, the plan must describe the required medical device and indicate whether the client will be able to use the medical device without assistance. If the client is unable to use the medical device without assistance, the plan must identify a client support person who will be available to assist the client with their medical device when required.¶
(B) If the client requires assistance with catheter, ostomy, or toileting assistance, ambulation or transfer mobility support, the plan must identify the type of assistance required and a client support person who will be available to assist the client.¶
(g) If a client answers yes to question (3)(g), the client and facilitator must work together to identify an appropriate client support person who will be present during the client's administration session to assist with the client's alternative communication device support or assistive listening device support during the administration session.¶
(h) If a client answers yes to question (3)(h), the client may not participate in an administration session.¶
(i) If a client answers yes to question (3)(i), a facilitator shall encourage the client to consult with a medical or clinical provider regarding the risk of consuming psilocybin.¶
(j) If a client answers yes to question (3)(j), the client may not participate in an administration session.¶
(k) If a client answers yes to question (3)(k), the facilitator must inform the client that the risks of consuming psilocybin while pregnant or feeding with breast milk are unknown.¶
(l) If a client answers yes to question (3)(l), the client and facilitator must work together to create a written plan that describes how the client will safely exit the service center in the event that an emergency occurs during their administration session.¶
(m) If a client answers yes to question (3)(m), the client and facilitator must work together to identify an appropriate client support person who will be present to assist the client with consuming psilocybin products during their administration session.¶
(n) If a client answers yes to question (3)(n), the client and facilitator must work with the client to create a written plan that describes how the facilitator will take reasonable steps to accommodate the conditions, sensitivities or health concerns identified by the client. For example, if a client has a compromised immune system, the written plan will describe efforts to prevent the transmission of viruses and bacteria.¶
(6) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

AMEND: 333-333-5070

RULE SUMMARY: Amend OAR 333-333-5070: Adjusts language for reference to Client Rights and Responsibilities, clarifies that students may not perform other duties while participating in practicum.

CHANGES TO RULE:

333-333-5070
Interpreters and Client Support Persons
(1) If an interpreter or client support person will be present during receipt of psilocybin services, a client and facilitator must meet with the interpreter or client support person prior to beginning the administration session.¶
(2) In addition to the client support persons identified in OAR 333-333-5050(5)(d), (f), (g) or (m), a client may choose to invite one client support person over 21 years of age to attend their administration session as an observer. Service centers and facilitators must ensure that client support persons who attend administration sessions as observers comply with all of the requirements for client support persons described in these rules. Service centers and facilitators may decline a client's request to invite a client support person to attend their administration session as an observer.~~-~~¶
(3) During the meeting required by section (1) of this rule a client and facilitator must work together with the interpreter or client support person to complete a written support person plan using the form published by the Oregon Health Authority (Authority) that contains the following information:¶
(a) The name of the interpreter or client support person who will attend the session.¶
(b) The specific purpose for which the interpreter or client support person will be present, including but not limited to identifying any prescription medications, non-prescription medication, nutritional supplements or medical devices that the client will utilize during administration session.¶
(c) Whether the interpreter or client support person will be present for the duration of an administration session or whether they will be available as needed.¶
(d) A signed statement that the interpreter or client support person agrees to the following conditions:¶
(A) Interpreters and client support persons will be present for the specific purposes described in their support person plan and shall not provide psilocybin services nor interfere or otherwise participate in the administration session.~~-~~¶
(B) Interpreters and client support persons must comply with the facilitator's reasonable directions during an administration session. Facilitators may request that client support persons acting as observers leave the administration session at any time.~~-~~¶
(C) Interpreters and client support persons, facilitators and service centers shall not share or disclose any information regarding clients' participation in psilocybin services.¶
(4) Client support persons shall perform only those activities identified in the written support person plan described in section (3) of this rule.¶
(5) Client support persons are prohibited from touching clients except as required to perform activities identified in the written support person plan described in section (3) of this rule. Facilitators must ensure that client support persons who are acting as observers are limited to giving hugs or placing hands on a client's hands, feet or shoulders with the client's prior written consent.~~-~~¶
(6) During the meeting required by section (1) of this rule a facilitator must instruct the client support person not to disclose any information that may be used to identify a client, nor disclose any communication made by a client related to psilocybin services.~~-~~¶
(7) During the meeting required by section (1) of this rule a facilitator must provide a copy of the Client ~~Bill of Right~~Rights and Responsibilities, discuss the process for making complaints to the Authority and allow the interpreter or client support person an opportunity to ask questions.¶
(8) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.¶
(9) Facilitators and licensee representatives of a service center are prohibited from acting as client support person during an administration session for which they are acting as a facilitator or licensee representative.¶
(10) Service centers and facilitators ~~may~~shall not:¶
(a) Provide nor compensate client support persons who attend client administration sessions.¶
(b) Require a client to ~~a~~use a specific client support person.¶
(c) Allow practicum students to act as client support persons.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

AMEND: 333-333-5120

RULE SUMMARY: Amend OAR 333-333-5120: Clarifies statutory provision regarding refusal of service to clients; clarifies prohibition on encouraging illegal activity.

CHANGES TO RULE:

333-333-5120
Facilitator Conduct
(1) Facilitators have a duty to put clients' interest above their own and to use a standard of care that other reasonable facilitators would use under similar circumstances.¶
(2) A facilitator shall not make any misrepresentations to clients regarding psilocybin products or services, the requirements of ORS 475A.210 to 475A.722 and these rules, or the facilitator's qualifications and experience.¶
(3) A facilitator must use a nondirective facilitation approach to providing psilocybin services to clients during preparation, administration and integration sessions, except for a facilitator who has notified the Oregon Health Authority (Authority) of their license status as required by OAR 333-333-5130 and provides health care or behavioral health care services during preparation and integration sessions.¶
(4) A facilitator who has notified the Authority of their license status as required by OAR 333-333-5130 must provide prior notice of this license status to clients and inform clients whether they will be providing health care or behavioral health care services during preparation and integration sessions.¶
(5) A facilitator shall utilize their training to distinguish between typical side effects of consuming psilocybin and medical emergencies. In the event of a medical emergency, a facilitator must contact emergency responders or other appropriate medical professionals immediately.¶
(6) A facilitator shall determine whether they are able to provide psilocybin services to a client. If a facilitator determines that they are unable to provide services to a client for any reason, the facilitator may refer the client to another facilitator. ¶
(7) A facilitator may refuse to provide psilocybin services to a client or potential client for any reason, except that a facilitator may not cease providing services to a client during an administration session. These rules do not excuse a facilitator from complying with applicable federal, state and local non-discrimination laws. ¶
(8) If a facilitator has supervisory, evaluative, or other authority over a client, the facilitator shall provide the client an opportunity to receive psilocybin services from another facilitator.¶
(~~8~~9) Facilitators may provide supportive touch during administration sessions when requested by the client and with the client's prior written consent ~~in a form and manner prescribed by the Oregon Heal~~using the form published on the Authority~~.¶~~
's website (a) Supportive touch is limited to hugs or placing hands on a client's hands, feet or shoulders. A facilitator shall not use any other forms of touch, nor permit another person to use any other form of touch during an administration session, except for client support persons who perform activities identified in a written support person plan pursuant to OAR 333-333-5070.¶
(b) Clients participating in a group administration session may provide prior written consent to authorize supportive touch from other clients participating in the administration session. Supportive touch is limited to hugs or placing hands on a client's hands, feet or shoulders.¶
(~~9~~10) A facilitator shall not assist a client with any of the activities required to be performed by a client support person pursuant to OAR 333-333-5070(5)(d), (f), (g) or (m).¶
(1~~0~~1) A facilitator shall not engage in any romantic relationship, sexual contact, or sexual intimacy with a client during the provision of psilocybin services including preparatory, administration, and integration sessions.¶
(1~~1~~2) A facilitator shall not engage in any romantic relationships, sexual contact, or sexual intimacy with clients, or clients' partners or immediate family members, for a period of one year following the last date that the facilitator provided psilocybin services to the client.¶
(1~~2~~3) A facilitator may not engage in any financial transactions with clients or the client's partners or immediate family members that violate a facilitator's duty to place client's interests above their own as required by section (1) of this rule.¶
(1~~3~~4) If a facilitator is a mandatory reporter of abuse under Oregon law, the facilitator must disclose their status and obligations to a client at the beginning of the client's first preparation session.¶
(1~~4~~5) A facilitator may not transfer psilocybin products to another person and may not supervise individuals experiencing the effect of consuming psilocybin products at any location other than a service center except as allowed by section (1~~5) of this rule.~~7) of this rule.¶
(16) A facilitator may not encourage activity that is illegal under state law, including promoting unregulated cultivation and processing of psilocybin products by providing information or instruction related to home cultivation, scheduling clients to consume psilocybin at an unlicensed location or recommending that clients

consume psilocybin products at any location within Oregon where it is unlawful to do so. ¶
(1~~5~~7) These rules do not prevent a facilitator from:¶
(a) Participating in harm reduction activities at festivals and events, via telephone hotlines and mobile applications, or in other situations when unforeseen circumstances arise that require harm reduction support.~~.~~¶
(b) Supervising individuals experiencing the effect of consuming psilocybin products during federally approved research and clinical trials.¶
(c) Supervising individuals experiencing the effect of consuming psilocybin products at locations outside of Oregon if they hold the necessary license or authorization or it is otherwise lawful to do so in that location.¶
(~~16~~d) Providing harm reduction information to clients and potential clients. ¶
(18) The requirements of these rules apply to all facilitators, regardless of whether a facilitator is also a licensee representative of a service center.¶
(1~~7~~9) The requirements of these rules apply to all facilitators, regardless of whether multiple facilitators provide services to the same client, or whether a lead or primary facilitator has been designated.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340, O~~regon Laws 2025, chapter 147~~RS 475A.370, ORS 475A.338
Statutes/Other Implemented: ORS 475A.340, O~~regon Laws 2025, chapter 147~~RS 475A.370, ORS 475A.338, ORS 475A.375

AMEND: 333-333-5130

RULE SUMMARY: Amend OAR 333-333-5130: Aligns with Oregon Laws 2026, Chapter 109 (HB 4040) provision on dual licensed facilitators by adding additional licensing board, clarifies exception to scope of practice requirement for dual licensed facilitators.

CHANGES TO RULE:

333-333-5130
Facilitator Scope of Practice
(1) ~~A~~With the exception of facilitators who provide health care or behavioral health care services during preparation and integration sessions as described in section (6) of this rule, a facilitator shall not engage in any conduct that requires additional professional licensure while providing psilocybin services to clients, including but not limited to diagnosing and treating physical or mental health conditions.¶
(2) A facilitator is prohibited from transferring, selling or otherwise handling any psilocybin product while they are facilitating a preparation, administration or integration session, regardless of whether the facilitator is also a licensee representative of a service center.¶
(3) ~~I~~With the exception of facilitators who provide health care or behavioral health care services during preparation and integration sessions as described in section (6) of this rule, if a facilitator holds a professional license in another field, the facilitator shall not exercise the privileges of that license while providing psilocybin services to clients during preparation, administration or integration sessions.¶
(4) A facilitator may only conduct administration sessions at a licensed psilocybin service center.¶
(5) A facilitator who holds a license issued by the following boards must notify the Oregon Health Authority (Authority) in a form and manner prescribed by the Authority:¶
(a) The Occupational Therapy Licensing Board.¶
(b) The Oregon Board of Licensed Professional Counselors and Therapists.¶
(~~b~~c) The Oregon Board of Naturopathic Medicine.¶
(~~c~~d) The Oregon Board of Physical Therapy. ¶
(e) The Oregon Board of Psychology.~~-~~¶
(~~d~~f) The Oregon Medical Board.~~-~~¶
(~~e~~g) The Oregon State Board of Nursing.~~-~~¶
(~~f~~h) The State Board of Licensed Social Workers.¶
(~~g~~i) The State Board of Pharmacy.¶
(6) ~~Notwithstanding section (1) and (3) of this rule, a~~A facilitator who has notified the Authority of their license status as required by section (5) may provide health care or behavioral health care services during preparation and integration sessions as long as the facilitator also notifies the client prior to providing health care or behavioral health care services.~~-~~¶
(7) A facilitator is prohibited from providing psilocybin services in a manner that violates these rules.¶
(8) A facilitator is prohibited from providing psilocybin services in a manner that violates any provision of ORS chapter 475A.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340, ORS 475A.338, Oregon Laws 202~~5~~6, chapter 14~~7~~09
Statutes/Other Implemented: ORS 475A.340, O~~regon Laws 2025, chapter 147~~RS 475A.338

AMEND: 333-333-5200

RULE SUMMARY: Amend OAR 333-333-5200: Removes requirement for low dose administration plan. Allows facilitators and licensee representatives to perform music and support clients with breathwork subject to rule requirements.

CHANGES TO RULE:

333-333-5200
Administration Session Requirements
(1) Administration sessions must be conducted by a facilitator and may only take place within a service center's designated administration area.¶
(2) The requirements of OAR 333-333-5000 and OAR 333-333-5020, if applicable, must be satisfied prior to any client participating in an administration session in an administration area.¶
(3)~~ For clients who intend to consume doses of less than 2.5 mg of psilocybin analyte during administration sessions that occur over the course of multiple days, facilitators shall create a plan with the individual client and coordinate with service centers to ensure the client may access planned administration sessions. This plan must be stored with the client records and made available to the Oregon Health Authority (Authority) upon request. ¶~~
~~(4)~~ A facilitator must always be present during administration sessions and shall continuously monitor any client participating in the administration session. Continuous monitoring means that a facilitator must maintain visual and audio contact with clients and monitor clients for signs of physical or emotional distress. Video monitoring or other equipment may not be used to satisfy the requirement to continuously monitor clients.¶
(~~5~~4) The requirements of section (~~4~~3) of this rule do not apply to client restroom breaks.¶
(~~6~~5) A facilitator may take restroom breaks of approximately five minutes or less during an administration session if the facilitator remains on the licensed premises and a service center licensee representative is available to monitor clients.¶
(~~7~~6) A facilitator or service center may provide recorded music or other recorded audio or visual materials during an administration session as long as ~~the client consents to the use of these materials prior to beginning an administration session. A~~all clients consent to the use of these materials prior to beginning an administration session. ¶
(7) A facilitator or licensee representative of a service center may perform music by singing or playing an instrument, or support clients by conducting breathwork during an administration session as long as all clients consent prior to beginning an administration session. A licensee representative who performs music or supports clients with breathwork during an administration session may not perform the duties required by section (9) of this rule. A facilitator who performs music or supports clients with breathwork during an administration session must continuously monitor clients as described in section (3) of this rule. A licensee representative who performs or engages in the activities described in this section during an administration session must hold a valid worker permit. ¶
(8) Music and other audio or visual media may not contain images or references to violence or harm to self or others. Facilitators and service centers must exercise reasonable judgement to avoid music and materials that are likely to cause distress for clients. Facilitators and service centers may only p~~rovide audio and visual materials that are non-directive~~erform or provide music and other audio and visual materials when requested to do so by clients. A client may decline the use of ~~these~~music and other audio and visual materials at any time, including during the administration session.~~-~~¶
(~~8~~9) In addition to a facilitator conducting the administration session and any licensee representatives who may be present during an administration session to perform music as described in section (7) of this rule, at least one licensee representative of a service center license must be present on the licensed premises at all times when an administration session is taking place at a service center. The licensee representative required by this rule may take restroom breaks of approximately five minutes or less during an administration session as long as they remain on the licensed premises and adequate measures to prevent unauthorized access to the licensed premises are in place as required by OAR 333-333-4550. Licensee representatives may traverse through client administration areas to access restrooms as long as they do not interfere with client administration sessions. If the licensee representative required by this rule holds a facilitator licensee, they are prohibited from transferring, selling or otherwise handling any psilocybin product while they are facilitating a preparation, administration or integration session.¶
(~~9~~10) Except for individuals described in OAR 333-333-5070 and service centers acting as practicum sites, only clients, facilitators and licensee representatives of a service center may be present during an administration session.¶
(1~~0~~1) Licensee representatives of a service center who are present during an administration session:¶

(a) May not provide psilocybin services.¶
(b) May only be present to perform music, conduct breathwork or assist with operations and must leave the administration area after performing, conducting breathwork, or assisting with operations.¶
(c) Shall not interfere with or otherwise participate in the administration session.¶
(d) May not share or disclose any information regarding clients' participation in psilocybin services without the client's prior written consent.¶
(1~~1~~2) A service center may not host administrative sessions for more than 100 clients at any given time regardless of whether the clients are participating in separate individual or group administration sessions.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.340

AMEND: 333-333-5230

RULE SUMMARY: Amend OAR 333-333-5230: Streamlines dosing tiers for facilitator to client ratios for group administration sessions.

CHANGES TO RULE:

333-333-5230
Group Administration Sessions
(1) Group administration sessions may be conducted pursuant to the requirements of OAR 333-333-5020 and this rule.~~.~~¶
(2) Client to Facilitator Ratio. The minimum facilitator to client ratio depends on the amount of psilocybin product clients participating in the group administration session will individually consume, including any secondary doses. If the clients consume different amounts of psilocybin, the largest amount consumed will dictate the required facilitator to client ratio.~~.~~¶
(a) For clients consuming equal to or less than 5.0 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 25.¶
(b) For clients consuming ~~equal or~~ greater than 5.0 mg and ~~less than 10 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 15.¶~~
~~(c) For clients consuming equal or greater than 10 mg and less than 15~~equal to or less than 15.0 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to ~~8~~15.¶
(~~d~~c) For clients consuming ~~equal or~~ greater than 15.0 mg and ~~less than 25 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 6. ¶~~
~~(e) For clients consuming equal or greater than 25 mg and~~equal to or less than 35.0 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to ~~4~~6.¶
(~~f~~d) For clients consuming ~~equal or~~ greater than 35.0 mg and up to 50.0 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 2.¶
(3) Group administration sessions may not exceed a total of 25 clients, or the service center's maximum occupancy for the administration area where the session takes place whichever is smaller, regardless of the number of facilitators present.~~.~~¶
(4) Client administration areas where group sessions take place~~,~~ must provide an appropriate setting for the group sessions that:¶
(a) Provide sufficient space for clients and facilitators to participate in the session without touching or coming into close physical contact with other clients. Client administration areas where group administration sessions will take place must contain at least twenty-five square feet of area for every person who will be present during the session.~~.~~ ¶
(b) Allows a facilitator to monitor clients as required by OAR 333-333-5200(~~4~~3).¶
(5) Clients participating in a group administration session are prohibited from touching one another except for supportive touch as described in OAR 333-333-5120(~~8~~9). If supportive touch will be used during an administrative session, each participating client must provide prior written consent as described in OAR 333-333-5000(~~5~~9)(b).~~.~~¶
(6) Every client participating in a group session must be provided with an opportunity to request individual support from a facilitator.~~.~~¶
(7) If a client becomes disruptive during a group administration session, a facilitator must make reasonable efforts to move that client to a separate area within the administration area that mitigates disruption to the other clients in the group.~~.~~¶
(8) Every client participating in a group administration session must be present at the beginning of the session.~~.~~¶
(9) Unless explicitly stated in this rule, all requirements of OAR 333-333-5200 apply to group administration sessions.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.340

AMEND: 333-333-5240

RULE SUMMARY: Amend OAR 333-333-5240: Clarifies form requirements. Aligns with Oregon Environmental Laboratory Accreditation Program (ORELAP) rules for significant figures and removes duplicative language.

CHANGES TO RULE:

333-333-5240
Consumption Limits
(1) A service center licensee or licensee representative may not allow a client to consume more than a total of 50.0 mg of psilocybin analyte, including initial and secondary doses, during an administration session or during a 24-hour period. Both initial doses and secondary doses described in this rule may be transferred and consumed in multiple packages. For example, a dose consisting of 20.0 mg of psilocybin analyte could be transferred to a client in the form of two packages containing 10.0 mg of psilocybin of analyte.¶
(2) A service center licensee or licensee representative may permit a client to consume secondary doses of psilocybin product during an administration session as long as the secondary dose is total amount of psilocybin analyte contained in the products is 50.0 mg of psilocybin analyte or less.¶
(3) If a client wants the option to consume secondary doses during their administration session, up to a total of 50.0 mg of psilocybin analyte, a service center must:¶
(a) Receive written consent ~~in a form and manner prescrib~~using the form published ~~by~~on the Oregon Health Authority's (Authority's) website from the client prior to the beginning of their administration session.¶
(b) Require the client to purchase and take possession of secondary doses prior to beginning their administration session.¶
(c) Require the client to store secondary doses at a designated secured location outside of a limited access area and within the service center's licensed premises.¶
(d) Require the client, or a client support person subject to the requirements of OAR 333-333-5050(5)(f)(B) or (m) and OAR 333-333-5070, to retrieve secondary doses from the designated location and consume without assistance from a licensee representative or facilitator if the client chooses to consume the secondary dose.¶
(e) Ensure that secondary doses remain in sealed client packaging until consumed.¶
(f) Require the client to return the secondary dose to the service center at the conclusion of their administration if they do not consume it during their administration session.¶
(4) A service center licensee or licensee representative may decline to make secondary doses available for purchase for any reason.¶
(5) During an administration session, a service center licensee representative, in consultation with the client's facilitator, may decline to make a secondary dose available to a client who has purchased the secondary dose pursuant to section (3) of this rule.~~ A service center must provide clients a refund for the purchase price of any secondary dose that is not made available to clients.~~¶
(6) A service center must provide clients a refund for the purchase price of any secondary dose that is not consumed and remains in its original sealed client packaging. After providing a refund, a service center may make the product in its original sealed client packaging available for sale to other clients.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.340, ORS 475A.504

AMEND: 333-333-5250

RULE SUMMARY: Amend OAR 333-333-5250: Replaces milligrams of psilocybin analyte with total psilocybin equivalent as the unit of measurement for lowest dosing tier, aligns with Oregon Environmental Laboratory Accreditation Program (ORELAP) rules for significant figures. Adjusts other dosing tiers to allow for whole numbers as the maximum dose.

CHANGES TO RULE:

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 ~~2.5~~3.40 mg of total psilocybin ~~analyte~~equivalent, 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) ~~F~~Except for clients consuming ~~equal or greater than 2.5 mg and~~psilocybin products that meet the requirements of subsection (1)(a) of this rule, for clients consuming equal to or less than 5.0 mg of psilocybin analyte, the minimum duration of the administration session shall be one hour.¶
(c) For clients consuming ~~equal or~~ greater than 5.0 mg and equal to or less than 10.0 mg of psilocybin analyte, the minimum duration of the administration session shall be two hours.¶
(d) For clients consuming ~~equal or~~ greater than 10.0 mg and equal to or less than 15.0 mg of psilocybin analyte, the minimum duration of the administration session shall be three hours.¶
(e) For clients consuming ~~equal or~~ greater than 15.0 mg and equal to or less than 25.0 mg of psilocybin analyte, the minimum duration of the administration session shall be four hours.~~.~~¶
(f) For clients consuming ~~equal or~~ greater than 25.0 mg and equal to or less than 35.0 mg of psilocybin analyte, the minimum duration of the administration session shall be five hours.¶
(g) For clients consuming ~~equal or~~ greater than 35.0 mg and up to 50.0 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 2.50 mg of psilocybin analyte.¶
(3) 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.¶
(4) 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 local time, the service center where the client received services, in consultation with the facilitator, shall notify the Oregon Health Authority (Authority) ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority's website 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.¶
(5) A facilitator shall record and retain the time and date that each administration session began and concluded ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority's website.~~.~~¶
(6) 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 ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority's website.~~.~~¶
(7) 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 document the client's refusal.~~ to document the client's refusal using the form published on the Authority's website.¶
(8) 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.¶
(9) When a facilitator contacts clients under section (~~8~~7) of this rule, the facilitator must inquire whether the client experienced any post-session reactions and, if applicable, document post session reactions ~~in a form and manner prescrib~~using the form published ~~by~~on the Authority's website 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

AMEND: 333-333-6030

RULE SUMMARY: Amend OAR 333-333-6030: Clarifies that labs may not promote unregulated cultivation and processing.

CHANGES TO RULE:

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

AMEND: 333-333-6100

RULE SUMMARY: Amend OAR 333-333-6100: Clarifies that licensees are responsible for advertising conducted on their behalf.

CHANGES TO RULE:

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.¶
(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

AMEND: 333-333-6150

RULE SUMMARY: Amend OAR 333-333-6150: Requires a licensee to be present during compliance inspection.

CHANGES TO RULE:

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) A~~ licensee or licensee representativ~~n individual named as a licensee 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.¶
(~~4~~5) A licensee, licensee representative, or permittee must cooperate with authorized Authority representative's reasonable requests during an inspection.¶
(~~5~~6) 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.~~-~~¶
(~~6~~7) If a licensee, licensee representative or permittee fails to permit the Authority to conduct an inspection the Authority may issue an investigative subpoena to inspect the licensed premises and gather books, payrolls, accounts, papers, documents or records.
Statutory/Other Authority: ORS 475A.235, ORS 475A.385
Statutes/Other Implemented: ORS 475A.235, ORS 475A.385

AMEND: 333-333-6160

RULE SUMMARY: Amend OAR 333-333-6160: Clarifies that information contained in the product tracking system is treated identically to other evidence.

CHANGES TO RULE:

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

AMEND: 333-333-7020

RULE SUMMARY: Amend OAR 333-333-7020: Requires products to be destroyed when test results expire.

CHANGES TO RULE:

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.¶
(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 ~~t~~dest~~ed again before it can be sold to a client, transferred to another licensee, or converted to another product typ~~roved 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

AMEND: 333-333-7050

RULE SUMMARY: Amend OAR 333-333-7050: Adds a decimal point to stated values in order to align with Oregon Environmental Laboratory Accreditation Program (ORELAP) rules for significant figures.

CHANGES TO RULE:

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 Oregon Health Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.590
Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

AMEND: 333-333-7090

RULE SUMMARY: Amend OAR 333-333-7090: Adds a decimal point to stated values in order to align with Oregon Environmental Laboratory Accreditation Program (ORELAP) rules for significant figures.

CHANGES TO RULE:

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

AMEND: 333-333-7120

RULE SUMMARY: Amend OAR 333-333-7120: Amends retesting provision to remove requirement that a second lab test the product because Oregon Psilocybin Services (OPS) currently has only one licensed lab.

CHANGES TO RULE:

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~~o resample the batch and confirm that result for the batch to pass testing.¶
(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.¶~~
~~(c) A manufacturer must inform the Oregon Health Authority (Authority)~~A manufacturer must inform the 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¶
(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 psylocibin 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

AMEND: 333-333-8100

RULE SUMMARY: Amend OAR 333-333-8100: Clarifies ambiguous language and notice process for product loss in transit.

CHANGES TO RULE:

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 license 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.¶
(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 th~~via phone ~~form and manner prescribed by the Authority~~ electronic mail, 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.¶
(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 psylocibin 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

AMEND: 333-333-8200

RULE SUMMARY: Amend OAR 333-333-8200: Clarifies requirements for training product tracking system users.

CHANGES TO RULE:

333-333-8200
Product Tracking - General Requirements
(1) A service center, manufacturer or laboratory licensee must use the product tracking system as an inventory and recordkeeping system to record and maintain an accurate inventory of psilocybin products as specified in OAR 333-333-8210(1)(b).¶
(2) Each individual service center, manufacturer and laboratory licensee will have access to the product tracking system. A licensee may authorize additional licensee representatives to use the product tracking system for their licensed premises in a form and manner prescribed by the Oregon Health Authority (Authority).¶
(3) Each service center, manufacturer and laboratory licensee must:¶
(a) Maintain an accurate and complete list of all product tracking system users for each licensed premises and must update the list in a form and manner prescribed by the Authority when a new product tracking system user is added or removed.¶
(b) ~~Train and a~~Authorize any new product tracking system users before those users are permitted to access the product tracking system or input, modify, or delete any information in the product tracking system.¶
(c) Ensure that all product tracking system users complete product tracking system training and document completion in a form and manner prescribed by the Authority. ¶
(d) Remove access for any product tracking system user from an associated product tracking system account if that individual is no longer a licensee representative.¶
(~~d~~e) 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

AMEND: 333-333-8210

RULE SUMMARY: Amend OAR 333-333-8210: Clarifies requirement to reconcile inventory before license expires.

CHANGES TO RULE:

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:¶
(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 subsection (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. ¶
(4) 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