

OFFICE OF THE SECRETARY OF STATE

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ARCHIVES DIVISION

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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED

10/31/2022 9:03 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Oregon Psilocybin Services Rules

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/21/2022 5:00 PM

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

CONTACT: Oregon Psilocybin Services
971-341-1713
publichealth.rules@odhsoha.oregon.gov

800 NE Oregon St.
Portland, OR 97232

Filed By:
Public Health Division
Rules Coordinator

HEARING(S)

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

DATE: 11/15/2022

TIME: 6:00 PM - 8:00 PM

OFFICER: Staff

ADDRESS: Virtual hearing via Zoom

Due to COVID-19 some public meetings are
being held virtually

Portland, OR 97232

SPECIAL INSTRUCTIONS:

Join ZoomGov Meeting

<https://www.zoomgov.com/j/1604020703?pwd=dExxSDlpc2RnKzQ4UndyOStsdHlyUT09>

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

Meeting ID: 160 402 0703

Passcode: 738029

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

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

OHA welcomes all participants. If you have any questions about accommodations or need any assistance to participate please contact the Oregon Psilocybin Services team at 971-341-1713, 711 TTY, or OHA.Psilocybin@odhsoha.oregon.gov, at least 48 hours before the meeting. Every effort will be made to provide services to requests received at least 48 hours in advance, however submitting your request as early as possible is greatly appreciated.

DATE: 11/16/2022

TIME: 12:00 PM - 2:00 PM

OFFICER: Staff

ADDRESS: Virtual hearing via Zoom

Due to COVID-19 some public meetings are
being held virtually

Portland, OR 97232

SPECIAL INSTRUCTIONS:

Join ZoomGov Meeting

<https://www.zoomgov.com/j/1609417624?pwd=TFdOQTBlZnQ4Y0FpL1RYc1VBek4xUT09>

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

Meeting ID: 160 941 7624

Passcode: 168528

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

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

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

DATE: 11/17/2022

TIME: 10:00 AM - 12:00 PM

OFFICER: Staff

ADDRESS: Virtual hearing via Zoom

Due to COVID-19 some public meetings are
being held virtually

Portland, OR 97232

SPECIAL INSTRUCTIONS:

Join ZoomGov Meeting

<https://www.zoomgov.com/j/1609722100?pwd=Z1I2b3RtYnpaeDVrUk83U1ZrVnFYUT09>

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

Meeting ID: 160 972 2100

Passcode: 315886

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

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

OHA welcomes all participants. If you have any questions about accommodations or need any assistance to participate

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NEED FOR THE RULE(S)

The rules are needed to implement ORS chapter 475A, the Oregon Psilocybin Services Act ("the Act"). ORS chapter 475A creates a first of its kind regulatory framework for licensed production of psilocybin products and sale of psilocybin products and services to clients. The rules address all aspects of this framework and support the Act's goals of promoting access and equity while protecting health and safety. The rules are necessary to implement the Act which requires that they must be adopted by January 1, 2023. The rules address a variety of subject matter including requirements for licensure including storage and security, standards for psilocybin products, packaging and labeling requirements, safety standards and guidelines for provision of psilocybin services, client rights and informed consent processes, facilitator duties, compliance, product tracking and transportation.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

ORS chapter 475A https://www.oregonlegislature.gov/bills_laws/ors/ors475a.html

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The rules will impact all psilocybin manufacturers, psilocybin service centers, psilocybin facilitators, psilocybin testing laboratories and clients receiving psilocybin services in Oregon. As part of our government-to-government agreements, OHA Public Health Division sent a "Dear Tribal Leader Letter" to OHA Tribal Affairs in accordance with OHA's Tribal Consultation Policy, for distribution to Oregon's nine federally recognized tribes to gather feedback on the proposed rules. Oregon Psilocybin Services ("OPS") has engaged with community members across Oregon communities throughout the rule making process, including Black, Indigenous, People of Color, Tribal members, during public listening sessions, culturally responsive community circles, partner meetings, and presentations to community organizations. Additionally, the rules were informed by recommendations from the Equity Subcommittee of the Oregon Psilocybin Advisory Board. The Equity Subcommittee consists of members who represent priority populations. OPS engaged communities through multiple Rules Advisory Committees held between September 12 and September 30, 2022. OPS will continue to engage communities via the public comment period, which begins on November 1, 2022 and concludes on November 21, 2022. Public hearings will take place during this time and offer Spanish interpretation, American Sign Language interpretation, and real-time captioning, as well as any other request language or accessibility requests.

The present rules, taken together with the training curriculum rules adopted in May 2022, will impact racial equity. ORS chapter 475A creates opportunities for workforce in Oregon, specifically for licensed facilitators from diverse backgrounds that may support the health of their communities through culturally responsive and equity centered psilocybin services. Culturally responsive and equity centered services may reduce harm to clients that have experienced trauma from societal structures that have exhibited control through power and privilege, implicit bias, and institutional racism. In addition, research suggests that psilocybin can be helpful in addressing mental health issues, including trauma, adversity, toxic stress, anxiety, and depression. Because people of color may experience trauma, adversity, toxic stress, anxiety, and depression due to the impacts of racism and oppression, these communities are likely to be impacted more positively when receiving psilocybin services in a manner that is culturally responsive. The rules require all licensees to create and maintain a social equity plan that describes the licensee's application of diversity, equity, justice, and inclusion principles to the licensed business' operations. Although the rules do not provide for reduced license fees for applicants who belong to communities of color, they do offer reduced fees for non-profit

organizations, veterans and individuals who receive certain forms of public assistance. These provisions encourage low-income applicants and individuals with diverse life experience to become licensed. Additionally, the rules allow flexibility to provide psilocybin services in a range of settings. This flexibility allows for greater access across all client populations, but it is particularly important for individuals who have had negative experiences in medical or clinical settings.

To the extent that cost of regulation is passed onto clients, the rules may have a negative impact on lower income individuals. Throughout the rule making process, OPS has attempted to craft rules that promote public health and safety without creating unnecessary costs for licensees and clients. Because OPS is entirely fee-funded, the program's options for creating affordable license fees are rather limited.

FISCAL AND ECONOMIC IMPACT:

Licensed businesses and state agencies will incur cost to comply with the psilocybin rules. However, the overall fiscal and economic impact of the rules cannot be quantified at this time. The rules are necessary to implement ORS chapter 475A with appropriate public health and safety considerations. Less restrictive rules could carry a lower cost of compliance. However, this lower cost could be coupled with higher risks of negative impacts to public health and safety for clients and communities. Additionally, an appropriately regulated market creates consumer confidence and encourages members of the public to access psilocybin services through the ORS chapter 475A model rather than purchasing psilocybin from sources in the unregulated market and participating in unregulated services.

There is currently no regulated market for psilocybin products and services. Like all new businesses, psilocybin businesses will incur start-up costs. It is difficult to determine how much these costs will be influenced by rule requirements and how much costs will be affected by other factors, such as the status of psilocybin under the Federal Controlled Substances Act. Existing business that transition to licensed psilocybin business will also incur cost for additional equipment and modifications to their facilities.

Because ORS chapter 475A creates a fee-based structure, licensing fees must cover the costs of the administration of the Oregon Psilocybin Services section's work. Affordability is a concern for small businesses that plan to apply for licensure; however, no other funding exists to subsidize these costs. In addition, we are unable to set or regulate the costs of psilocybin products or services.

COST OF COMPLIANCE:

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

(1) OPS will incur costs to implement these rules. This activity is required by statute. The extent to which these rules create costs that are beyond the statutory requirements is unknown. OPS will devote resources to licensing and inspecting premises, monitoring compliance, and educating licensees. Oregon Department of Revenue will incur costs to administer psilocybin product tax. Oregon Department of Agriculture will incur cost to inspect and license manufacturers who produce food products containing psilocybin. The Oregon Environmental Laboratory Accreditation Program will incur costs to accredit laboratories that perform psilocybin tests. Agency costs will be covered by the fees state agencies charge to provide required services.

Local governments may incur administrative costs if they chose to amend their zoning code or adopt time, place and

manner regulations for the operation of psilocybin business in their jurisdiction. The public may be subject to costs if psilocybin licensees choose to pass on the cost of compliance to clients.

(2)(a) OPS estimates that many licensed psilocybin businesses will meet the definition of small businesses. There are currently no licensed psilocybin businesses in Oregon as the program is in the development period. At this time OPS cannot accurately predict how many licensed psilocybin businesses will operate.

(b) The rules contain various reporting and recordkeeping activities that exceed the typical requirements for non-psilocybin business. Most aspects of psilocybin production and sale will be recorded and tracked in a psilocybin tracking system pursuant to statutory requirements. The cost of additional record keeping requirements contained in these rules is difficult to quantify. It is unclear whether the requirements in rule will result in costs that significantly exceed the cost for maintenance of ordinary business records.

(c) There are currently no licensed psilocybin businesses in Oregon. Many of the rule requirements could lead to increased costs for equipment, supplies, labor, and administration. For example, the rules require enhanced security for psilocybin businesses including video recording. The rules are designed to contemplate the unique challenges facing psilocybin businesses. OPS cannot predict what portion of a businesses' overall startup cost will be impacted by rule requirements.

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

Small businesses participated in the rules advisory committee. Representatives from small businesses also provided public comment and served on the Oregon Psilocybin Advisory Board and its subcommittees.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-333-1010, 333-333-2015, 333-333-2200, 333-333-2300, 333-333-2310, 333-333-2400, 333-333-2410, 333-333-3005, 333-333-3200, 333-333-4000, 333-333-4010, 333-333-4020, 333-333-4030, 333-333-4040, 333-333-4050, 333-333-4060, 333-333-4070, 333-333-4100, 333-333-4110, 333-333-4120, 333-333-4130, 333-333-4140, 333-333-4200, 333-333-4210, 333-333-4250, 333-333-4260, 333-333-4270, 333-333-4280, 333-333-4300, 333-333-4400, 333-333-4450, 333-333-4460, 333-333-4465, 333-333-4470, 333-333-4480, 333-333-4490, 333-333-4500, 333-333-4510, 333-333-4520, 333-333-4550, 333-333-4600, 333-333-4620, 333-333-4630, 333-333-4640, 333-333-4650, 333-333-4660, 333-333-4700, 333-333-4810, 333-333-4820, 333-333-4830, 333-333-5000, 333-333-5020, 333-333-5040, 333-333-5050, 333-333-5070, 333-333-5080, 333-333-5090, 333-333-5100, 333-333-5120, 333-333-5130, 333-333-5140, 333-333-5150, 333-333-5160, 333-333-5170, 333-333-5180, 333-333-5200, 333-333-5210, 333-333-5230, 333-333-5240, 333-333-5250, 333-333-5260, 333-333-6000, 333-333-6030, 333-333-6040, 333-333-6100, 333-333-6110, 333-333-6120, 333-333-6150, 333-333-6200, 333-333-6210, 333-333-6220, 333-333-8000, 333-333-8100, 333-333-8200, 333-333-8210, 333-333-8220, 333-333-8230, 333-333-8240, 333-333-8250, 333-333-8260

AMEND: 333-333-1010

RULE SUMMARY: 333-333-1010-Adopts and amends definitions that will be used throughout psilocybin rules.

CHANGES TO RULE:

Definitions

For purposes of chapter 333, division 333 the following definitions apply:¶

(1) "Adulterant" means 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. Adulterant does not include naturally occurring substances contained in food items such as, but not limited to chocolate.¶

(2) "Authority" means the Oregon Health Authority.¶

(3) "Adverse behavioral reaction" means client behavior that a facilitator reasonably believes may endanger the safety of the client, facilitator, or others.¶

(3) "Adverse medical reaction" means a client's physiological reaction occurring during an administration session that a facilitator reasonably believes may lead to medical harm. For example, a cardiac event or other health emergency.¶

(4) "Advertising" means publicizing the trade name of a licensee together with words or symbols referring to psilocybin or publicizing the brand name of a psilocybin product.¶

(5) "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. ¶

(6) "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. ¶

(7) "Authority" means the Oregon Health Authority.¶

(8) "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.¶

(9) "Batch" means a quantity of whole fungi from a harvest lot, or a quantity of psilocybin product from a process lot. ¶

(10) "Billboard" means a large outdoor advertising structure.¶

(11) "Capsule" means a small soluble pill, tablet or container that contains liquid or powdered psilocybin product and is intended for human consumption. ¶

(5) "Chemical synthesis" means the production of psilocybin using precursor ingredients rather than cultivation of fruiting bodies and mycelium. ¶

(6) "Edible psilocybin product" means psilocybin extract or homogenized fungi that has been incorporated into a food item or potable beverage.¶

(7) "Extraction" means:¶

(a) The process of separating psilocybin from fungi by using a solvent; and ¶

(b) Manufacturing psilocybin extracts. ¶

(12) "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.¶

(13) "Chemical synthesis" means the production of psilocybin using precursor ingredients rather than cultivation of fruiting bodies and mycelium. ¶

(14) "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; and ¶

(c) Administration sessions may take place. ¶

(15) "Client information form" means the form required by ORS 475A.350. ¶

(16) "Client packaging" means packaging containing psilocybin products intended to be sold to clients.¶

(17) "Client support person" means a person who will be present during a client's administration session for any purposes described in OAR 333-333-5050(5)(d), (f), (g) or (j). ¶

(18) "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 license representative acting under the direction of a licensee. ¶
- (19) "Cultivation batch" means a quantity of unharvested fruiting body or mycelium that is grown together under the same conditions. ¶
- (20) "Cultural equity" means values, policies, and practices that ensure all people, especially those who have been historically marginalized based on race, ethnicity, 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. ¶
- (21) "Curriculum" means the topics, subjects, and activities that make up courses taught by a training program. ¶
- (22) "De-identified data" means client information from which the Authority or other entity has deleted, redacted, or blocked identifiers so the remaining information cannot reasonably be used to identify an individual. ¶
- (23) "Edible psilocybin product" means psilocybin extract or homogenized fungi that has been incorporated into a food item or potable beverage. ¶
- (24) "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, kindergarten, or a combination of pre-kindergarten and kindergarten. ¶
- (25) "Extraction" means: ¶
- (a) The process of separating psilocybin from fungi by using a solvent; and ¶
- (b) Manufacturing psilocybin extracts. ¶
- (26) "Facilitation" means the provision of services to a client by a licensed facilitator during a preparation, administration, or integration session. ¶
- (27) "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(5) or 333-333-4030. ¶
- (d) Does not include an investment interest that the investor does not control in nature, amount or timing. ¶
- (28) "Fruiting bodies" means the spore producing organs of the fungi *Psilocybe cubensis*. ¶
- (29) "Fungi" means the fruiting bodies or mycelium of the fungi *Psilocybe cubensis*. ¶
- (30) "Harvest" means the act of removing mycelium or fruiting bodies from a production environment for drying or processing. ¶
- (31) "Harvest lot" means a specifically identified quantity of fungi that is cultivated and dried under the same conditions and harvested within a 24-hour period at the same location within the licensed premises. ¶
- (11) "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 products may contain inactive ingredients such as binders, dilutants and carrying agents. ¶
- (12) "Laboratory" means a laboratory licensed under ORS 475A.594. ¶
- (132) "Health equity" means the opportunity for all people to reach their full health potential and well-being without being disadvantaged by their race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities or other socially determined circumstances. ¶
- (33) "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 products may contain inactive ingredients such as binders, dilutants and carrying agents. ¶
- (34) "Intervention" means taking proactive steps to respond to the client's behavior, experience, or condition during an administration session. ¶
- (35) "Intoxicant" means any substance that has intoxicating effects, and includes alcohol, prescription drugs, non-prescription drugs and any other controlled substances. ¶
- (36) "Laboratory" means a laboratory licensed under ORS 475A.594. ¶
- (37) "Lead educator" means a person affiliated with a training program who is responsible for tracking the progress of students throughout the program. ¶
- (38) "License 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. ¶
- (39) "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. ¶
- (40) "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.¶
- (41) "Limited access area" means any area of a licensed premises where psilocybin products or waste are stored or produced.¶
- (42) "Manufacturer" means a manufacturer licensed under ORS 475A.290.¶
- (443) "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. ¶
- (144) "Marijuana" has the meaning given that term in ORS 475C.009.¶
- (45) "Mycelium" means the fungal threads or hyphae of *Psilocybe cubensis*. ¶
- (146) "Pesticide" means any substance or mixture of substances included in ORS 634.006(8).¶
- (17) "Nondirective facilitation" means a client-directed approach to facilitation in which the facilitator maintains a consistent disposition with a client, while avoiding giving the client direct advice or directly interpreting a client's statements, behaviors or needs unless appropriate for health and safety reasons. ¶
- (47) "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.¶
- (48) "Oregon Psilocybin Services Act" means ORS 475A.210 to ORS 475A.722.¶
- (49) "Pesticide" means any substance or mixture of substances included in ORS 634.006(8).¶
- (50) "Permittee" means a person who holds a permit issued under ORS 475A.480.¶
- (51) "Practicum site" means a designated service center that provides practicum training.¶
- (52) "Practicum site supervisor" means an onsite practicum supervisor of assigned trainees, affiliated with a practicum site.¶
- (53) "Pre-production 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.¶
- (54) "Process lot" means homogenized fungi, psilocybin extract or edible psilocybin product of the same type that was processed at the same time using the same processing method, ingredients, and standard operating procedures. ¶
- (18) "Psilocybin" means psilocybin or psilocin.¶
- (55) "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.¶
- (56) "Psilocybin" has the meaning described in ORS 475A.220.¶
- (57) "Psilocybin analyte" has the meaning described in OAR 333-064-0025. As used in these rules psilocybin analyte refers to content of a psilocybin analyte as measured by potency tests required by OAR 333-333-7040.¶
- (19) (58) "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.¶
- (20) (59) "Psilocybin Tracking System" or "PTS" means the system for tracking psilocybin products required by ORS 475A.400. ¶
- (21) (60) "Psilocybin product" means psilocybin-producing fungi, mycelium and mixtures or substances containing a detectable amount of psilocybin, including whole fungi, homogenized fungi, psilocybin extract and edible psilocybin products. ¶
- (22) "These rules" mean Oregon Administrative Rules, chapter 333, division 33361) "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.¶

(62) "Residence" means real property inhabited by an owner, renter or tenant, including manufactured homes and vehicles used as domiciles.¶

(63) "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.¶

(64) "Safe" means a fireproof metal cabinet with a mechanical or electronic combination lock that is capable of storing psilocybin products and weighs at least 375 pounds.¶

(65) "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.¶

(66) "Secondary school" means a learning institution containing any combination of grades 9 through 12 and includes junior high schools that have 9th grade.¶

(67) "Service center" means a premises licensed under ORS 475A.305.¶

(68) "Sublet" means to sublease or otherwise allow a person who is not a license 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.¶

(69) "Synchronous learning" means that students learn from their instructor at the same time as their fellow students.¶

(70) "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.¶

(71) "These rules" means Oregon Administrative Rules (OAR) 333-333-1010 through 333-333-8260.¶

(72) "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.¶

(2473) "Training, Licensing and Compliance System (TLC)" 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.¶

(74) "Training program" means a program that has been approved to offer training to psilocybin facilitators as described in ORS 475A.380.¶

(75) "Training program applicant" means a program that has applied to offer training to psilocybin facilitators as described in ORS 475A.380.¶

(76) "Unique identification number" means a unique number generated by the Authority's designated vendor for the psilocybin tracking system for the purpose of tracking psilocybin products within the psilocybin tracking system.¶

(77) "Unique identification tag" means a tag that contains a unique identification number that was ordered and received from the Authority's designated vendor for the psilocybin tracking system for the purpose of tracking psilocybin products in the psilocybin tracking system.¶

(78) "Whole fungi" means dried fruiting bodies of Psilocybe cubensis, or portions thereof, that have not been homogenized.¶

(2579) "Wood chips" mean substrates consisting primarily of wood products that have not been composted.¶

(80) "Worker permit" means a permit required by ORS 475A.480.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-2015

RULE SUMMARY: 333-333-2015-Describes allowable species of fungi

CHANGES TO RULE:

333-333-2015

Allowable Species

A manufacturer may only cultivate, manufacture or possess fruiting bodies of the fungi species Psilocybe cubensis and psilocybin products derived from Psilocybe Cubensis on the licensed premises.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-2200

RULE SUMMARY: 333-333-2200-Describes product quantity limits for manufacturer and service center licenses

CHANGES TO RULE:

333-333-2200

Psilocybin Product Quantity Limits

- (1) Quantities of psilocybin products shall be measured in total grams of psilocybin analyte contained in a product that has been tested for potency as required by OAR 333-333-3070.¶
- (2) A manufacturer must ensure that potency tests required by OAR 333-333-3070 are completed within 180 days of recording a harvest lot or production lot in the psilocybin tracking system. ¶
- (3) A manufacturer may possess a total of no more than 200 grams of psilocybin analyte, as described in section (1) of this rule, at any given time. ¶
- (4) A service center may possess a total of no more than 100 grams of psilocybin analyte, as described in section (1) of this rule, at any given time. ¶
- (5) A manufacturer or service center may request authorization in writing to exceed the limits described in sections (3) and (4) of this rule in a form and manner prescribed by the Authority. ¶
- (6) Psilocybin products that have been designated as waste will not be considered when calculating the limits described in sections (3) and (4) of this rule.

Statutory/Other Authority: ORS 475A.235, ORS 475A.300

Statutes/Other Implemented: ORS 475A.300

ADOPT: 333-333-2300

RULE SUMMARY: 333-333-2300-Describes requirements for client packaging

CHANGES TO RULE:

333-333-2300

Packaging for Sale to Client

- (1) Client packaging must protect the packaged psilocybin product from contamination and excessive moisture and must not impart any toxic or harmful substance to the packaged item.¶
- (2) All psilocybin products must be transferred to a service center in sealed client packaging for ultimate sale to a client.¶
- (3) Psilocybin products for ultimate sale to a client must:¶
 - (a) Not be packaged or labeled in a manner that is attractive to minors.¶
 - (b) Comply with serving size requirements identified in OAR 333-333-2310.¶
 - (c) Be labeled in accordance with OAR 333-333-2400.¶
- (4) Client packaging may not display any untruthful or misleading content.

Statutory/Other Authority: ORS 475A.235, ORS 475A.634

Statutes/Other Implemented: ORS 475A.634

ADOPT: 333-333-2310

RULE SUMMARY: 333-333-2310-Describes requirements for product serving size

CHANGES TO RULE:

333-333-2310

Packaging and Serving Size

(1) A serving of a psilocybin product may not contain more than 25 mg of psilocybin analyte. ¶

(2) Client packaging may not contain more than one serving of a psilocybin product.

Statutory/Other Authority: ORS 475A.235, ORS 475A.642

Statutes/Other Implemented: ORS 475A.642

ADOPT: 333-333-2400

RULE SUMMARY: 333-333-2400-Describes requirements for product labeling

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. Client packaging must display:

(a) The manufacturer's business or trade name and license number.

(b) One of the following product type names: whole fungi, homogenized fungi, psilocybin extract, or edible psilocybin product.

(c) The net quantity of contents using the metric system of measurement and expressed in terms of fluid measure if the item is liquid, or in terms of weight if the item is solid, semi-solid, or viscous.

(d) The quantity of psilocybin analyte contained in the product, expressed in milligrams, and calculated using laboratory test results required by OAR 333-333-7040.

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

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

Statutory/Other Authority: ORS 475A.235, ORS 475A.626

Statutes/Other Implemented: ORS 475A.626

ADOPT: 333-333-2410

RULE SUMMARY: 333-333-2410-Describes product information document that is required to be shared with clients

CHANGES TO RULE:

333-333-2410

Product Information Document

(1) Manufacturers must provide a product information document with all products transferred to a service center that lists the following information in English on a printed or electronic document in 12-point font or larger.¶

(a) The manufacturer's business or trade name and license number.¶

(b) The business or trade name of the manufacturer that packaged the product, if different from the original manufacturer.¶

(c) One of the following product type names: whole fungi, homogenized fungi, psilocybin extract, or edible psilocybin product.¶

(d) Net quantity of contents using the metric system of measurement and expressed in terms of fluid measure if the item is liquid, or in terms of weight if the item is solid, semi-solid, or viscous.¶

(e) Results of all laboratory tests required by OAR 333-333-7040. ¶

(f) Species of fungi. ¶

(g) Harvest date for whole fungi.¶

(h) Date of manufacture for all products other than whole fungi.¶

(i) Unique identification number as defined in OAR 333-333-1010.¶

(j) List of all 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) Estimated activation time, expressed in minutes.¶

(m) "Best by" date indicating the time that the manufacturer has determined that their product will retain its original quality.¶

(n) If the psilocybin product is perishable, a statement that the product must be refrigerated or kept frozen.¶

(2) A facilitator must provide a product information document for all 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. ¶

(3) 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

REPEAL: 333-333-3005

RULE SUMMARY: 333-333-3005-This rule is being repealed because the definitions are being consolidated into OAR 333-333-1010. Definitions found in OAR 333-333-3005 have been moved to OAR 333-333-1010.

CHANGES TO RULE:

~~333-333-3005~~

~~Psilocybin Training Definitions~~

~~As used in OAR 333-333-3010 through OAR 333-333-3090 the following definitions apply: ¶¶~~

~~(1) "Adverse behavioral reaction" means client behavior that a facilitator reasonably believes may endanger the safety of the client, facilitator, or others. ¶¶~~

~~(2) "Adverse medical reaction" means a client's physiological reaction occurring during an administration session that a facilitator reasonably believes may lead to medical harm. For example, a cardiac event or other health emergency. ¶¶~~

~~(3) "Client information form" means the form required by ORS 475A.350. ¶¶~~

~~(4) "Cultural equity" means values, policies, and practices that ensure all people, especially those who have been historically marginalized based on race, ethnicity, 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. ¶¶~~

~~(5) "Curriculum" means the topics, subjects, and activities that make up courses taught by a training program. ¶¶~~

~~(6) "Facilitation" means the provision of services to clients by a licensed facilitator during preparation, administration, and integration sessions. ¶¶~~

~~(7) "Health equity" means that Oregon will have established a health system that creates health equity when all people can reach their full health potential and well-being and are not disadvantaged by their race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances. Achieving health equity requires the ongoing collaboration of all regions and sectors of the state, including tribal governments to address: the equitable distribution or redistribution of resources and power; and recognizing, reconciling and rectifying historical and contemporary injustices. ¶¶~~

~~(8) "Intervention" means taking proactive steps to respond to the client's behavior, experience, or condition during an administration session. ¶¶~~

~~(9) "Lead educator" means a person affiliated with a training program who is responsible for tracking the progress of students throughout the program. ¶¶~~

~~(10) "Nondirective facilitation" means an approach to facilitation in which the facilitator maintains a consistent disposition with a client, while avoiding giving the client direct advice or directly interpreting a client's statements or behaviors. ¶¶~~

~~(11) "Oregon Psilocybin Services Act" means ORS 475A.210 to ORS 475A.722. ¶¶~~

~~(12) "Practicum site" means a designated service center that provides practicum training. ¶¶~~

~~(13) "Practicum site supervisor" means an onsite practicum supervisor of assigned trainees, affiliated with a practicum site. ¶¶~~

~~(14) "Program director" means a person authorized by a training program to track student progress, grant student enrollment and certify program completion. ¶¶~~

~~(15) "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. ¶¶~~

~~(16) "Service Center" means a premises licensed under ORS 475A.305. ¶¶~~

~~(17) "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. ¶¶~~

~~(18) "Synchronous learning" means that students learn from their instructor at the same time as their fellow students. ¶¶~~

~~(19) "Training program applicant" means a program that has applied to offer training to psilocybin facilitators as described in ORS 475A.380. ¶¶~~

~~(20) "Training program" means a program that has been approved to offer training to psilocybin facilitators as described in ORS 475A.380.~~

~~Statutory/Other Authority: ORS 475A.235~~

~~Statutes/Other Implemented: ORS 475A.235, ORS 475A.380~~

ADOPT: 333-333-3200

RULE SUMMARY: 333-333-3200-Describes process for taking required facilitator exam

CHANGES TO RULE:

333-333-3200

Facilitator Exam

(1) Every applicant for a facilitator license must take the exam required by ORS 475A.330 and receive a passing score prior to being issued a facilitator license. ¶

(2) A passing score on the exam is 75 percent correct. After the applicant takes the exam, the Authority will provide the applicant with the exam results. ¶

(3) An applicant who does not pass the exam may retake the exam. ¶

(4) The Authority will offer the exam at no cost via online interface. Applicants may take the exam at any location of their choosing. An applicant may retake the exam as many times as they chose to do so. ¶

(5) Applicants may request to take the exam in alternative format or in a language other than English. The Authority will make reasonable efforts to accommodate requests for accommodation. Requests for accommodation must be made in advance of taking the exam.

Statutory/Other Authority: ORS 475A.235, ORS 475A.330

Statutes/Other Implemented: ORS 475A.330

ADOPT: 333-333-4000

RULE SUMMARY: 333-333-4000-Describes application process for all license types

CHANGES TO RULE:

333-333-4000

Application Process

- (1) Applications must be submitted to the Authority in the form and manner prescribed by the Authority.¶
- (2) The application fee specified in OAR 333-333-4060(1) must be submitted at the time of application in the form and manner prescribed by the Authority.¶
- (3) An application must include the following:¶
 - (a) The names and required information for all individuals and legal entities who are applicants as required by OAR 333-333-4030.¶
 - (b) Any forms and information required by the Authority to evaluate the license application.¶
 - (c) A social equity plan as required by OAR 333-333-4020.¶
 - (d) Until January 1, 2025, proof of residency if required by OAR 333-333-4050. ¶
 - (e) For manufacturer, service center and laboratory license applicants, a map or sketch 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. ¶
 - (f) If the applicant for a manufacturer license is not the owner of the real property proposed to be licensed, a written statement signed by the property owner that shows that the owner consents to manufacturing of psilocybin products on the property. This requirement may be satisfied by lease documents or in a form and manner specified by the Authority. ¶
 - (g) For service center applicants, a service center emergency plan as described in OAR 845-025-4460.¶
 - (h) 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. ¶
 - (i) 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.¶
 - (j) For facilitator applicants, documentation that the applicant has completed the training and passed the exam required by ORS 475A.325.¶
- (4) In addition to submitting an application form and the items described in section (3) of this rule, the Authority may require:¶
 - (a) Information or fingerprints required to perform a criminal background 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 fee has not been paid, or additional information required under this rule has not been submitted. ¶
- (6) An applicant may submit a written request for reconsideration of an application that is deactivated as incomplete. Such a request must be received by the Authority within 10 days of the date the deactivation notice was mailed to the applicant. The Authority shall give an applicant the opportunity to be heard if an application is deactivated. A hearing under this subsection is not subject to the requirements for contested case proceedings under ORS 183.310 to 183.550.

Statutory/Other Authority: ORS 475A.235, ORS 475A.245, ORS 475A.255

Statutes/Other Implemented: ORS 475A.235, ORS 475A.245, ORS 475A.255

ADOPT: 333-333-4010

RULE SUMMARY: 333-333-4010-Specifies how licensees and applicants will communicate with the Authority

CHANGES TO RULE:

333-333-4010

Communication with the Authority

(1) If an applicant or licensee is required to or elects to submit anything in writing to the 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.

(3) Applicants must designate an applicant who will serve as the primary point of contact for communication with the Authority.

(4) The primary point of contact required by section (3) of this rule is responsible for ensuring all persons identified as licensees or applicants are aware of relevant communications from the Authority, including but not limited to notices issued under ORS chapter 183.

Statutory/Other Authority: ORS 475A.235, ORS 475A.245

Statutes/Other Implemented: ORS 475A.235, ORS 475A.245

ADOPT: 333-333-4020

RULE SUMMARY: 333-333-4020-Describes social equity plans that are required for all licensees

CHANGES TO RULE:

333-333-4020

Social Equity Plans

(1) In addition to the requirements of OAR 333-333-4000 applicants for a manufacturer, service center, facilitator or laboratory license must submit a social equity plan for their initial application to be considered complete. ¶

(2) Social equity plans required by section (1) of this rule must include a description of the following:¶

(a) Application of diversity, equity, justice and inclusion principles to the licensee's internal practices and policies.¶

(b) Objective performance measures that the licensee will use to evaluate their social equity plan. ¶

(3) In addition to the requirements of OAR 333-333-4250 an applicant for renewal of manufacturer or service center license must provide documentation of the evaluation of implementation of their social equity plan based on the objective performance measures required in social equity plans. ¶

(4) Licensees must provide written notice, in a form and manner prescribed by the Authority, of any material changes to their social equity plan within 60 days of making the change.

Statutory/Other Authority: ORS 475A.235, ORS 475A.245

Statutes/Other Implemented: ORS 475A.235, ORS 475A.245

ADOPT: 333-333-4030

RULE SUMMARY: 333-333-4030-Describes which entities and individuals must be disclosed as applicants

CHANGES TO RULE:

333-333-4030

True Name on Application

- (1) An application for a service center, manufacturing or laboratory license must specify the legal names of all individuals and legal entities who qualify as applicants. ¶
 - (2) An application for a facilitator license must identify the legal name of the individual who will hold the license. ¶
 - (3) License privileges are only available to licensees and license representatives. For service centers, manufacturers and laboratories, license privileges are only available for the licensed premises. ¶
 - (4) If a legal entity is an applicant, the following individuals within the legal entity are also applicants: ¶
 - (a) If an applicant is a limited partnership, each general partner in the limited partnership. ¶
 - (b) If an applicant is a limited liability company, each manager and managing member of the limited liability company. ¶
 - (c) If the applicant is a for-profit corporation, each principal officer of the corporation. ¶
 - (d) If the applicant is a non-profit entity, each principal officer of the entity. ¶
 - (e) Any individual within the legal entity who meets the definition of applicant in OAR 333-333-1010. ¶
 - (5) The Authority may deny an application if a person: ¶
 - (a) Identified as an applicant for the entity proposed to be licensed does not meet the definition of applicant in OAR 333-333-1010; or ¶
 - (b) Who meets the definition of applicant in OAR 333-333-1010 has not been disclosed on the application.
- Statutory/Other Authority: ORS 475A.235, ORS 475A.245
Statutes/Other Implemented: ORS 475A.235, ORS 475A.245

ADOPT: 333-333-4040

RULE SUMMARY: 333-333-4040-Describes requirements for persons with a financial interest in licensed businesses

CHANGES TO RULE:

333-333-4040

Financial Interests

(1) Applicants and licensees must create and maintain complete lists of all individuals and legal entities that hold a financial interest in the entity, including contact information for each individual or entity and a description of their financial interest. Applicants and licensees must provide the information required by this section to the Authority within 15 calendar days of the Authority's written request for such information. ¶

(2) If a legal entity holds a financial interest, the following individuals within the legal entity also hold a financial interest:¶

(a) For limited partnerships, each general partner in the limited partnership.¶

(b) For limited liability companies, each manager and managing member of the limited liability company.¶

(c) For for-profit corporations, each principal officer of the corporation.¶

(d) For non-profit entities, each principal officer of the entity.¶

(3) The Authority may refuse to issue a license if an applicant does not satisfy the requirements of section (1) of this rule. ¶

(4) The Authority shall deny an application for a manufacturer license if an individual or legal entity that holds a financial interest in the entity proposed to be licensed holds a financial interest in another manufacturer license. ¶

(5) The Authority shall deny an application for a service center license if an individual or legal entity that holds a financial interest in the entity proposed to be licensed holds a financial interest in five or more service center licenses.

Statutory/Other Authority: ORS 475A.235, ORS 475A.245

Statutes/Other Implemented: ORS 475A.235, ORS 475A.245, ORS 475A.280

ADOPT: 333-333-4050

RULE SUMMARY: 333-333-4050-Describes residency requirements for license applicants

CHANGES TO RULE:

333-333-4050

Residency

(1) Until January 1, 2025, in order to qualify for a manufacturing or service center license:¶

(a) If the entity proposed to be operated under the license is a legal entity, an applicant must provide proof that more than 50 percent of the shares, membership interests, partnership interests, or other ownership interests of the legal entity are held, directly or indirectly, by one or more individuals who have been residents of this state for two or more years.¶

(b) If the entity proposed to be operated under the license is a partnership that is not a legal entity, an applicant must provide proof that more than 50 percent of the partnership interests of the partnership are held, directly or indirectly, by one or more individuals who have been residents of this state for two or more years.¶

(c) If the entity proposed to be operated under the license is operated and owned by an individual, an applicant must provide proof that the individual has been a resident of this state for two or more years.¶

(2) Until January 1, 2025, in order to qualify for a facilitator license, an applicant must provide proof that they have been a resident of this state for two or more years.¶

(3) Proof of residency required by subsections (1)(a) and (b) of this rule, may be demonstrated by providing a statement in a form and manner prescribed by the Authority which verifies that more than 50 percent of the interests in the entity are held by individuals who have been residents of this state for two or more years. ¶

(4) Proof of residency as required under subsection (1)(c) and section (2) of this rule may be demonstrated by providing any of the following:¶

(a) A valid Oregon driver license or Oregon identification card issued at least two years prior to the date of application. ¶

(b) Oregon full-year resident tax returns for the last two years. ¶

(c) Proof of Oregon voter registration issued at least two years prior to the date of application. ¶

(d) Utility bills, lease agreements, rental receipts, mortgage statements or similar documents that contain the name and address of the applicant dated at least two years prior to the date of application and from the most recent month.¶

(e) Letter from a homeless shelter, nonprofit entity, employer or government agency attesting that applicant has been an Oregon resident for at least two years. ¶

(f) Any other documentation that the Authority determines to reliably demonstrate proof of Oregon residency for the last two years¶

(5) If an applicant demonstrates proof of residency under section (3) of this rule, the applicant must request and retain documentation described in section (4) of this rule for all individuals within the applicant legal entity that qualify as Oregon residents. Documentation required by this section must be provided to the Authority upon request.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.290, ORS 475A.305, ORS 475A.325

ADOPT: 333-333-4060

RULE SUMMARY: 333-333-4060-Describes 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 \$500 non-refundable application fee:¶

(b) An applicant for a facilitator license must pay a \$150 non-refundable application fee.¶

(2) If the Authority approves an initial license application or renewal and grants an annual license, the following fees must be paid:¶

(a) Manufacturer \$10,000.¶

(b) Service Center \$10,000.¶

(c) Facilitator \$2,000.¶

(d) Laboratory \$10,000.¶

(3) Notwithstanding section (2) of this rule, if the applicant is a non-profit entity the following fees must be paid:¶

(a) Manufacturer \$5,000.¶

(b) Service Center \$5,000.¶

(4) Notwithstanding section (2) of this rule, if the applicant is an individual person the following fees must be paid, if they satisfy any of the requirements of section (5) of this rule: ¶

(a) Manufacturer \$5,000.¶

(b) Service Center \$5,000. ¶

(c) Facilitator \$1,000. ¶

(5) In order to qualify for the reduced fees described in section (4) of this rule, an individual applicant must qualify under one of the following circumstances: ¶

(a) Be receiving Social Security Income benefits. To qualify for the reduced fee, the applicant must submit at the time of application a copy of a current monthly Social Security Income benefit statement showing dates of coverage.¶

(b) Be enrolled in Oregon Health Plan. To qualify for the reduced fee the applicant must submit a copy of the applicant's current eligibility statement or card.¶

(c) Be receiving food stamp benefits through the Oregon Supplemental Nutrition Assistance Program. To qualify for the reduced fee the applicant must submit at the time of application current proof of their food stamp benefits.¶

(d) Has served in the Armed Forces of the United States. To qualify for the reduced fee, the applicant must provide proof of having served in the Armed Forces, such as but not limited to, submitting a Veteran's Administration form DD-214.¶

(6) The Authority will charge a change fee of \$250 per applicant for any change to a previously approved license that results in addition of an applicant. This change fee applies regardless of whether the licensee requests the change at renewal or during the term of their license. ¶

(7) The Authority will charge a change fee of \$250 per inspection for any change to a previously approved license that requires an inspection of the licensed premises. 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

ADOPT: 333-333-4070

RULE SUMMARY: 333-333-4070-Describes worker permit requirements and fees

CHANGES TO RULE:

333-333-4070

Worker Permit Term and Fees

(1) An individual who is a license 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) 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 service permit if they perform any of the activities listed in subsections (1)(a) through (d) of this rule.

(3) If the Authority approves an initial or renewal application and grants a worker permit, the permit shall have a term of five years.

(4) Once the Authority has made a determination to grant an application as described in section (3) of this rule, the individual must pay a \$25 fee to receive the permit.

Statutory/Other Authority: ORS 475A.235, ORS 475A.483

Statutes/Other Implemented: ORS 475A.235, ORS 475A.483

ADOPT: 333-333-4100

RULE SUMMARY: 333-333-4100-Describes background check process for license applicants

CHANGES TO RULE:

333-333-4100

Background Checks

(1) Any person identified as an applicant on a worker permit or license application may be required to undergo a criminal background check and fitness determination as required by this rule. ¶

(2) The Authority will require a licensee or worker permit holder to undergo a criminal background check if the Authority learns that the individual has been convicted of a crime after their license or permit has been issued. ¶

(3) When the Authority requires an individual to undergo a criminal background check, background 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). ¶

(4) When the Authority requires an individual to undergo a criminal background check, the individual must provide: ¶

(a) A criminal background 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; ¶

(D) Driver license information; and ¶

(E) Address and recent residency information. ¶

(b) Fingerprints in accordance with the instructions on the Authority's webpage. ¶

(5) 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. ¶

(6) 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. ¶

(7) The fitness determination described in section (3) of this rule will determine whether the applicant is ineligible to be licensed. ¶

(8) Refusal to participate in a background check required by this rule is a violation. ¶

(9) 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

Statutes/Other Implemented: ORS 475A.235, ORS 475A.255, ORS 475A.486, ORS 475A.598

ADOPT: 333-333-4110

RULE SUMMARY: 333-333-4110-Describes application review process

CHANGES TO RULE:

333-333-4110

Application Review

(1) Once the 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. 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 30 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

ADOPT: 333-333-4120

RULE SUMMARY: 333-333-4120-Describes process for approving applications and issuing licenses

CHANGES TO RULE:

333-333-4120

Approval and Issuance

(1) If the Authority approves an application, the Authority will notify the applicant in writing that the application has been approved, pending payment. The approval is effective upon receipt of the license fee. After payment of the license fee, the Authority will provide the applicant proof of licensure, that includes a unique license number, the effective date of the license, date of application and description of the licensed premises. If the applicant has paid the license fee by check, the Authority will not issue a license until it has confirmed that the check has cleared.

¶

(2) A licensee may not operate until the effective date of licensure. ¶

(3) Manufacturer, service center and laboratory licensees must display a proof of licensure in a prominent place on the licensed premises. ¶

(4) Facilitator licensees must be able to provide proof of licensure when performing preparation, administration or integration sessions. ¶

(5) 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. ¶

(6) Facilitator licenses are only issued to the individual listed on the application. ¶

(7) 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

ADOPT: 333-333-4130

RULE SUMMARY: 333-333-4130-Describes process and requirements for denying license applications

CHANGES TO RULE:

333-333-4130

Application Denial

(1) The Authority shall deny an application if:

(a) An applicant is under the age of 21.

(b) The applicant for a facilitator license is not an individual person.

(c) The applicant for a facilitator license has not completed training required by ORS 475A.325.

(d) The applicant for a facilitator license has not passed the exam required by ORS 475A.325.

(e) The applicant's land use compatibility statement shows that the proposed land use is prohibited if a land use compatibility statement is required by these rules.

(f) The proposed licensed premises is located on public land.

(h) If required, the applicant does not have an approved fitness determination in accordance with OAR 333-333-4100.

(i) The applicant is an entity that is required to be registered with the Oregon Secretary of State and has failed to register.

(j) The application identifies more than one licensed premises.

(2) Until January 1, 2025, the Authority shall deny an application for a service center or manufacturer license if:

(a) An individual applicant who does not qualify as an Oregon resident owns or controls greater than 50 percent of the entity proposed to be licensed; or

(b) At least 50 percent of individuals who hold shares, membership interests, partnership interests, or other ownership interests in the entity proposed to be licensed do not qualify as Oregon residents.

(3) Until January 1, 2025, the Authority shall deny an application for a facilitator license if the applicant is not an Oregon resident.

(4) An applicant for a service center is ineligible for a license and the Authority shall deny an application if any portion of the proposed licensed premises for a service center applicant is located:

(a) Except as provided in ORS 475A.310 within 1,000 feet of:

(A) A public elementary or secondary school for which attendance is compulsory under ORS 339.020; or

(B) A private or parochial elementary or secondary school, teaching children as described in ORS 339.030(1)(a).

(b) For purposes of determining the distance between a service center and a school, "within 1,000 feet" means a straight -line measurement in a radius extending for 1,000 feet or less in any direction from the closest point anywhere on the boundary line of the real property comprising a school to the closest point of the licensed premises of a service center.

(5) The Authority may deny an application when a person with a financial interest meets any license denial criteria that apply to applicants.

(6) The Authority may revoke a license for any reason it may deny an application.

Statutory/Other Authority: ORS 475A.235, ORS 475A.250

Statutes/Other Implemented: ORS 475A.235, ORS 475A.250, ORS 475A.290, ORS 475A.305, ORS 475A.325

ADOPT: 333-333-4140

RULE SUMMARY: 333-333-4140-Describes application withdrawal requirements

CHANGES TO RULE:

333-333-4140

Application Withdrawal

An applicant for a license or worker permit may withdraw an initial or renewal application at any time prior to the Authority acting on the application unless the Authority reasonably believes that the applicant submitted false or misleading information in which case the Authority may refuse to accept the withdrawal and may issue a proposed denial in accordance with OAR 333-333-4130.

Statutory/Other Authority: ORS 475A.235, ORS 475A.250

Statutes/Other Implemented: ORS 475A.235, ORS 475A.250

ADOPT: 333-333-4200

RULE SUMMARY: 333-333-4200-Describes process for notification and approval of changes to license or application

CHANGES TO RULE:

333-333-4200

Notification of Changes

(1) An applicant or licensee must notify the Authority in writing within 10 business days of any of the following:¶

(a) Adding or removing an individual or legal entity who qualifies as an applicant under OAR 333-333-1010 or OAR 333-333-4030.¶

(b) A change in contact information for any person listed as an applicant or licensee.¶

(c) Any closure of the licensed premises lasting more than 30 days.¶

(d) Any conviction for any misdemeanor or felony committed by an individual listed as an applicant or licensee. ¶

(e) Any arrest for conduct that occurred on the licensed premises.¶

(f) Any theft of psilocybin products or cash from the licensed premises.¶

(2) If after receipt of information required under subsection (1)(a) of this rule the Authority determines that the addition of an individual or legal entity applicant could result in an initial or renewal application denial under OAR 333-333-4130 or serve as the basis of a license suspension or revocation, the Authority:¶

(a) Will notify the licensee of its determination.¶

(b) Will give the licensee 30 calendar days to take actions to ensure the individual or entity does not qualify as an applicant and provide documentation to the Authority that demonstrates such actions have been taken.¶

(c) May propose license suspension or revocation under OAR 333-333-4130 if the licensee does not comply with subsection (b) of this section. ¶

(3) If applicable, the licensee must pay the change fee specified in OAR 333-333-4060 prior to making changes to their licensed premises or approved licensees that require inspections or additional applicants.¶

(4) A licensee who wishes to change the location of the licensed premises must submit a change of location request including required forms and documents and the license application fee specified in OAR 333-333-4060(1). ¶

(a) A licensee that submits a change of location request is not required to pay an additional annual license fee.¶

(b) A change of location request submitted under this rule must 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 sketch 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. ¶

(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 signed by the property owner that shows that the owner consents to manufacturing of psilocybin products on the property. This requirement may be satisfied by lease documents or in a form and manner specified by the Authority. ¶

(5) 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.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4210

RULE SUMMARY: 333-333-4210-Describes required process for modifications to a licensed premises

CHANGES TO RULE:

333-333-4210

Modifying Licensed Premises

- (1) A licensee may not make any changes that materially or substantially alter the licensed premises or the usage of the licensed premises without the Authority's prior written approval. ¶
- (2) A licensee who wishes to make any material or substantial changes to the licensed premises must submit a form prescribed by the Authority, and submit any information identified in the form. ¶
- (3) For the purposes of this rule a material or substantial change includes, but is not limited to:¶
 - (a) Any change to the footprint of the licensed premises.¶
 - (b) Any change to ingress and egress of the licensed premises. ¶
 - (c) Any change that would require installation of additional video surveillance cameras or a change to the security system.¶
 - (d) Any changes to limited access areas or client administration areas on the licensed premises;¶
 - (e) Any addition or change to a residence or other unlicensed structure located on the same tax lot as the licensed premises in areas that the licensee controls or has the right to access. ¶
- (4) Emergency repairs to the licensed premises made to ensure safety and security do not require prior approval under section (1) of this rule. Licensee must provide notice of emergency repairs in a form and manner prescribed by the Authority within five business days of making repairs.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4250

RULE SUMMARY: 333-333-4250-Describes process for license renewal

CHANGES TO RULE:

333-333-4250

License Renewal

(1) Renewal Applications:

(a) A renewal application must include the licensee fee, documents, and information required by the Authority to be complete.

(b) A renewal application will be considered timely if a complete renewal application is received by the Authority at least 60 calendar days before the date the license expires. Applications received less than 60 days before the date the license expires will be considered untimely.

(c) 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.

(d) 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.

(e) A person who, while not actively licensed, engages in any activity that would require a license may be subject to administrative and criminal sanctions regardless of their prior licensure status.

(2) The Authority may require a licensee with a pending renewal application to submit forms, documents and information described in OAR 333-333-4000 in order to complete an investigation of a renewal application. Failure to submit fees, forms, documents or information requested by the Authority under this section within a time period prescribed by the Authority may result in denial of the renewal application.

Statutory/Other Authority: ORS 475A.235, ORS 475A.483

Statutes/Other Implemented: ORS 475A.235, ORS 475A.483

ADOPT: 333-333-4260

RULE SUMMARY: 333-333-4260-Describes standards for operating a licensed business as trustee

CHANGES TO RULE:

333-333-4260

Standards for Authority to Operate a Licensed Business as a Trustee, a Receiver, a Personal Representative, or a Secured Party

(1) The Authority may issue a temporary certificate of authority to operate a licensed entity to a trustee, the receiver of an insolvent or bankrupt licensee, the personal representative of a deceased licensee, or a person holding a security interest in the licensed entity for a reasonable period of time to allow orderly disposition of the licensed entity.

(a) The trustee, receiver or personal representative must provide the Authority with the following information:

(A) Proof that the person is the legal trustee, receiver or personal representative for the legal entity; and

(B) A written request for a certificate of authority to operate as a trustee, receiver or personal representative of the licensee, listing the address and telephone number of the trustee, receiver or personal representative.

(b) The secured party must provide the Authority with the following information:

(A) Proof of a security interest in the licensed entity;

(B) Proof of the licensee's default on the secured debt;

(C) Proof of legal access to the real property; and

(D) A written request for authority to operate as a secured party listing the secured party's address and telephone number.

(2) The Authority may revoke or refuse to issue or extend a certificate of authority for the trustee, receiver, personal representative, or secured party to operate:

(a) If the trustee, receiver, personal representative or secured party does not propose to exercise licensed privileges immediately or does not begin exercising licensed privileges immediately upon receiving the temporary certificate of authority;

(b) For any of the reasons that the Authority may revoke or refuse to issue or renew a license;

(c) If the trustee, receiver, personal representative or secured party operates in violation of ORS 475A, or these rules; or

(d) If a reasonable time for disposition of the legal entity has elapsed.

(3) No person or entity described in section (1) of this rule may operate the licensed entity until a certificate of authority has been issued under this rule, except that the personal representative of a deceased licensee may operate the licensed entity for up to 10 days after the death provided that the personal representative submits the information required in subsection (1)(a) of this rule and obtains a certificate of authority within that time period.

(4) A certificate of authority under this rule is initially issued for a 60-day period and may be extended as reasonably necessary to allow for the disposition of the licensed entity.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.243

ADOPT: 333-333-4270

RULE SUMMARY: 333-333-4270-Describes requirements for closure of a licensed business

CHANGES TO RULE:

333-333-4270

Closure of Licensed Entity

(1) License privileges cease upon death of a licensee unless the Authority issues an order as described in section (2) of this rule.¶

(2) The Authority may issue an order providing for the manner and condition under which:¶

(a) Psilocybin products left by a deceased, insolvent or bankrupt licensee, or subject to a security interest, may be transferred or destroyed pursuant to an order issued by the Authority.¶

(b) The licensed entity of a deceased, insolvent or bankrupt licensee may be operated for a reasonable period, as specified in the order issued under this rule or OAR 333-333-4260, following the death, insolvency or bankruptcy.¶

(3) If a license is revoked, the Authority may address in its order the manner and condition under which psilocybin products held by the licensee may be transferred or sold to other licensees or must be otherwise disposed.¶

(4) If a license is surrendered or expires the Authority may address by order the manner and condition under which psilocybin products held by the licensee may be transferred or sold to other licensees or must be otherwise disposed of.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.243

ADOPT: 333-333-4280

RULE SUMMARY: 333-333-4280-Describes requirements for license surrender

CHANGES TO RULE:

333-333-4280

License Surrender

A licensee may request the Authority accept the surrender of a license. The license remains in effect until the Authority accepts the surrender. If the Authority accepts the surrender, 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.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4300

RULE SUMMARY: 333-333-4300-Describes requirements for licensed premises location

CHANGES TO RULE:

333-333-4300

Licensed Premises Location Requirements

- (1) A licensed premises may not be located on publicly owned land.¶
- (2) The interior and exterior areas of a licensed premises may not overlap with: ¶
 - (a) An area that has been issued an adult-use cannabis license issued under ORS 475C.065, ORS 475C.085, ORS 475C.093 or ORS 475C.097.¶
 - (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 that has been issued a liquor license issued under ORS chapter 471 or a retail liquor agent appointed by the Oregon Liquor and Cannabis Commission.¶
 - (f) A health care facility licensed under ORS chapter 441.¶
 - (g) A location 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. ¶
- (3) The licensed premises of a service center may not be located:¶
 - (a) Except as provided in ORS 475A.310, within 1,000 feet of:¶
 - (A) A public elementary or secondary school for which attendance is compulsory under ORS 339.020; or¶
 - (B) A private or parochial elementary or secondary school, teaching children as described in ORS 339.030.¶
 - (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 at a location 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; ¶
 - (c) Process food intended for commercial sale that does not contain psilocybin; or¶
 - (d) Use a psilocybin product to produce edible psilocybin products unless that psilocybin product was processed or cultivated in a food establishment licensed by the Oregon Department of Agriculture in compliance with the applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28. ¶
- (5) A manufacturer, service center or laboratory license is prohibited from subletting any portion of the licensed premises. A licensee may authorize the temporary use of the licensed premises 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.

Statutory/Other Authority: ORS 475A.235

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

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 on a licensed premises except as described in this rule.¶

(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)(e).¶

(3) Log. A licensee must keep a daily log of all employees and permitted visitors who perform work on the licensed premises, except for 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.¶

(a) A licensee must record the following information for each current employee and license representative in the training, licensing and compliance system:¶

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

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

(b) All employees and permitted visitors present on the licensed premises must wear clothing or a badge issued by the licensee that easily identifies the individual as an employee or permitted visitor. ¶

(c) All permitted visitors must be accompanied by a license representative at all times.¶

(d) 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. ¶

(e) A licensee must maintain a copy of the daily log required by 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 license representatives, the following visitors are permitted to be present in limited access areas on a licensed premises, subject to the requirements of this rule and other pertinent rules:¶

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

(b) A contractor, vendor or service provider authorized by a license 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) A licensee may not sublet any portion of a licensed premises. A licensee may authorize the temporary use of a licensed premises, 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. ¶

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

(8) A licensee who sells or handles food, as that term is defined in ORS 616.695, or edible psilocybin products must also be licensed by the Oregon Department of Agriculture under ORS 616.706.¶

(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.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4450

RULE SUMMARY: 333-333-4450-Describes requirements for areas where clients will consume psilocybin

CHANGES TO RULE:

333-333-4450

Client Administration Areas

(1) Client administration areas must be designed to create an appropriate and comfortable setting for experiencing the effects of consuming psilocybin products. Client administration areas must offer clients comfortable options for sitting or reclining during administration session. Indoor administration areas must be temperature controlled and adequately lit to allow for safe exit if necessary.¶

(2) Client administration areas must be free of conditions that could pose a risk to clients experiencing the effects of consuming psilocybin products. ¶

(3) During an administration session, only clients and facilitators may access a client administration area unless each client receiving services in that area has given prior written consent for other individuals to be present during their administration session. Licensees must take reasonable steps to prevent access to client administration areas by unauthorized individuals while administration sessions are taking place. The requirements of this section do not apply to service center representatives who are present to deliver psilocybin products to clients to be consumed during an administration session. ¶

(4) A client may leave an administration area briefly during an administration session for reasons including accessing a restroom, moving to a separate administration area or retrieving personal belongings. A client who leaves an administration area under this section, must be accompanied by a facilitator. Service centers and facilitators must make reasonable efforts to ensure that clients do not travel through areas that could present safety hazards for clients experiencing the effects of consuming psilocybin products. Service centers must make reasonable efforts to ensure that clients who leave administration areas do not interact with vendors, contractors, other clients, or any persons who may be present at the service center. A client who leaves an administration area under this section is not required to be accompanied inside a restroom. ¶

(5) Service centers must ensure that clients and facilitators are able to exit the client administration areas as needed. Service centers may not lock client administration areas from the outside, nor take any other actions that prevent individuals within the client administration areas from exiting. ¶

(6) Psilocybin products may only be consumed in a client administration area.

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

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

ADOPT: 333-333-4460

RULE SUMMARY: 333-333-4460-Describes requirements for emergency plans at service centers

CHANGES TO RULE:

333-333-4460

Service Center Emergency Plan

(1) Every service center shall create and maintain a service center emergency plan that documents procedures for evacuating and relocating clients to a safe location. when the client administration areas become unsafe due to unforeseen circumstances such as fire or a power outage. ¶

(2) The emergency plan described in section (1) of this rule must be:¶

(a) Included with an initial application. ¶

(b) Provided to every facilitator who will offer psilocybin services at the service center prior to the facilitator providing psilocybin services at that location. ¶

(3) A licensee must provide written notice of any changes to an emergency plan to the Authority in a form and manner prescribed by the Authority.

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

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

ADOPT: 333-333-4465

RULE SUMMARY: 333-333-4465-Describes requirements for client restrooms at service centers

CHANGES TO RULE:

333-333-4465

Client Restrooms

(1) Service centers must make at least one accessible single occupancy restroom located within the licensed premises available for clients' use during an administration session. The rest room required by this rule is not required to be located within an administration area. ¶

(2) In addition to a restroom described in section (1) of this rule, a service center may identify alternate restrooms that are located in unlicensed areas of the same structure where the licensed premises is located. Service center applicants and licensees must identify alternate restrooms on the floor plan required by OAR 333-333-4000(3)(e). ¶

(3) Clients may use alternate restrooms described in section (2) of this rule when restrooms within the licensed premises are occupied, subject to the following conditions: ¶

(a) A facilitator must escort a client to and from the alternate restroom location. ¶

(b) A facilitator must remain at the restroom door to ensure that no other people are present in the alternate restroom during the time the client is using the restroom.

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

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

ADOPT: 333-333-4470

RULE SUMMARY: 333-333-4470-Describes requirements for service centers that act as practicum sites

CHANGES TO RULE:

333-333-4470

Practicum Site

(1) Any service center may function as a practicum site under OAR 333-333-3070.¶

(2) A service center that functions as practicum site must notify the Authority that practicum will be offered at their location and identify any training program affiliated with the practicum prior to practicum taking place at their location.¶

(3) A service center that functions as a practicum site must comply with all applicable requirements of these rules, including but not limited to OAR 333-333-5200.

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

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

ADOPT: 333-333-4480

RULE SUMMARY: 333-333-4480-Describes privileges and prohibitions for service center licenses

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.

(d) Allow a laboratory licensee to obtain samples for purposes of performing testing as provided in OAR 333-333-7100.

(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 weapons on the licensed premises if possession is permitted.

(5) A service center may not:

(a) Discount a psilocybin product or offer a psilocybin product for free if the retail sale of the psilocybin product is made in conjunction with the retail sale of any other item or service.

(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 license 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.

(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(7) and 333-333-4400(1)(c). Service centers must store food items that require refrigeration at a temperature of 41 degrees Fahrenheit or less.

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

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

ADOPT: 333-333-4490

RULE SUMMARY: 333-333-4490-Describes requirements for verification of age

CHANGES TO RULE:

333-333-4490

Verification of Age

Prior to completing the sale of a psilocybin product or providing psilocybin services to a client, a service center license representative and a facilitator must verify that the client has a valid, unexpired government-issued photo identification and must verify that the client is 21 years of age or older by viewing the client's:

(1) Passport;

(2) Driver license, whether issued by the State of Oregon or by another state of the United States;

(3) Identification card issued under ORS 807.400;

(4) United States military identification card;

(5) An identification card issued by a federally recognized Indian tribe with photo, name and date of birth; or

(6) Any other identification card issued by a state or territory that bears a picture of the person, the name of the person, the person's date of birth and a physical description of the person.

Statutory/Other Authority: ORS 475A.235, ORS 475A.445

Statutes/Other Implemented: ORS 475A.235, ORS 475A.445

ADOPT: 333-333-4500

RULE SUMMARY: 333-333-4500-Describes prohibitions that apply to all license types

CHANGES TO RULE:

333-333-4500

Licensee Prohibitions

(1) A licensee or permittee may not:

(a) Import into this state or export from this state any psilocybin products.

(b) Give psilocybin products as a prize, premium or consideration for a lottery, contest, game of chance or game of skill, or competition of any kind.

(c) Sell, give, or otherwise make available any psilocybin products to any person who is visibly intoxicated except for service center license representatives who provide additional psilocybin products to clients who are under the influence of psilocybin consumed during an administration session and have provided written consent pursuant to OAR 333-333-5000(7)(h).

(d) Make false representations or statements to the Authority in order to induce or prevent action by the Authority.

(e) Misrepresent any psilocybin product to a client or to the public.

(f) Deliver or transfer psilocybin products to any person off the licensed premises or to any unlicensed location.

(g) Allow any client to leave the licensed premises with psilocybin products.

(h) Sell or offer to sell a psilocybin product that does not comply with the minimum standards prescribed by the statutory laws of this state.

(2) No licensee or license representative may be under the influence of intoxicants while present on a licensed premises. The requirements of this section do not apply to licensees and license representatives who are off duty and consume psilocybin products while receiving psilocybin services as a client.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4510

RULE SUMMARY: 333-333-4510-Describes requirements for storage of psilocybin products

CHANGES TO RULE:

333-333-4510

Storage

(1) All psilocybin products must be stored within a limited access area on a licensed premises.¶

(2) All psilocybin products stored on a licensed premises must be kept within:¶

(a) A locked, enclosed area within a limited access area of the licensed premises that is secured with at a minimum, a properly installed steel door with a steel frame, and a commercial grade, non-residential lock; or ¶

(b) A locked safe located within a limited access area of the licensed premises. ¶

(3) The requirements of section (2) of this rule do not apply to fungi and mycelium stored at manufacturer that has not been harvested or is undergoing a drying process.¶

(4) Psilocybin products that require refrigeration must be stored in appropriate, temperature-controlled environments. ¶

(5) Psilocybin products offered for sale by a service center must be stored in such a manner that the items are only accessible to license representatives until such time as the sale to the client is completed. Clients who wish to examine psilocybin products prior to purchase may do so only under the direct supervision of a license representative.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4520

RULE SUMMARY: 333-333-4520-Describes Client Bill of Rights

CHANGES TO RULE:

333-333-4520

Client Bill of Rights

(1) A service center must post the following "Client Bill of Rights" in a prominent location within the licensed premises and must provide every client with a copy during their preparation session:¶

"Clients receiving psilocybin services in Oregon have the following rights: ¶

To be treated with dignity and respect while receiving psilocybin services. ¶

To receive culturally competent care. ¶

To be free from physical, sexual, psychological, and financial abuse before, during, and after receiving psilocybin services. ¶

To receive the most current and complete information regarding the risks associated with psilocybin services. ¶

To make decisions without coercion or undue influence. ¶

To be fully 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 while receiving psilocybin services. ¶

To refuse to release any personal 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 Oregon Health Authority. ¶

To full disclosure of any facilitator conflicts of interest.¶

To a full accounting and explanation of the costs associated with receiving psilocybin services before receiving those services. ¶

To store personal belongings securely while receiving psilocybin services. ¶

To access their client records after providing reasonable notice to a facilitator or service center and to correct information that is inaccurate. ¶

To request a private space in which to receive psilocybin services. ¶

To be monitored and supported by a licensed facilitator for the duration of psilocybin services until it is safe for the client to leave the service center¶

To receive psilocybin services from a licensed facilitator for the duration of those services, except in cases of emergency. ¶

To access service centers, therapy rooms, and psilocybin services that are welcoming and accessible to people with disabilities. ¶

To have access to a clean, single occupancy restroom for the duration of psilocybin services. ¶

To discuss this Bill of Rights with licensed facilitators and service center operators without facing discrimination or retaliation. ¶

To report violations of this Bill of Rights to the Oregon Health Authority, or other appropriate governing body, without facing discrimination or retaliation.¶

To withdraw or alter my consent to receive psilocybin services or release information.¶

To receive services in a manner that considers my individual conditions, sensitivities and health concerns¶

To make complaints to the Oregon Health Authority regarding psilocybin products and services" ¶

(2) The text of the Client Bill of Rights may not be altered and must be printed in an easily legible font. ¶

(3) A facilitator or service center must provide the Client Bill of Rights in other languages or accessible formats upon a client's request.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4550

RULE SUMMARY: 333-333-4550-Describes security requirements for all license types

CHANGES TO RULE:

333-333-4550

Security Requirements

(1) A service center, manufacturer or laboratory licensee is responsible for the security of all psilocybin products on the licensed premises or in transit, including providing adequate safeguards against theft or diversion of psilocybin products. ¶

(2) During hours when the licensee is not operating, the licensee must ensure that all points of ingress and egress to and from indoor areas of the licensed premises are securely locked. ¶

(3) Licensees must ensure that all limited access areas of a licensed premises are accessible only to license representatives and other personnel authorized to be present under these rules. ¶

(4) The requirements of these rules apply to all licensed premises regardless of whether the licensed premises is located within a building that contains separate unlicensed areas or located at an address that contains separate unlicensed structures.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4600

RULE SUMMARY: 333-333-4600-Describes required alarm systems for licensees

CHANGES TO RULE:

333-333-4600

Alarm System

(1) A service center, manufacturer or laboratory must have a fully operational security alarm system on the licensed premises, activated at all times when the licensed premises is closed for business.¶

(2) The security alarm system for the licensed premises must:¶

(a) Be able to detect unauthorized entry onto the licensed premises and unauthorized activity within the licensed premises.¶

(b) Notify the licensee, license representative or authorized personnel in the event of an unauthorized entry.¶

(c) Have at least two operational "panic buttons" located inside the licensed premises linked with the alarm system that immediately notifies a security company or law enforcement.¶

(3) Upon request, licensees shall make all information related to security alarm systems, monitoring and alarm activity available to the Authority.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4620

RULE SUMMARY: 333-333-4620-Describes required video surveillance equipment for licensees

CHANGES TO RULE:

333-333-4620

Video Surveillance Equipment

(1) A licensed premises must have a fully operational video surveillance recording system.¶

(2) Video surveillance equipment must, at a minimum:¶

(a) Consist of:¶

(A) Digital or network video recorders.¶

(B) Cameras capable of meeting the requirements of OAR 333-333-4630 and this rule.¶

(C) Video monitors.¶

(D) Digital archiving devices.¶

(E) A minimum of one monitor on premises capable of viewing video.¶

(F) Interface devices, if required to adequately operate system or machinery such as a mouse and keyboard.¶

(b) Have the capability of producing and printing a still photograph from any camera image.¶

(c) Have sufficient battery backup to support a minimum of one hour of recording time in the event of a power outage.¶

(3) Except for mounted cameras and monitors, all video surveillance equipment and recordings must be stored in a locked secure area that is accessible only to authorized personnel, Authority employees and contractors, and other state or local government officials that have jurisdiction over some aspect of the licensed premises or licensee.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4630

RULE SUMMARY: 333-333-4630-Describes required camera placement

CHANGES TO RULE:

333-333-4630

Required Camera Coverage and Camera Placement

(1) A licensed premises must have camera coverage, if applicable, for:

(a) All points of ingress and egress to and from indoor areas of the licensed premises, unless those points are located within a client administration area.

(b) All areas where psilocybin products are stored or produced.

(c) All areas where psilocybin waste is required to be stored, destroyed or rendered unusable as required by OAR 333-333-8000.

(2) A licensee must ensure that cameras are placed so that they capture clear and certain images of any individual and activity occurring:

(a) All points of ingress and egress to and from indoor areas of the licensed premises.

(b) In all locations on the licensed premises where psilocybin products are produced or stored.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4640

RULE SUMMARY: 333-333-4640-Describes requirements and conditions for video recording client sessions

CHANGES TO RULE:

333-333-4640

Video Recordings of Administration Sessions

(1) A service center licensee may not install video surveillance equipment in client administration areas. Service centers may make video and audio recordings of administration sessions using portable equipment with the prior written consent of every client and facilitator who will be recorded. ¶

(2) Service centers must make recordings made under this rule available to view for recorded clients and facilitators upon request. Service centers are prohibited from charging a fee to view recordings. ¶

(3) Service centers must securely store recordings made under this rule and may not publish, share or otherwise distribute without the obtaining the prior written consent of every person recorded using the form described in OAR 333-333-4810(3). ¶

(4) Service centers must retain recordings made under this rule for a period of five years. ¶

(5) Clients and facilitators may withdraw their written consent described in sections (1) and (3) of this rule at any time. ¶

(6) Recordings made under this rule are not subject to OAR 333-333-4620 and OAR 333-333-4630, except that any video recordings of administration sessions in the licensee's possession must be provided to the Authority upon request.

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

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

ADOPT: 333-333-4650

RULE SUMMARY: 333-333-4650-Describes general requirements for video recording at licensed premises

CHANGES TO RULE:

333-333-4650

Video Recording Requirements for Licensed Facilities

(1) A service center, manufacturer or laboratory licensee must 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 surveillance recordings for a minimum of 30 calendar days.¶

(d) Maintain surveillance recordings in a format approved by the Authority that can be easily accessed for viewing and easily reproduced.¶

(e) Upon request of the Authority, keep surveillance recordings for periods exceeding the retention period specified in subsection (2)(c) of this rule.¶

(f) Have the date and time embedded on all surveillance 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 surveillance records and 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.¶

(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 prolonged periods of inactivity.¶

(a) At least 24 hours before stopping recording, a licensee must submit written notice to the Authority by electronic mail using a designated form as published by the Authority on its website and the notice must include:¶

(A) A description of the total number and location of cameras that will be deactivated.¶

(B) The date and time recording will stop.¶

(C) An explanation for why recording will be stopped.¶

(D) The date and time recording will resume.¶

(b) A licensee must resume all required recording no later than the date and time specified in the notice submitted under subsection (a) of this section.¶

(c) A licensee may not engage in any licensed privileges in any areas where recording was stopped under this section.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4660

RULE SUMMARY: 333-333-4660-Describes requirements for location and maintenance of video equipment

CHANGES TO RULE:

333-333-4660

Location and Maintenance of Surveillance Equipment

- (1) A service center, manufacturer or laboratory licensee must house the surveillance recording equipment in a designated, locked, and secured room or other enclosure with access limited to:
- (a) The licensee, license representatives, and authorized personnel.
 - (b) Employees of the 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 surveillance system and room on the licensed premises.
- (3) Service center, manufacturer or laboratory licensees must keep a surveillance equipment maintenance activity log on the licensed premises to record all service activity including the identity of any individual performing the service, the service date and time and the reason for service to the surveillance system.
- (4) Service center, manufacturer or laboratory licensees must keep a surveillance equipment outage log on the licensed premises to record all camera outages lasting more than 30 minutes. 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.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4700

RULE SUMMARY: 333-333-4700-Describes duty to contact emergency services

CHANGES TO RULE:

333-333-4700

Duty to Contact Emergency Services

(1) Facilitators and service center license representatives must immediately contact appropriate emergency services when activity or conditions on the licensed premises endanger the safety of any person present on the premises. If licensee is unable to contact emergency services while the activity is taking place, they must contact emergency services as soon as it is possible to do so. ¶

(2) Facilitators and service center license representatives must contact emergency services when any person on the licensed premises requires immediate medical attention. ¶

(3) In addition to the requirements of sections (1) and (2) of this rule, licensees must notify the Authority in writing in a form and manner prescribed by the authority within 48 hours of contacting emergency services.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4810

RULE SUMMARY: 333-333-4810-Describes requirements for maintaining client confidentiality

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 any communication made by a client during the course of providing psilocybin services or selling psilocybin products to the client, except with client's consent or otherwise as allowed by ORS 475A.450.¶

(2) A service center or facilitator 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 patient.¶

(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 Oregon Psilocybin Services to meet the requirements of section (2) of this rule. The consent form is available at on the Oregon Psilocybin Services website. ¶

(4) 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 24 hours after the conclusion of the client's administration session. ¶

(5) A service center or facilitator must provide a client with a disclosure form during a preparation session if the facilitator or service center intends to share the client's de-identified data. ¶

(6) A service center or facilitator must use the disclosure form provided by Oregon Psilocybin Services to meet the requirements of section (5) of this rule. The disclosure form is available on the Oregon Psilocybin Services website.¶

(7) A service center or facilitator may not condition the provision of psilocybin services on whether a client consents to the use or disclosure of their identifiable information.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.450

ADOPT: 333-333-4820

RULE SUMMARY: 333-333-4820-Describes requirements for record retention

CHANGES TO RULE:

333-333-4820

Record Retention

(1) Licensees shall store, maintain and destroy records in a manner that prevents unauthorized access and protects client confidentiality. ¶

(2) Unless otherwise specified in these rules, licensees must retain required records for a period of five years. ¶

(3) Licensed facilitators and service centers must allow current and former clients to access and examine client records and request corrections to those records. Following the retention period described in section (2) of this rule a facilitator or service center must destroy client records upon the client's request.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4830

RULE SUMMARY: 333-333-4830-Describes requirements for creating business records

CHANGES TO RULE:

333-333-4830

Financial and Business Records

In addition to any other recordkeeping requirements in these rules, a licensee must have and maintain records that clearly reflect all financial transactions and the financial condition of the licensed entity. The following records may be kept in either paper or electronic form in a manner that prevents unauthorized access and protects confidential employment records. Records required by this rule must be maintained for a five-year period and must be made available for inspection if requested by the Authority:¶

(1) Purchase invoices and supporting documents for items and services purchased for use in the production, processing, research, testing and sale of psilocybin products that include from whom the items were purchased and the date of purchase.¶

(2) Bank statements for any accounts associated with the licensed entity.¶

(3) Accounting and tax records associated with the licensed entity.¶

(4) Documentation of all financial transactions related to the licensed entity, including contracts and agreements for services performed or received that relate to the licensed entity.¶

(5) All employee records, including training.¶

(6) Information relating to the structure and ownership of the entity, including:¶

(a) A list of all individuals and legal entities identified as applicants.¶

(b) For each legal entity identified as an applicant, complete information about the ownership structure of that legal entity.¶

(c) A list of all individuals and legal entities who are entitled to receive a portion of revenue, proceeds, or profits from the licensed entity.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

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 twenty-four hours but no more than 90 days prior to the commencement of the client's first administration session with the facilitator. If different facilitators will conduct a client's preparation, administration sessions or integration session, the client must provide written consent as described in subsection (7)(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. ¶
- (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) 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 immediately following the administration session. ¶
- (5) For every client who will participate in an administration session, a facilitator must coordinate with the client to complete a client safety plan as described in OAR 333-333-5080. ¶
- (6) A facilitator must provide a client with the following during or prior to a preparation session and review each document with the client during a preparation session: ¶
 - (a) Informed consent document as described in OAR 333-333-5040. ¶
 - (b) Client Bill of Rights as described in OAR 333-333-4520. ¶
 - (c) Product information document as described in OAR 333-333-2410 for any products that may be consumed during an administration session. ¶
 - (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. ¶
 - (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. ¶
 - (f) Applicable sections of the service center emergency plan required by OAR 845-025-4460. ¶
 - (g) Disclosure form for de-identified client data required by OAR 845-025-4810(5). ¶
- (7) In addition to the documents required by sections (3)(4)(5) and (6) of this rule, a facilitator must obtain prior written consent from a client during a preparation session for the following activities and circumstances: ¶
 - (a) Participation in a group administration session, including the opportunity to meet other clients and facilitators participating in the group session as described in OAR 333-333-5020. ¶
 - (b) Use of supportive touch during an administration session, if any, as described in OAR 333-333-5120(6). ¶
 - (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 total amount of psilocybin analyte that a client agrees to consume, not to exceed 50 mg of psilocybin analyte. ¶
 - (i) Participating in an administration session where licensed representatives of a service center will be present pursuant to OAR 333-333-5200(9). ¶
- (8) 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. ¶

(9) Preparation sessions may be completed in person or virtually using video conferencing technology. ¶

(10) The requirements of this rule may be satisfied by conducting multiple preparation sessions. ¶

(11) A facilitator must complete an initial preparation session with every client before conducting an administration session with that client for the first time. After completing the initial preparation session, a facilitator is not required to complete additional preparation sessions prior to conducting an administration session with that client for a period of 12 months. ¶

(12) If a facilitator does not complete additional preparation sessions as allowed by section (11) 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 additional administration sessions. ¶

(13) A facilitator must discuss the process for verification of license status and process for making complaints to the Authority during a preparation session.

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

ADOPT: 333-333-5020

RULE SUMMARY: 333-333-5020-Describes requirements for group preparation sessions

CHANGES TO RULE:

333-333-5020

Group Preparation Sessions

(1) In addition to the requirements of OAR 333-333-5000 clients who will participate in a group session must be informed of additional considerations for participating in group administration sessions. ¶

(2) Clients who will participate in a group administration session must have the opportunity to meet and interact with other clients and any interpreters or client support persons who will participate in the group administration session prior to the session commencing. ¶

(3) Clients who will participate in a group administration session must have an opportunity to meet every facilitator who will participate in the group administration session prior to the session commencing. ¶

(4) The requirements of sections (2) and (3) of this rule may be satisfied at any time prior to commencement of the group administration session, including the day of the administration session. Clients must have the opportunity to reschedule their administration session with alternate groups or facilitators after the meetings described in sections (2) and (3) of this rule.

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

CHANGES TO RULE:

333-333-5040

Informed Consent

(1) A facilitator must provide every client a copy of the following informed consent document during the client's preparation session:¶

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 while existing research has shown promising results, 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. 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 professional before participating in an administration session. ¶
8. I understand that the risks of psilocybin during pregnancy and breastfeeding 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 facilitators 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, facilitators 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 being administered psilocybin is completely voluntary and I may decide not to receive 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 de-identified data collected by my facilitator or service center may be shared with

- people and institutions outside of the facilitator or psilocybin service center for research and other purposes. ¶
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, up to approximately 5 minutes, 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 locations of client restrooms and protocols for use of restrooms during an administration session. ¶
21. My facilitator has shared information regarding verification of license status and process for making complaints to the Oregon Health Authority. ¶
22. I have had the opportunity to ask questions regarding anything I may not understand or that I believe should be made clear. ¶
23. 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. ¶
24. If consuming greater than 35 mg of psilocybin analyte during an administration session, I acknowledge that clinical trials have not typically administered doses of greater than 35 mg of psilocybin analyte. 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 a facilitator has a duty to call emergency services if required and a client assumes responsibility for costs of emergency services. ¶
27. I understand that I may be charged a cancellation fee if I cancel a scheduled preparation, administration or integration session with less than 24 hours' notice. ¶

¶
 _____ ¶
 Name (Print) ¶

_____ ¶
 Signature Date ¶

- ¶
- (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. Statutory/Other Authority: ORS 475A.235, ORS 475A.340 Statutes/Other Implemented: ORS 475A.340

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. ¶

(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 medications 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) Do you have a recent history of causing harm, or wanting to cause harm, to self or others? ¶

(i) Do you require any assistive mobility devices?¶

(j) Will you require assistance to consume psilocybin products?¶

(k) 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 or may choose not to answer. ¶

(a) Would you like to share anything about your medical history, including current medications, 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 or past history of causing harm, or wanting to cause harm, to self or others, that you feel would be helpful for an administration session?¶

(c) 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?¶

(d) Would you like to share any past experiences with psychedelics or altered states of consciousness?¶

(e) 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 medication. 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 medication during an administration session, the client and facilitator must work together to identify whether the client will be able to administer the medication themselves. If the client is unable to administer the medication themselves, the client must identify a client support person who will be available to administer the medication when required. ¶

(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 or medical device plan. ¶

(A) If the client requires a medical device, the medical device 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 written medical device 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 assistance 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), a facilitator shall encourage the client to consult with a qualified mental health care provider regarding the risk of consuming psilocybin. ¶

(i) If a client answers yes to question (3)(i), 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. ¶

(j) If a client answers yes to question (3)(j), 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. ¶

(k) If a client answers yes to question (3)(k), 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.

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

ADOPT: 333-333-5070

RULE SUMMARY: 333-333-5070-Describes requirements for interpreters and client support persons

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) 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 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 medications 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 interfere or otherwise participate in the administration session. ¶

(B) Interpreters and client support persons, facilitators and service centers shall not share or disclose any information regarding clients' participation in psilocybin services. ¶

(3) Client support persons shall perform only those activities identified in the written support person plan described in section (2) of this rule. ¶

(4) Client support persons are prohibited from touching clients except as required to perform activities identified in the written support person plan described in section (2) of this rule. ¶

(5) During the meeting required by section (1) of this rule a facilitator must provide a copy of the Client Bill of Rights and allow the interpreter or client support person an opportunity to ask questions.

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

ADOPT: 333-333-5080

RULE SUMMARY: 333-333-5080-Describes requirements for client safety and support plans

CHANGES TO RULE:

333-333-5080

Safety and Support Plans

(1) A facilitator must work with every client who will participate in an administration session to draft a safety and support plan that identifies risks and challenges specific to the client's circumstances and resources available to mitigate those risks and challenges, including the client's existing support network and appropriate external resources. ¶

(2) Safety and support plans may not be changed during an administration session.

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

ADOPT: 333-333-5090

RULE SUMMARY: 333-333-5090-Describes required client acknowledgements

CHANGES TO RULE:

333-333-5090

Client Acknowledgement

(1) Prior to beginning an administration session, a client must sign and complete a client acknowledgement document that attests to the following:¶

(a) The client has received a copy of the Client Bill of Rights and has had an opportunity to discuss that document with their facilitator.¶

(b) The client has reviewed and signed an informed consent document and has had an opportunity to discuss that document with their facilitator.¶

(c) The client has completed a client information form in coordination with a facilitator and the information contained in the document is true and accurate. ¶

(d) The client has completed a transportation plan in coordination with a facilitator and agrees to follow the transportation plan. ¶

(2) If applicable, a client must acknowledge that they have completed the following documents prior to beginning an administration session.¶

(a) If an interpreter or client support person will be present during the administration session as described in OAR 333-333-5070, consent for that person to be present during an administration session. ¶

(b) Consent for any applicable circumstances in OAR 333-333-5000(5).¶

(c) Consent to receive additional psilocybin products after the administration session has begun as described in OAR 333-333-5240(3). ¶

(d) Consent to disclose identifiable client information as described in OAR 333-333-4810(3).¶

(e) Disclosure form for sharing de-identified client data as described in OAR 333-333-4810(5).

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

ADOPT: 333-333-5100

RULE SUMMARY: 333-333-5100-Describes requirements for client records

CHANGES TO RULE:

333-333-5100

Facilitator and Service Center Record Keeping and Confidentiality

(1) A facilitator shall create and retain the following records for every client to whom they provide psilocybin services. A copy of these records must be also stored at the service center where the client received services:¶

(a) Completed information form described in OAR 333-333-5050.¶

(b) Completed informed consent document described in OAR 333-333-5040.¶

(c) Transportation plan described in OAR 333-333-5150.¶

(d) Client acknowledgement form described in OAR 333-333-5090.¶

(e) The date, start time and end time, for every preparation, administration and integration session. ¶

(f) The psilocybin products, including unique identification number, consumed by each client, including the amount of product consumed and whether it was consumed in a single dose or multiple doses. ¶

(g) Any deviation from the client's transportation plan. ¶

(h) Any adverse reactions that required medical attention or emergency services. ¶

(2) If applicable and as required by these rules, a facilitator shall create the following records, and these records must be stored at the service center where the client received services:¶

(a) Consent for any applicable circumstances described in OAR 333-333-5000(7).¶

(b) Support person plans as required by OAR 333-333-5070.¶

(c) Safety and support plans as described in OAR 333-333-5080.¶

(3) Records required by this rule must be provided to the client upon request pursuant to OAR 333-333-4820(3).¶

(4) Records required by this rule must identify the client receiving services. ¶

(5) Facilitators and service centers shall not share or disclose any records required by this rule unless permitted or required to do so by ORS 475A.450 or these rules.

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340, ORS 475A.450

ADOPT: 333-333-5120

RULE SUMMARY: 333-333-5120-Describes requirements for facilitator conduct

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 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. ¶
- (4) A facilitator shall only provide psilocybin services within the limits of their professional competence. When a client demonstrates circumstances or conditions that exceed the limits of a facilitator's professional competence, a facilitator has a duty to make reasonable efforts to refer that client to another facilitator. ¶
- (5) Except when acting as a practicum site supervisor under OAR 333-333-3070, a facilitator shall not provide psilocybin services to clients over whom they have supervisory, evaluative, or other authority. ¶
- (6) Facilitators may provide supportive touch during administration sessions when requested by the client and with the client's prior written consent. Supportive touch is limited to hugs or the facilitator placing their hands on a client's hand or shoulder. 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. ¶
- (7) 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. ¶
- (8) 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. ¶
- (9) 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. ¶
- (10) 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. ¶
- (11) 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. ¶
- (12) The requirements of this rule apply to all facilitators, regardless of whether facilitator is also a license representative of a service center.

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

ADOPT: 333-333-5130

RULE SUMMARY: 333-333-5130-Describes scope of practice for facilitators

CHANGES TO RULE:

333-333-5130

Facilitator Scope of Practice

(1) A facilitator shall not engage in any conduct that requires additional professional licensure while providing psilocybin services to clients, including but not limited to diagnosing and treating physical or mental health conditions.¶

(2) A facilitator is prohibited from transferring, selling or otherwise handling any psilocybin product while they are facilitating a preparation, administration or integration session, regardless of whether the facilitator is also a license representative of a service center. ¶

(3) If a facilitator holds a professional license in another field, the facilitator shall not exercise the privileges of that license while providing psilocybin services to clients.

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

ADOPT: 333-333-5140

RULE SUMMARY: 333-333-5140-Describes duty to report misconduct

CHANGES TO RULE:

333-333-5140

Duty to Report Misconduct

(1) Any licensee, license representative or permittee who witnesses or becomes aware of conduct involving a client that violates ORS chapter 475A or these rules must report that conduct to the Authority within 24 hours.¶

(2) Any licensee, license representative or permittee who witnesses or becomes aware of conduct that harms or potentially endangers a client must report that conduct to the Authority within 24 hours in a form and manner prescribed by the Authority.¶

(3) Failure to report as required by sections (1) and (2) of this rule is violation, separate from any violations that may have occurred as a result of the underlying conduct.

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

ADOPT: 333-333-5150

RULE SUMMARY: 333-333-5150-Describes required client transportation plans

CHANGES TO RULE:

333-333-5150

Transportation Plans

- (1) A facilitator must create and record a transportation plan for every client that receives psilocybin services. ¶
 - (2) Transportation plans must be signed by the client and describe how the client will access safe transportation away from the service center at the conclusion of an administration session. ¶
 - (3) Transportation plans shall advise a client not to operate a motor vehicle directly following an administration session. Facilitators shall make reasonable efforts to prevent clients from operating a motor vehicle at the conclusion of an administration session. If a client's failure to follow their transportation plan creates a danger to the client's safety or the safety of others, a facilitator must contact appropriate emergency services. ¶
 - (4) If a client is unable to follow their transportation plan, a facilitator must make reasonable efforts to arrange for alternative transportation. ¶
 - (5) A facilitator must document in writing all instances in which a client does not follow their transportation plan.
- Statutory/Other Authority: ORS 475A.235, ORS 475A.340
- Statutes/Other Implemented: ORS 475A.340

ADOPT: 333-333-5160

RULE SUMMARY: 333-333-5160-Describes requirements for sale of psilocybin services

CHANGES TO RULE:

333-333-5160

Sale of Psilocybin Services

A facilitator must list fees for psilocybin products separately from fees for preparation, administration and integration sessions and must specify whether those fees will be paid directly to the facilitator or to the service center where the client receives psilocybin services.

Statutory/Other Authority: ORS 475A.235, ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

ADOPT: 333-333-5170

RULE SUMMARY: 333-333-5170-Describes requirements for sale of psilocybin products

CHANGES TO RULE:

333-333-5170

Sale and Transfer of Psilocybin Products to Clients

- (1) Psilocybin products may only be sold and transferred to clients by license representatives of a service center. ¶
- (2) Payment for psilocybin products must be received prior to beginning an administration session. If purchased psilocybin products are not transferred to a client, a service center must provide a refund for the purchase price. ¶
- (3) A license representative of a service center must transfer psilocybin products to clients within a designated administration area and clients must consume psilocybin products promptly following transfer. ¶
- (4) A license representative of a service center must transfer psilocybin products to clients in sealed client packaging. ¶
- (5) A license representative of a service center must ensure that a client consumes psilocybin products promptly after psilocybin products are transferred to the client. ¶
- (6) A license representative of a service center must observe a client consume any psilocybin products transferred to that client and dispose of packaging waste appropriately. Any portion of a product that is not consumed must be returned to a license representative and must be destroyed at the conclusion of the client's administration session. If a client is unable to open or consume a psilocybin product without assistance, they may identify a client support person to assist them subject to the requirements of OAR 333-333-5050(5)(j) and OAR 333-333-5070. ¶
- (7) Facilitators are prohibited from transferring, preparing or otherwise handling psilocybin products, unless the facilitator is also a license representative of a service center. ¶
- (8) Facilitators are 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 license representative of a service center. ¶
- (9) Clients may mix psilocybin products with packaged food or beverages prior to consuming, as long as the packaged food or beverage was unopened prior to mixing. ¶
- (10) Licensees shall not permit clients to mix psilocybin products with any items other than packaged food and beverages, including but not limited to: ¶
 - (a) Homemade food and beverage items. ¶
 - (b) Dietary and nutritional supplements, including herbal supplements and products derived from cannabis. ¶
 - (c) Prescription and non-prescription drugs. ¶
 - (d) Any intoxicant.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.468

ADOPT: 333-333-5180

RULE SUMMARY: 333-333-5180-Describes requirements for collection of taxes

CHANGES TO RULE:

333-333-5180

Collection of Taxes

(1) A service center must collect from clients, at the point of sale, the tax imposed on psilocybin products under ORS 475A.662 and ORS 475A.666.¶

(2) A service center must hold the tax described in section (1) of this rule in trust for the State of Oregon and remit the tax to the Oregon Department of Revenue in accordance with Department of Revenue rules.¶

(3) A service center must separately state the cost of psilocybin products and the tax owed on any invoice or receipt provided to clients.¶

(4) A service center may not collect a tax on any goods other than psilocybin products, nor on the cost for psilocybin services.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.666

ADOPT: 333-333-5200

RULE SUMMARY: 333-333-5200-Describes general requirements for client administration sessions

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) 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. ¶

(4) The requirements of section (3) of this rule do not apply to client restroom breaks. ¶

(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 license representative is available to monitor clients. ¶

(6) In addition to a facilitator conducting the administration session, at least one license 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. If the additional license representative required by this rule holds a facilitator license, they are prohibited from transferring, selling or otherwise handling any psilocybin product while they are facilitating a preparation, administration or integration session. ¶

(7) Facilitators must ensure that a back-up facilitator is available to assist in case of unforeseen circumstances that prevent the primary facilitator from completing the session. Back up facilitators must be able to reach the licensed premises within a reasonable period of time. ¶

(8) Except for individuals described in OAR 333-333-5070 and service centers acting as practicum sites, only clients, facilitators and license representatives of a service center may be present during an administration session. ¶

(9) License representatives of a service center who are present during an administration session: (a) May not provide psilocybin services. ¶

(b) May only be present to assist with operations and shall not interfere or otherwise participate in the administration session. ¶

(c) Shall not share or disclose any information regarding clients' participation in psilocybin services. ¶

(10) 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

ADOPT: 333-333-5210

RULE SUMMARY: 333-333-5210-Describes requirements for outdoor administration sessions

CHANGES TO RULE:

333-333-5210

Outdoor Administration Sessions

(1) Facilitators may conduct outdoor administration sessions within designated outdoor administration areas at a service center. ¶

(2) Outdoor administration areas must be free of falling hazards, drowning hazards and any other conditions that could pose a safety risk to clients.¶

(3) The boundaries of an outdoor administration area must be clearly marked with visible signage or barriers. ¶

(4) Facilitators may not conduct outdoor administration sessions in adverse weather conditions, including, but not limited to extreme heat or cold, heavy precipitation, thunder and lightning storms, high winds or wildfire smoke. ¶

(5) Service centers with designated outdoor administration areas must also provide an indoor administration area for clients who request to move indoors after their administration session has begun.

Statutory/Other Authority: ORS 475A.235

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

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 up to 5 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 25. ¶

(b) For clients consuming equal or greater than 5 mg and less than 10 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 15. ¶

(c) For clients consuming equal or greater than 10 mg and less than 15 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 8. ¶

(d) For clients consuming equal or greater than 15 mg and less than 25 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 6. ¶

(e) For clients consuming equal or greater than 25 mg and up to 35 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 4. ¶

(f) For clients consuming equal or greater than 35 mg and up to 50 mg of psilocybin analyte, the minimum facilitator to client ratio is 1 to 2. ¶

(3) Group administration sessions may not exceed a total of 25 clients, or the service center's maximum occupancy for the administration area where the session takes place whichever is smaller, regardless of the number of facilitators present. ¶

(4) Client administration areas where group sessions take place, must provide an appropriate setting for the group sessions that: ¶

(a) Provide sufficient space for clients and facilitators to participate in the session without touching or coming into close physical contact with other clients. Client administration areas where group administration sessions will take place must contain at least twenty-five square feet of area for every person who will be present during the session. ¶

(b) Allows a facilitator to monitor clients as required by OAR 333-333-5200(3). ¶

(5) Clients participating in a group administration session are prohibited from touching one another except for supportive touch as described in OAR 333-333-5120(6). If supportive touch will be used during an administrative session, each participating client must provide prior written consent as described in OAR 333-333-5000(5)(b). ¶

(6) Every client participating in a group session must be provided with an opportunity to request individual support from a facilitator. ¶

(7) If a client becomes disruptive during a group administration session, a facilitator must make reasonable efforts to move that client to a separate area within the administration area that mitigates disruption to the other clients in the group. ¶

(8) Every client participating in a group administration session must be present at the beginning of the session. ¶

(9) Unless explicitly stated in this rule, all requirements of OAR 333-333-5200 apply to group administration sessions.

Statutory/Other Authority: ORS 475A.235

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

ADOPT: 333-333-5240

RULE SUMMARY: 333-333-5240-Describes client consumption limits

CHANGES TO RULE:

333-333-5240

Consumption Limits

(1) A service center licensee or license representative may not allow a client to consume more than a total of 50 mg of psilocybin analyte during an administration session. ¶

(2) A service center licensee or license representative may permit a client to consume a secondary dose of psilocybin product during an administration session as long as the total amount of psilocybin analyte contained in the products is 50 mg or less. ¶

(3) Clients who want the option to consume a secondary dose during their administration sessions, up to a total of 50 mg of psilocybin analyte, must provide written consent prior to the beginning of their administration session.

Statutory/Other Authority: ORS 475A.235

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

ADOPT: 333-333-5250

RULE SUMMARY: 333-333-5250-Describes requirements for duration of administration sessions

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 a client consumes during that session, including any secondary dose consumed. ¶

(a) For clients consuming up to 5 mg of psilocybin analyte, the minimum duration of the administration session shall be one hour. ¶

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

(c) For clients consuming equal or greater than 10 mg and less than 25 mg of psilocybin analyte, the minimum duration of the administration session shall be four hours. ¶

(d) For clients consuming equal or greater than 25 mg and up to 35 mg of psilocybin analyte, the minimum duration of the administration session shall be five hours. ¶

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

(2) Following the conclusion of the minimum duration period described in section (1) of this rule, a facilitator, in consultation with the client, shall determine whether to continue an administration session. 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. ¶

(3) If following the consultation described in section (2) of this rule, a facilitator determines that it is appropriate to continue the administration session beyond 11:59 PM local time, the facilitator and service center where the client received services shall notify the Authority in a form and manner prescribed by the Authority no later than 11:00 AM the next calendar day. ¶

(4) A facilitator shall record and retain the time and date that each administration session began and concluded. ¶

(5) A facilitator shall require every client to 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. ¶

(6) 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.

Statutory/Other Authority: ORS 475A.235

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

ADOPT: 333-333-5260

RULE SUMMARY: 333-333-5260-Describes requirements for integration sessions

CHANGES TO RULE:

333-333-5260

Integration Session

(1) A facilitator shall offer clients the opportunity to participate in one or more integration sessions following participation in an administration session. ¶

(2) A facilitator must use a non-directive approach to an integration session and comply with OAR 333-333-5130 during an integration session. ¶

(3) A facilitator may provide a client information regarding other services, including but not limited to peer support groups and community resources, in support of a client's ongoing integration needs.

Statutory/Other Authority: ORS 475A.235

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

CHANGES TO RULE:

333-333-6000

Prohibited Conduct

- (1) Sale to a person under 21 years of age. A licensee or permittee may not sell, deliver, transfer or make available any psilocybin product to a person under 21 years of age.¶
- (2) Services to a person under 21 years of age. A facilitator may not provide psilocybin services to a person under 21 years of age. ¶
- (3) Identification for Products. A licensee or license representative must require a person to produce identification as required by ORS 475A.445 before selling or providing a psilocybin product to that person. ¶
- (4) Identification for Services. A facilitator must require a person to produce identification before providing psilocybin services to that person. ¶
- (5) Access to Licensed Premises.¶
- (a) A licensee, license representative or permittee may not:¶
- (A) During regular business hours for the licensed premises, refuse to admit or fail to promptly admit an authorized Authority representative who identifies themselves and who enters or wants to enter a licensed premises to conduct an inspection to ensure compliance with ORS 475A.210 to 475A.722 or these rules;¶
- (B) Outside of regular business hours or when the licensed premises appear closed, refuse to admit or fail to promptly admit an authorized Authority representative who identifies themselves and requests entry on the basis that there is a reason to believe a violation of ORS 475A.210 to 475A.722 or these rules is occurring; or¶
- (C) Ask the authorized Authority representative to leave until the authorized Authority representative has had an opportunity to conduct an inspection to ensure compliance with ORS chapter 475A or these rules.¶
- (b) A licensee must retain control of, or the right of access to, all or any part of the licensed premises. ¶
- (6) Use or Consumption of Intoxicants on Duty and Under the Influence on Duty.¶
- (a) No licensee, license representative, or permittee may consume any intoxicants while on duty.¶
- (b) No licensee, license representative, or permittee may be under the influence of intoxicants while present on a licensed premises. The requirements of this subsection do not apply to licensees, license representatives and permittees who are off duty and consume psilocybin products while receiving psilocybin services as a client. ¶
- (c) As used in this section "intoxicants" means any substance that has intoxicating effects, and includes alcohol, prescription drugs, non-prescription drugs and any other controlled substances.¶
- (7) Import and Export. A licensee or permittee may not import psilocybin products into this state or export psilocybin out of this state. ¶
- (8) Permitting, Disorderly or Unlawful Conduct. A licensee or permittee may not permit disorderly activity or activity that is unlawful under Oregon state law on the licensed premises or in areas adjacent to or outside the licensed premises under the control of the licensee.¶
- (a) If the prohibited activity under this section results in death or serious physical injury, or results in a sexual offense the violation is a Category I violation and could result in license or permit cancellation.¶
- (b) As used in this section:¶
- (A) "Disorderly activities" means activities that harass, threaten or physically harm oneself or another person.¶
- (B) "Disorderly activities" include offensive conduct towards another person based on race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, or social class. ¶
- (C) "Unlawful activity" means activities that violate the laws of this state, including but not limited to any activity that violates a state criminal statute.¶
- (c) The Authority does not require a conviction to establish a violation of this section.¶
- (9) Psilocybin as a Prize, Premium or Consideration. No licensee or permittee may give or permit the giving of any psilocybin product as a prize, premium, or consideration for any lottery, contest, game of chance or skill, exhibition, or any competition of any kind on the licensed premises. ¶
- (10) Visibly Intoxicated Persons. No licensee or permittee may sell, give, or otherwise make available any psilocybin products or provide psilocybin services to any person who is visibly intoxicated. The requirements of this subsection (10) do not apply to clients who have provided prior written consent to consume additional psilocybin products during an administration session.¶
- (11) Additional Prohibitions. A licensee or permittee may not:¶
- (a) Deliver psilocybin products to a person or location off the licensed premises.¶
- (b) Permit psilocybin products to be present on the licensed premises, except as allowed by these rules.
- Statutory/Other Authority: ORS 475A.235
- Statutes/Other Implemented: ORS 475A.235, ORS 475A.340

ADOPT: 333-333-6030

RULE SUMMARY: 333-333-6030-Describes prohibited conduct for laboratory licenses

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

(2) The 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

ADOPT: 333-333-6040

RULE SUMMARY: 333-333-6040-Describes prohibited dishonest conduct

CHANGES TO RULE:

333-333-6040

Dishonest Conduct

(1) False Statements. A licensee or permittee may not make a false statement or representation to the Authority in order to induce or prevent action or investigation by the Authority. ¶

(2) Psilocybin Product Misrepresentations. A licensee or permittee may not misrepresent any psilocybin item to a consumer, licensee, or the public, including:¶

(a) Misrepresenting the contents of a psilocybin product.¶

(b) Misrepresenting the testing results of a psilocybin product.¶

(c) Making representations or claims that the psilocybin product has curative or therapeutic effects.¶

(3) A licensee may not produce, possess or supply adulterated psilocybin items.¶

(4) Evidence. A licensee or permittee may not:¶

(a) Destroy, damage, alter, remove or conceal potential evidence, or attempt to do so, or ask or encourage another person to do so.¶

(b) Refuse to provide, or fail to promptly provide, an authorized Authority representative evidence when requested to do so.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-6100

RULE SUMMARY: 333-333-6100-Describes advertising restrictions

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.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-6110

RULE SUMMARY: 333-333-6110-Describes requirements for promotions

CHANGES TO RULE:

333-333-6110

Advertising Media, Coupons, and Promotions

(1) A licensee may not utilize television, radio, billboards, print media or internet advertising unless the licensee has reliable evidence that no more than 30 percent of the audience for the program, publication or Internet website in or on which the advertising is to air or appear is reasonably expected to be under the age of 21.

(2) A licensee who advertises via webpage must make reasonable efforts to prevent individuals under 21 years of age from visiting the webpage.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-6120

RULE SUMMARY: 333-333-6120-Describes requirements for removal of non-conforming advertising

CHANGES TO RULE:

333-333-6120

Removal of Objectionable and Non-Conforming Advertising

(1) A licensee must remove any sign, display, or advertisement if the Authority determines it violates these rules.

(2) The Authority will notify the licensee to identify any non-conforming advertising and provide a reasonable period for the licensee to remove any sign, display or advertisement that does not comply with these rules.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-6150

RULE SUMMARY: 333-333-6150-Describes requirements and process for premises inspections

CHANGES TO RULE:

333-333-6150

Inspections

(1) The 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, license representative, or permittee must cooperate with authorized Authority representative's reasonable requests during an inspection.¶

(4) Authorized Authority representatives will not inspect client administration areas when administration sessions are taking place unless necessary to prevent a serious danger to public health or safety. ¶

(5) If a licensee, license 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

ADOPT: 333-333-6200

RULE SUMMARY: 333-333-6200-Describes penalties for administrative violations

CHANGES TO RULE:

333-333-6200

Suspension, Cancellation, Civil Penalties, Sanction Schedule

(1) The Authority may suspend or revoke:¶

(a) A license issued under ORS chapter 475A for violation of a provision of ORS chapter 475A or these rules, in accordance with section (4) of this rule.¶

(b) A permit issued under ORS 475A.480 for violation of a provision of ORS chapter 475A or these rules, in accordance with section (4) of this rule.¶

(2) Civil Penalties.¶

(a) The Authority may impose a civil penalty under ORS 475A.513, ORS 475A.618, or ORS 475A.654 for violation of a provision of ORS chapter 475A or these rules, in accordance with section (4) of this rule. ¶

(b) Failure to pay a civil penalty imposed by final order of the Authority is a violation. ¶

(3) The Authority uses the following violation categories for licensees licensed under ORS chapter 475A:¶

(a) Category I - Violations that pose the highest risk to public health and safety or make a licensee ineligible for a license.¶

(b) Category II - Violations that create a threat or substantial likelihood of a threat to public health or safety.¶

(c) Category III - Violations that create an increased risk to public health or safety.¶

(d) Category IV - Violations that are technical in nature and are inconsistent with the orderly regulation of the testing, sale or manufacture of psilocybin products and the provision of psilocybin services. ¶

(4) Violation sanctions.¶

(a) The Authority may sanction a licensee or permittee in accordance with the guidelines set forth in Exhibit 1, incorporated by reference. ¶

(b) Exhibit 1 lists the proposed sanctions for single or repeat violations that occur within a two-year period for each category described in section (3) of this rule. The Authority may allege multiple violations in a single notice and may count violations alleged in notices issued within the previous two-year period toward the total number of violations. In calculating the total number of violations, the Authority may consider a proposed violation for which the Authority has not yet issued a final order.¶

(c) The proposed sanctions in Exhibit 1 are guidelines. If the Authority finds one or more mitigating or aggravating circumstances, it may assess a lesser or greater sanction, up to and including revocation. Mitigating circumstances may decrease the sanction but will not result in dismissal of the violation. The Authority may decrease or increase a sanction to prevent inequity or to take account of particular circumstances in the case.¶

(d) Mitigating circumstances include, but are not limited to:¶

(A) Making a good faith effort to prevent a violation. ¶

(B) Extraordinary cooperation in the violation investigation demonstrating the licensee or permittee accepts responsibility.¶

(e) Aggravating circumstances include, but are not limited to:¶

(A) Receiving a prior warning about one or more compliance problems.¶

(B) Repeated failure to comply with laws.¶

(C) Efforts to conceal a violation.¶

(D) Intentionally committing a violation.¶

(E) A violation involving more than one client or employee.¶

(F) A violation involving unwanted or inappropriate touching of a client.¶

(G) A violation involving injury or death.¶

(H) A violation involving the transfer of psilocybin products to anyone other than a client during an administration session. ¶

(I) A violation that resulted in a monetary benefit for the licensee or conduct that intended to create a monetary benefit for the licensee.¶

(J) Three or more violations within a two-year-period, regardless of the category, where the number of violations indicate a disregard for the law or failure to control the licensed premises.¶

(5) A licensee may not avoid the sanction for a violation or the application of the provision for successive violations by changing their corporate structure for example, by adding or dropping a partner or converting to another form of legal entity when the individuals who own, operate, or control the licensed entity are substantially similar.

Statutory/Other Authority: ORS 475A.235, ORS 475A.420, ORS 475A.425

Statutes/Other Implemented: ORS 475A.235, ORS 475A.420, ORS 475A.425

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

333-333-6200

Suspension, Cancellation, Civil Penalties, Sanction Schedule

Exhibit 1

Licensees:

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

Worker Permits:

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

ADOPT: 333-333-6210

RULE SUMMARY: 333-333-6210-Describes licensee responsibility for administrative violations

CHANGES TO RULE:

333-333-6210

Licensee Responsibility

(1) A licensee is responsible for:

(a) The violation of any of these rules and any provision of ORS 475A.210 to 475A.722.

(b) Any act or omission of a license representative in violation of these rules or of ORS 475A.210 to 475A.722.

(2) If a facilitator is a license representative of a service center, a service center shall be responsible for any violation of these rules or ORS 475A.210 to 475A.722 that occurs on the service center's licensed premises.

(3) If a facilitator is not a license representative of a service center, a service center shall be responsible for any violations of these rules or ORS 475A.210 to 475A.722 if:

(a) The violation occurs on the licensed premises; and

(b) The service center fails to take reasonable steps to prevent the violation.

(4) Sections (1), (2) and (3) of this rule apply to every individual and legal entity identified as a licensee on a license issued by the Authority.

(5) Violation of any of these rules or any provision of ORS 475A.210 to 475A.722 shall be attributed to every individual and legal entity identified as a licensee on a license issued by the Authority for the purpose of considering the individual or legal entities record of compliance under 475A.250(2)(h).

Statutory/Other Authority: ORS 475A.235, ORS 475A.420

Statutes/Other Implemented: ORS 475A.235, ORS 475A.420

CHANGES TO RULE:

333-333-6220

Suspended Licenses: Posting of Suspension Notice Sign, Activities Allowed During Suspension

- (1) Before 6:00 AM on the date a license suspension goes into effect, and until the suspension is completed, Authority staff must ensure that a suspension notice sign is posted on each outside entrance or door to the licensed premises of a service center, manufacturer or laboratory.¶
 - (2) The suspension notice sign must be posted in a way that allows any person entering the licensed premises to read it. Licensees must use the suspension notice sign provided by the Authority. The sign will state that the license has been suspended by order of the Authority. If there are multiple licenses at the location, the sign will specify which license privileges have been suspended.¶
 - (3) During the period of license suspension, the licensee is responsible for ensuring:¶
 - (a) Compliance with all applicable laws and rules.¶
 - (b) That the suspension notice sign is not removed, altered, or covered.¶
 - (4) A service center licensee or license representative may not allow sale, delivery to or from, or receipt of psilocybin products at the licensed premises, or provision of psilocybin services at licensed premises, during the period that the license is under suspension, except as otherwise permitted by the Authority in the order of suspension. During the period that the license is under suspension, a licensee may operate the licensed entity only in compliance with this rule.¶
 - (5) A manufacturer licensee or license representative may not allow sale, delivery to or from, or receipt of psilocybin products at the licensed premises, harvesting or drying of fungi, processing of psilocybin product during the period that the license is under suspension, except as otherwise permitted by the Authority in the order of suspension. During the period that a license is suspended, a licensee may operate the licensed entity only in compliance with this rule.¶
 - (6) A facilitator licensee may not provide psilocybin services during the period that the license is under suspension, except as otherwise permitted by the Authority in the order of suspension. ¶
 - (7) A laboratory licensee or license representative may not allow delivery to or from, or receipt of psilocybin products at the licensed premises or testing of psilocybin products during the period that the license is under suspension, except as otherwise permitted by the Authority in the order of suspension. During the period that the license is under suspension, a licensee may operate the licensed entity only in compliance with this rule.¶
 - (8) A permittee may not perform any of the activities described in OAR 333-333-4700 during the period that their worker permit is under suspension, except as otherwise permitted by the Authority in the order of suspension.
- Statutory/Other Authority: ORS 475A.235, ORS 475A.420
- Statutes/Other Implemented: ORS 475A.235, ORS 475A.420

ADOPT: 333-333-8000

RULE SUMMARY: 333-333-8000-Describes requirements for waste management

CHANGES TO RULE:

333-333-8000

Waste Management

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

(a) Store, manage and dispose of solid and liquid wastes generated during production and processing of psilocybin products in accordance with applicable state and local laws and regulations which may include but are not limited to:

(A) Solid waste requirements in ORS chapter 459 and OAR chapter 340, divisions 93 to 96.

(B) Hazardous waste requirements in ORS chapter 466 and OAR chapter 340, divisions 100 to 106.

(C) Wastewater requirements in ORS chapter 468B and OAR chapter 340, divisions 41 to 42, 44 to 45, 53, 55 and 73.

(b) Store psilocybin waste in a locked waste receptacle or limited access area in the possession of and under the control of the licensee.

(2) If a licensee generates the waste after a harvest or process lot has been recorded, or if the waste was previously designated as a finished psilocybin product, the licensee must document:

(a) A reason for the waste in the psilocybin tracking system.

(b) The exact time and method of destruction in the psilocybin tracking system.

(3) In addition to the requirements of sections (1) and (2) of this rule, waste items consisting of psilocybin products must be rendered unfit for consumption and disposed of on the licensed premises or transferred to another licensee for disposal. Psilocybin products may be rendered unusable by composting, mixing with inactive ingredients, or any other method which renders the product unfit for consumption but does not pose a safety risk for accidental consumption.

(4) All psilocybin waste must be disposed of in a manner that effectively prevents spontaneous growth of fruiting bodies or mycelium containing psilocybin.

(5) Material that has been designated as waste must be disposed of pursuant to this rule and may not be used in the production of psilocybin products.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

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 license 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 license representative of the receiving laboratory.¶

(c) Every manufacturer, service center and laboratory licensee must maintain a list of license 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 license 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 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 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 psilocybin tracking system manifest for each receiving location in order to maintain transaction confidentiality.¶

(H) Contact the Authority as soon as possible under the circumstances and in the form and manner prescribed by the Authority, 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 in advance 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) Psilocybin 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 psilocybin 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 psilocybin tracking system.¶

- (B) The destination location's license number and address as it appears in the psilocybin tracking system.¶
 - (C) The unique identification number, product name, and quantity of each psilocybin product.¶
 - (D) The actual date and estimated time of departure.¶
 - (E) Location 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 license representatives accompanying the transport.¶
 - (b) A physical, printed copy of the generated manifest must accompany every transport of psilocybin products. ¶
 - (4) Psilocybin tracking system requirements when receiving psilocybin products. Upon receipt of a delivery of psilocybin products, the receiving licensee must:¶
 - (a) Record each applicable unique identification number as accepted and received or rejected in the psilocybin 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 psilocybin 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 psilocybin tracking system.
- Statutory/Other Authority: ORS 475A.235, ORS 475A.400
- Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-8200

RULE SUMMARY: 333-333-8200-Describes general requirements for product tracking

CHANGES TO RULE:

333-333-8200

Product Tracking - General Requirements

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

(a) Use the psilocybin tracking system as an inventory and recording keeping system.

(b) Have a psilocybin tracking system account activated and functional within five business days of being licensed.

(c) Maintain an active psilocybin tracking system account while licensed.

(2) Each service center, manufacturer and laboratory licensee must have at least one licensee who is a psilocybin tracking system administrator. A licensee may authorize additional licensees or license representatives to obtain psilocybin tracking system administrator accounts.

(3) In order to obtain a psilocybin tracking system administrator account, a license holder must attend and successfully complete all required psilocybin tracking system training, except as provided in section (4) of this rule. The Authority may also require additional ongoing, continuing education for individual administrators to retain his or her psilocybin tracking system administrator account.

(4) A service center, manufacturer or laboratory licensee may designate license representatives as psilocybin tracking system users. A designated user must be trained by a psilocybin tracking system administrator in the proper use of the psilocybin tracking system. Notwithstanding section (3) of this rule, a licensee may designate a license representative to attend and successfully complete required psilocybin tracking system training so long as both the licensee and the designated representative obtain psilocybin tracking system administrator accounts.

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

(a) Maintain an accurate and complete list of all psilocybin tracking system administrators and psilocybin tracking system users for each licensed premises and must update the list when a new psilocybin tracking system user is trained.

(b) Train and authorize any new psilocybin tracking system users before those users are permitted to access the psilocybin tracking system or input, modify, or delete any information in the psilocybin tracking system.

(c) Cancel any psilocybin tracking system administrator or user from an associated psilocybin tracking system account if that individual is no longer a license representative.

(d) Correct any data that is entered into the psilocybin tracking system in error.

(6) Each service center, manufacturer and laboratory licensee is accountable for all actions license representatives take while logged into the psilocybin tracking system or while otherwise conducting inventory tracking activities.

(7) 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. If a licensee uses a separate software application that links to the psilocybin tracking system, it must get approval from the psilocybin tracking system vendor contracting with the Authority and the software application must:

(a) Accurately transfer all relevant psilocybin tracking system data to and from the psilocybin tracking system for the purposes of reconciliation with any secondary systems.

(b) Preserve original psilocybin tracking system data when it is transferred to and from a secondary application.

(8) If at any point a service center, manufacturer or laboratory licensee loses access to the psilocybin 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 psilocybin 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 psilocybin tracking system unless the Authority has provided written authorization to do so.

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

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

ADOPT: 333-333-8210

RULE SUMMARY: 333-333-8210-Describes requirements for reconciliation of inventory

CHANGES TO RULE:

333-333-8210

Product Tracking - Reconciliation of Inventory

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

(a) Use the psilocybin 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 psilocybin tracking system to reflect the prior day's activity.

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

(2) The requirements of subsection (1)(b) of this rule do not apply to psilocybin spores or mycelium that are in a preproduction process at a manufacturer's licensed premises.

(3) The requirements of subsection (1)(b) of this rule do not apply, 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.

(4) The requirements in subsection (1)(b) of this rule do not apply during the first fourteen calendar days of licensure for a service center, manufacturer or laboratory licensee so long as the licensee, has ordered unique identification tags and unique identification tags are in transit to the receiving party.

(5) The requirements in subsection (1)(b) of this rule do not apply 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.

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

(7) Information that is not required to be recorded and reconciled daily pursuant to section (4) of this rule must be recorded and reconciled within three calendar days of the service center, manufacturer or laboratory licensee's receipt of unique identification tags.

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

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

ADOPT: 333-333-8220

RULE SUMMARY: 333-333-8220-Describes requirements for use of unique identification numbers

CHANGES TO RULE:

333-333-8220

Product Tracking - Unique Identification Numbers

(1) A service center, manufacturer or laboratory license must:

(a) Use unique identification tags issued by an Authority-approved vendor that is authorized to provide unique identification tags for the psilocybin tracking system. Each licensee is responsible for the cost of all unique identification tags and any associated vendor fees.

(b) Have an adequate supply of unique identification tags at all times, except during the first 14 calendar days of licensure so long as unique identification tags have been ordered and are in transit to the licensed premises.

(c) Assign and affix a unique identification tag to each separated area containing a cultivation batch of mycelium or fruiting bodies as described in OAR 333-333-8230.

(d) After harvest, assign and affix a unique identification tag to all psilocybin products or receptacles containing psilocybin products.

(e) Assign and affix unique identification tags in a manner that:

(A) Establishes an accurate record of cultivation, harvest and drying of fungi, including documentation of harvest lots and batches as described in OAR 333-333-2020 and OAR 333-333-7090.

(B) Establishes an accurate record when one psilocybin product is converted to another product type.

(C) Uses a new unique identification tag each time a psilocybin product is added to a quantity of psilocybin products grouped together under a pre-existing unique identification tag.

(f) Place tags in a position that can be clearly read by an individual standing next to the item.

(g) Keep tags free from dirt and debris.

(2) To allow for a drying period, the requirements of subsection (1)(e) of this rule do not apply to harvested mycelium or fruiting bodies in the first 15 days after harvest.

(3) The requirements of section (1) of this rule do not apply to psilocybin spores or mycelium that are in a preproduction process at a manufacturer's licensed premises.

(4) A manufacturer licensee may not combine psilocybin products of different size, potency, or type under a single unique identification tag, except for:

(a) Mixed lots of homogenized fungi.

(b) Psilocybin extracts that will undergo further processing.

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

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

ADOPT: 333-333-8230

RULE SUMMARY: 333-333-8230-Describes requirements for cultivation batches

CHANGES TO RULE:

333-333-8230

Product Tracking - Cultivation Batches

(1) Within 72 hours of beginning a production process, a manufacturer must create a cultivation batch that will contain all fruiting bodies and mycelium produced by that production process. ¶

(2) A manufacturer must assign each cultivation batch a unique user-generated sequential batch name and record the batch name and location in the psilocybin tracking system ¶

(3) Batch names and unique identification tags must be physically affixed to the cultivation batch or the separated area where the cultivation batch is physically located as required by OAR 333-333-8220. ¶

(4) A manufacturer may have an unlimited number of cultivation batches at any one time.

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

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

ADOPT: 333-333-8240

RULE SUMMARY: 333-333-8240-Describes requirements for inventory audits

CHANGES TO RULE:

333-333-8240

Product Tracking - Inventory Audits

(1) The Authority may perform a physical audit of the inventory of any service center, manufacturer or laboratory licensee at the agency's discretion and with reasonable notice to the licensee. ¶1

(2) A variance between the physical audit and the inventory reflected in the psilocybin tracking system at the time of the audit, which cannot be attributed to normal moisture variation in psilocybin products, is a violation.

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

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

ADOPT: 333-333-8250

RULE SUMMARY: 333-333-8250-Describes requirements for tracking system users

CHANGES TO RULE:

333-333-8250

Product Tracking - User Requirements

(1) A service center, manufacturer or laboratory licensee and any designated psilocybin tracking system administrator or user shall enter data into the psilocybin tracking system that fully and transparently accounts for all inventory tracking activities.¶

(2) A service center, manufacturer or laboratory licensee is responsible for the accuracy of all information entered into the psilocybin tracking system.¶

(3) An individual entering data into the psilocybin tracking system may only use their own individual psilocybin tracking system account. ¶

(4) Each psilocybin tracking system administrator and psilocybin tracking system user must have a unique log-on and password, which may not be used by any other person.¶

(5) Every psilocybin tracking system user and administrator must hold a valid worker permit as required by ORS 475A.480.

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

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

ADOPT: 333-333-8260

RULE SUMMARY: 333-333-8260-Describes requirements for tracking system notifications

CHANGES TO RULE:

333-333-8260

Product Tracking - System Notifications

A service center, manufacturer or laboratory licensee must monitor all compliance notifications from the psilocybin tracking system and resolve the issues detailed in the compliance notification in a timely fashion. A licensee may not dismiss a compliance notification in the psilocybin tracking system until the licensee resolves the compliance issues detailed in the notification.

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

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