OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

# PERMANENT ADMINISTRATIVE ORDER

**FILED**
12/21/2023 3:19 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

## PH 58-2023
CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Oregon Psilocybin Services

EFFECTIVE DATE: 01/01/2024

AGENCY APPROVED DATE: 12/14/2023

CONTACT: Oregon Psilocybin Services
971-673-0322
publichealth.rules@odhsoha.oregon.gov

800 NE Oregon St.
Portland,OR 97232

Filed By:
Public Health Division
Rules Coordinator

RULES:
333-333-1010, 333-333-2010, 333-333-2020, 333-333-2030, 333-333-2050, 333-333-2060, 333-333-2200, 333-333-2300, 333-333-2400, 333-333-2410, 333-333-3010, 333-333-3020, 333-333-3030, 333-333-3035, 333-333-3060, 333-333-3070, 333-333-3080, 333-333-3090, 333-333-4000, 333-333-4010, 333-333-4020, 333-333-4060, 333-333-4070, 333-333-4120, 333-333-4130, 333-333-4200, 333-333-4210, 333-333-4250, 333-333-4300, 333-333-4400, 333-333-4450, 333-333-4480, 333-333-4510, 333-333-4520, 333-333-4550, 333-333-4620, 333-333-4640, 333-333-4650, 333-333-4660, 333-333-4810, 333-333-4820, 333-333-4900, 333-333-4910, 333-333-4920, 333-333-5000, 333-333-5040, 333-333-5050, 333-333-5070, 333-333-5080, 333-333-5100, 333-333-5120, 333-333-5140, 333-333-5150, 333-333-5170, 333-333-5200, 333-333-5240, 333-333-5250, 333-333-5260, 333-333-6000, 333-333-6030, 333-333-6040, 333-333-7020, 333-333-7030, 333-333-7040, 333-333-7060, 333-333-7070, 333-333-7080, 333-333-7090, 333-333-7120, 333-333-7150, 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

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-1010-Amends existing definitions for clarity and includes new definitions required to implement SB 303.

CHANGES TO RULE:

333-333-1010
Definitions
For purposes of chapter 333, division 333, in addition to the definitions in ORS 475A.220, the following definitions apply:¶
(1)(a) "Adulterant" means ~~c~~:¶
(A) Chemicals, drugs, plants or substances that alter the potency, intoxicating effect, duration of effect, toxicity or potential for excessive use when added to psilocybin products. ~~Ad~~¶
(B) Any additives that are intended to manipulate~~rant does not include~~ the ratio of any analyte or to manipulate the ratio of compound relative to another analyte or compound present in the fungi used in extraction or

processing.¶
(b) Adulterant does not mean naturally occurring substances contained in food items such as, but not limited to chocolate.¶
(2) "Adverse ~~behavioral~~ reaction" means ~~client behavior that a facilitator reasonably believes may endanger the safety of the client, facilitator, or others.~~an adverse behavioral or medical reaction that occurred during an administration session and does not require transport to a hospital. ¶
(3) "Adverse ~~medic~~behavioral reaction" means a client's ~~physiological reaction~~behavioral reaction to consuming psilocybin products that required contacting emergency services or receiving care from a medical care provider that occurr~~inged~~ during an administration session ~~that a facilitator reasonably believes may lead to medical harm. For example, a cardiac event o~~. ¶
(4) "Adverse medical reaction" means a client's medical reaction to consuming psilocybin products that required contacting emergency services or receiving care from a medical care provider ~~oth~~er ~~health emergency.~~at occurred during an administration session. ¶
(~~4~~5) "Advertising" means publicizing the trade name of a licensee together with words or symbols referring to psilocybin or publicizing the brand name of a psilocybin product.¶
(~~5~~6) "Aggregate ~~data" means summary data that has been compiled from individual-level data,~~" for the purpose of reporting 303 service center data and 303 client data, means to combine and categorize quantitative data in a manner that prevents a client or an individual from whom the data was collected, from being identified, taking into consideration how the data could be used in combination with other data sources. ¶
(~~6~~7) "Applicant" means an individual who applies for a facilitator license and an individual or legal entity who:¶
(a) Holds or controls an interest of more than 20 percent in the entity proposed to be licensed;¶
(b) Is entitled to receive 20 percent or more of revenue, profits or proceeds from the entity proposed to be licensed; or¶
(c) Is entitled to exercise control over the entity proposed to be licensed.¶
(~~7~~8) "Attractive to minors" means:¶
(a) Cartoons;¶
(b) A design, brand or name that resembles a non-psilocybin consumer product of the type that is typically marketed to minors;¶
(c) Symbols or celebrities that are commonly used to market products to minors;¶
(d) Images of minors; or¶
(e) Words that refer to products that are commonly associated with minors or marketed by minors.¶
(~~8~~9) "Authority" means the Oregon Health Authority.¶
(~~9~~10) "Authorized Authority representative" means an employee of the Authority who is authorized to conduct inspections or investigations and otherwise enforce ORS chapter 475A and any rules adopted thereunder.¶
(1~~0~~1) "Batch" means a quantity of whole fungi from a harvest lot, or a quantity of psilocybin product from a process lot.¶
(1~~1~~2) "Billboard" means a large outdoor advertising structure.¶
(1~~2~~3) "Capsule" means a small soluble pill, tablet or container that contains ~~liquid or powdered psilocybin product~~psilocybin extract or homogenized fungi and is intended for human consumption.¶
(1~~3~~4) "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.¶
(1~~4~~5) "Chemical synthesis" means ~~the production of~~a method of producing psilocybin products using precursor ingredients rather than cultivation of fruiting bodies and mycelium, or a method of producing psilocybin products that results in psilocybin products that contain analytes or compounds that were not present in the source fruiting bodies, mycelium and other ingredients.¶
(1~~5~~6) "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.¶
(1~~6~~7) "Client information form" means the form required by ORS 475A.350.¶
(1~~7~~8) "Client packaging" means packaging containing psilocybin products intended to be sold to clients.¶
(1~~8~~9) "Client records" means information held or known by a service center or facilitator that may be used to identify a client or prospective client, including any communication made by a client or prospective client and any information related to providing psilocybin services or selling psilocybin products to a client.¶

(20) "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 (jm).¶
(219) "Control over the entity" includes but is not limited to the authority to bind the entity to contracts, obligations or debt and does not include a licensee representative acting under the direction of a licensee.¶
(202) "Cultivation batch" means a quantity of unharvested fruiting body or mycelium that is grown together under the same conditions., that may contain fungi that originates from diverse spores or mycelial tissue of psilocybe cubensis. ¶
(213) "Cultural equity" means values, policies, and practices that ensure all people, especially those who have been historically marginalized based on race, ethnicity, religion, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances are considered in the development of social pathways to health equity.¶
(224) "Curriculum" means the topics, subjects, and activities that make up courses taught by a training program.¶
(235) "De-identified data" means aggregate data from which the Authority or licensee has deleted, redacted, or blocked identifiers to ensure that the remaining information cannot reasonably be usdata that cannot be reasonably used to infer information about, or otherwise be linked to, an identify an individual client. ¶
(24) "Edible psilocybin product" means psilocybin extract or homogenized fungi that has been incorporatied or identifiable client, or to a device that identifies, is linked into a food item or potable beverage.or is reasonably linkable to a client. ¶
(256) "Direct Oowner" means an individual, legal entity or partnership that holds an ownership interest in a business proposed to be licensed directly rather than holding that interest through ownership of or affiliation with another legal entity or partnership.¶
(26¶
(27) "Disciplinary actions," for the purpose of Oregon Laws 2023, chapter 150, means any final order issued under ORS chapter 183 finding a licensee violated ORS chapter 475A or these rules. ¶
(28) "Edible psilocybin product" means psilocybin extract or homogenized fungi that has been incorporated into a food product or potable beverage.¶
(29) "Elementary school":¶
(a) Means a learning institution containing any combination of grades kindergarten through 8.¶
(b) Does not mean a learning institution that includes only pre-kindergarten, only kindergarten, or only a combination of pre-kindergarten and kindergarten.¶
(2730) "Extraction" means:¶
(a) The process of separating psilocybin from fungi by using a solvent; and¶
(b) Manufacturing psilocybin extracts.¶
(2831) "Facilitation" means the provision of services to a client by a licensed facilitator during a preparation, administration, or integration session.¶
(329) "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.¶
(303) "Fruiting bodies" means the spore producing organs of the fungi Psilocybe cubensis.¶
(314) "Fungi" means the fruiting bodies or mycelium of the fungi Psilocybe cubensis.¶
(325) "Harvest" means the act of removing mycelium or fruiting bodies from a production environment for drying or processing.¶
(336) "Harvest lot" means a specifically identified quantity of fungi that is cultivated and dried under the same conditions and harvested within a 24-hourseven calendar-day period at the same location within the licensed premises, that may be partially harvested, and may use the substrate material for multiple harvests. ¶
(347) "Health equity" means the opportunity for all people to reach their full health potential and well-being without being disadvantaged by their race, ethnicity, religion, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities or other socially determined circumstances.¶
(358) "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 productsfungi may be packaged in capsules and may contain inactive ingredients such as binders, dilutants and carrying agents.¶
(369) "Intervention" means taking proactive steps to respond to the client's behavior, experience, or condition during an administration session.¶

(~~37~~40) "Intoxicant" means any substance that has intoxicating effects, and includes alcohol, prescription drugs, non-prescription drugs and any other controlled substances. Intoxicant does not include caffeine or nicotine.¶
(~~38~~41) "Laboratory" means a laboratory licensed under ORS 475A.594.¶
(~~39~~42) "Lead educator" means a person affiliated with a training program who is responsible for tracking the progress of students throughout the program.¶
(~~40~~3) "Licensee representative":¶
(a) Means an owner, director, officer, manager, employee, agent or other representative of a manufacturer, service center, or laboratory licensee.¶
(b) Does not mean a facilitator who provides services at a service center unless that facilitator is also an owner, director, officer, manager, employee, agent or other representative of the service center.¶
(c) Includes an independent contractor of a manufacturer, service center, or laboratory licensee who acts in a representative capacity.¶
(~~41~~4) "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.¶
(~~42~~5) "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. ¶
(~~43~~6) "Limited access area" means any area of a licensed premises where psilocybin products or psilocybin waste are stored or produced.¶
(~~44~~7) "Manufacturer" means a manufacturer licensed under ORS 475A.290.¶
(~~45~~8) "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.¶
(~~46~~9) "Marijuana" has the meaning given that term in ORS 475C.009.¶
(~~47~~50) "Mycelium" means the fungal threads or hyphae of Psilocybe cubensis.¶
(~~48~~51) "Nondirective facilitation" means a client-~~direct~~centered approach to facilitation in which the client makes decisions related to their participation in psilocybin services and the facilitator maintains a consistent disposition with a client, while avoiding giving the client direct advice or ~~directly~~offering an interpret~~ing~~ation of a client's statements, behaviors or needs unless appropriate for health and safety reasons. ~~¶~~
~~(49~~Nondirective facilitation does not prohibit a facilitator from offering options, resources, referrals or providing health and safety support to clients within their scope of practice.¶
(52) "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.¶
(5~~0~~3) "Operational name" means an individual, legal entity or business name listed on an application and license certificate of a service center, manufacturer or laboratory license that the licensee(s) will use for purposes of advertising and doing business with the public. ¶
(54) "Oregon Psilocybin Services Act" means ORS 475A.210 to ORS 475A.722.¶
(5~~1~~5) "Pesticide" means any substance or mixture of substances included in ORS 634.006(8).¶
(5~~2~~6) "Permittee" means a person who holds a permit issued under ORS 475A.480.¶
(5~~3~~7) "Practicum site" means a designated service center that provides practicum training.¶
(5~~4~~8) "Practicum site supervisor" means an onsite practicum supervisor of assigned trainees, affiliated with a practicum site.¶
(5~~5~~9) "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.¶
(~~56~~60) "Process lot" means homogenized fungi, psylocibin extract or edible psilocybin product of the same type that was processed at the same time using the same processing method, ingredients, and standard operating procedures.¶
(~~57~~61) "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.¶

(~~58~~62) "Psilocybin" has the meaning described in ORS 475A.220.¶
(~~59~~63) "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.¶
(6~~0~~4) "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.¶
(6~~1~~5) "P~~silocybin T~~roduct tracking ~~S~~system" or "PTS" means the system for tracking psilocybin products required by ORS 475A.400.¶
(6~~2~~6) "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.¶
(67) "Psilocybin waste" means:¶
(a) Waste material that is a byproduct of manufacturing psilocybin products that contains a detectable amount of psilocybin. ¶
(b) Partially consumed psilocybin products, excluding client packaging.¶
(c) Psilocybin products that a manufacturer, service center or laboratory disposes.¶
(d) Any psilocybin product that is required to be designated as waste by these rules. ¶
(6~~3~~8) "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.¶
(64~~9~~) "Residence" means real property inhabited by an owner, renter or tenant, including but not limited to manufactured homes and vehicles used as domiciles.~~¶~~
~~(65~~, and attached garages or other structures that may be directly accessed from any ingress or egress of a residence. ¶
(70) "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.¶
(~~66~~71) "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.¶
(~~67~~2) "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.¶
(~~68~~73) "Secondary school" means a learning institution containing any combination of grades 9 through 12 and includes junior high schools that have 9th grade.¶
(~~69~~74) "Service center" means a premises licensed under ORS 475A.305.¶
(7~~0~~5) "Severe adverse reaction" means an adverse behavioral or medical reaction that requires a client to be transported to a hospital. ¶
(76) "Stabilized compost" means any organic material that has undergone the process to further reduce pathogens and has reached a stage of reduced biological activity as indicated by a lower temperature and a rate of respiration below that of active compost. ¶
(77) "Sublet" means to sublease or otherwise allow a person who is not a licensee representative to exercise privileges that require a manufacturer, service center, facilitator or laboratory license on the licensed premises. Sublet does not include a facilitator providing psilocybin services at a service center.¶
(7~~1~~8) "Synchronous learning" means that students learn from their instructor at the same time as their fellow students.¶
(7~~2~~9) "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.¶
(~~73~~80) "These rules" means O~~regon Administrative Rules (OAR)~~AR 333-333-1010 through 333-333-82~~60~~¶
~~(74~~50.¶
(81) "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.¶
(~~75~~82) "Training, Licensing and Compliance System" means the online training, license and compliance portal maintained by the Authority to receive applications, communicate with applicants, licensees, permittees and training programs, and track compliance actions.¶
(~~76~~83) "Training program" means a program that has been approved to offer training to psilocybin facilitators as

described in ORS 475A.380.¶
(~~77~~84) "Training program applicant" means a program that has applied to offer training to psilocybin facilitators as described in ORS 475A.380.¶
(~~78~~5) "Unique identification number" means a unique number generated by the ~~Authority's designated vendor for the psilocybin~~product tracking system for the purpose of tracking psilocybin products within the p~~silocybin tracking system.¶~~
~~(79) "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~~roduct tracking system.~~¶~~
(8~~0~~6) "Whole fungi" means dried fruiting bodies of Psilocybe cubensis, or portions thereof, that have not been homogenized.¶
(8~~1~~7) "Wood chips" mean substrates consisting primarily of wood products that have not been composted.~~¶~~
(8~~2~~8) "Worker permit" means a permit required by ORS 475A.480.¶
(89) "303 client data" means information that OAR 333-333-4900 requires service centers to collect from clients, store and maintain. ¶
(90) "303 service center data" means information that OAR 333-333-4910(3) and (4) require service centers to compile, aggregate, compute and report to the Authority.
Statutory/Other Authority: ORS 475A.235, OL 2023, ch. 150
Statutes/Other Implemented: ORS 475A.235, OL 2023, ch. 150

AMEND: 333-333-2010

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-2010¬-Amends requirements for manufacturers who produce their own compost.

CHANGES TO RULE:

333-333-2010
Psilocybin Production
(1) A manufacturer is prohibited from:¶
(~~1~~a) Using manure in cultivation or production of psilocybin products. ¶
(~~2~~b) Using wood chips as a growing medium in cultivation or production of psilocybin products.¶
(~~3~~c) Producing psilocybin by using genetically modified organisms such as bacteria.~~¶~~
~~(4) Producing psilocybin by chemical synthesis~~¶
(d) Producing psilocybin by chemical synthesis.¶
(2) Manufacturers who produce their own compost in cultivation must comply with the following requirements:¶
(a) Compost shall not exceed the maximum acceptable pathogen concentrations described in subsection (2)(b) of this rule. Compost that contains any pathogens in amounts that exceed these pathogen reduction requirements shall be designated for additional processing, disposal, or other use as approved by local or state agencies having appropriate jurisdiction.¶
(b) Manufacturers that produce their own compost shall ensure that:¶
(A) The density of fecal coliform in compost, that is or has at one time been active compost, shall be less than 1,000 Most Probable Number per gram of total solids (dry weight basis), and the density of Salmonella sp. bacteria in compost shall be less than three Most Probable Number per four grams of total solids (dry weight basis).¶
(B) If using a vessel composting process, active compost is maintained at a temperature of 55 degrees Celsius or higher for a pathogen reduction period of three days.¶
(C) If using a windrow composting process, active compost is maintained under aerobic conditions at a temperature of 55 degrees Celsius higher for a pathogen reduction period of 15 days or longer. During the period when the compost is maintained at 55 degrees Celsius or higher, there shall be a minimum of five turnings of the windrow.¶
(D) If using an aerated static pile composting process, all active compost is covered with 6 to 12 inches thickness of insulating material, and the active compost shall be maintained at a temperature of 55 degrees Celsius or higher for a pathogen reduction period of three days.¶
(c) Manufacturers that utilize a windrow composting process or an aerated static pile composting process shall monitor as follows to ensure that the standards in subsection (2)(b) of this rule are met:¶
(A) Each day during the pathogen reduction period, at least one temperature reading shall be taken per every 150 feet of windrow, or fraction thereof, or for every 200 cubic yards of active compost, or fraction thereof.¶
(B) Temperature measurements for pathogen reduction are measured as follows:¶
(i) Windrow composting processes and agitated bays shall be monitored 12 to 24 inches below the pile surface.¶
(ii) Aerated static pile composting processes shall be monitored 12 to 18 inches from the point where the insulation cover meets the active compost.¶
(d) Alternative methods of compliance to meet the pathogen reduction requirements of this section may be approved by the Oregon Health Authority (Authority) if the Authority determines that the alternative method will provide equivalent pathogen reduction.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.290

AMEND: 333-333-2020

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-2020-Amends requirements for manufacturer facilities and use of product tracking system

CHANGES TO RULE:

333-333-2020
General Manufacturer Requirements
(1) A manufacturer must:¶
(a) Use equipment, counters and surfaces for post-harvest processing that are food-grade and do not react adversely with any solvent being used.¶
(b) Construct and maintain floors, walls, ceilings, counters and surface areas in a manner that reduces the potential development of microbials, molds and unintended fungi ~~and that can be easily cleaned~~.¶
(c) Maintain the licensed premise in a manner that is free from conditions which may result in contamination of psilocybin products and that is suitable for safe and sanitary operations.¶
(d) Store all psilocybin products in a locked area when not in use, including psilocybin products that require refrigeration.¶
(e) Ass~~ign~~ociate every process lot and harvest lot with a unique identification number and enter this information into the ~~Psilocybin T~~product tracking ~~S~~system.¶
(2) A manufacturer may not produce, transfer or sell a psilocybin product that appeals to minors, including but not limited to:¶
(a) Products that are modeled after non-psilocybin products primarily consumed by and marketed to children; or¶
(b) Products in the shape of an animal, vehicle, person or character.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.290

AMEND: 333-333-2030

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-2030-Amends rule to correct drafting error.

CHANGES TO RULE:

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

AMEND: 333-333-2050

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-2050-Amends adulterant rule to clarify prohibitions on adulterated psilocybin products.

CHANGES TO RULE:

333-333-2050
Adulterants
(1) A licensee may not add to psilocybin products, substrates, growing medium or client packaging any chemical, drug, plant, or substance that has the effect of altering potency, intoxicating effect, duration of effect, toxicity or potential for excessive use, including but not limited to monoamine oxidase inhibitors (MAOI's), beverage alcohol or cannabis. ~~A psilocybin product that has added chemicals, drugs, plants or substances that alter the potency, intoxicating effect, duration of effe~~¶
(2) A licensee may not produce, store or transfer adulterated psilocybin products. ¶
(3) A psilocybin product, ~~toxicity or addictiveness is considered adulterated.¶~~
~~(2) A licensee may not produce, store or transfer adulterated psilocybin products. In addition to the provisions of~~hat contains an adulterant is considered adulterated¶
(4) In addition to section (~~1~~3) of this rule, a psilocybin product may be considered adulterated if:¶
(a) It bears or contains any poisonous or deleterious substance in a quantity rendering the psilocybin product a risk to human health;¶
(b) It bears or contains any added poisonous or deleterious substance exceeding a safe tolerance if such tolerance has been established;¶
(c) It consists in whole or in part of any unsanitary, putrid, or decomposed substance, or is otherwise unfit for human consumption;¶
(d) It is processed, prepared, packaged or held under improper time-temperature conditions or under conditions increasing the probability of contamination with excessive microorganisms or physical contaminants;¶
(e) It is processed, prepared, packaged, or held under unsanitary conditions increasing the probability of contamination or cross-contamination;¶
(f) It is held or packaged in containers composed, in whole or in part of any poisonous or deleterious substance rendering the contents potentially injurious to health;¶
(g) Any substance has been substituted wholly or in part;¶
(h) Damage or inferiority has been concealed in any manner; or¶
(i) Any substance has been added, mixed or packaged to make it appear ~~a~~ better or of greater value than it is.¶
(5) Except for extraction allowed under these rules, a licensee may not utilize any manufacturing process that alters potency, intoxicating effect, duration of effect, toxicity or potential for excessive use.¶
(~~3~~6) Psilocybin products that are intended for ~~research and~~product development and will not be made available for consumption must be labeled in bold, capital letters, no smaller than 12-point font, "NOT FOR CONSUMPTION" and may be stored in states that are unfit for human consumption.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-2060

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-2060¬-Amends extraction rule to clarify allowable methods of psilocybin extraction.

CHANGES TO RULE:

333-333-2060
Psilocybin Extract Manufacturing Requirements
(1) A manufacturer with a psilocybin extraction endorsement may use only water, vegetable glycerin, acetic acid, ethanol and methanol as solvents in extraction. All other solvents are prohibited.¶
(2) A manufacturer with a psilocybin extraction endorsement may not use ~~denatured alcohol.¶~~
~~(3~~extraction processes intended to manipulate the ratio of any analyte or to manipulate the ratio of compound relative to another analyte or compound present in the fungi used in extraction.¶
(3) A manufacturer with a psilocybin extraction endorsement may not remove psilocybin analyte from psilocybin extracts. This section does not prevent diluting extracts with inactive ingredients.¶
(4) A manufacturer with a psilocybin extraction endorsement may not use denatured alcohol.¶
(5) A manufacturer with a psilocybin extraction endorsement may not apply pressure or heat over 140 degrees Fahrenheit when using the solvents ethanol or methanol to manufactur~~inge~~ psilocybin extracts.¶
(4~~6~~) If using methanol or ethanol, a manufacturer must process psilocybin extracts in a room with equipment, including all electrical installations that meet the requirements of the Oregon Structural Specialty Code, related Oregon Specialty Codes and the Oregon Fire Code.¶
(5~~7~~) ~~If a manufacturer with a psilocybin extraction endorsement produces a psilocybin extract that will be used in an edible psilocybin product, t~~The manufacturer's licensed premises must be licensed by the Oregon Department of Agriculture as a food establishment and must comply with applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-2200

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-2200-Amends rule to correct drafting error.

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-~~307~~7040.¶
(2) A manufacturer must ensure that potency tests required by OAR 333-333-~~307~~7040 are completed within 180 days of recording a harvest lot or process lot in the p~~silocybin~~roduct 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 Oregon Health Authority.¶
(6) Psilocybin products that have been designated as psilocybin 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

AMEND: 333-333-2300

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-2300-Amends client packaging rule to clarify that packaging may be re-used.

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.¶
(5) Client packaging may be reused as long as it is effectively sanitized and complies with the requirements of these rules.
Statutory/Other Authority: ORS 475A.235, ORS 475A.634
Statutes/Other Implemented: ORS 475A.634

AMEND: 333-333-2400

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-2400-Amends labeling rule to align with statutory requirements.

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. ~~C~~All client packaging must display:¶
(a) The manufacturer's business or trade name and license number.¶
(b) One of the following product type names: whole fungi, homogenized fungi, psilocybin extract, or edible psilocybin product.¶
(c) The net quantity of contents using the metric system of measurement and expressed in terms of fluid measure if the item is liquid, or in terms of weight if the item is solid, semi-solid, or viscous.¶
(d) The quantity of psilocybin analyte contained in the product, expressed in milligrams, and calculated using laboratory test results required by OAR 333-333-7040.¶
(e) 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.¶
(g) A statement that "Activation times for psilocybin products are variable and cannot be accurately predicted."¶
(h) A statement that "The risks, benefits, and drug interactions of psilocybin are not fully understood, and individual results may vary."¶
(4) Client packaging for edible psilocybin products must be consistent with applicable state food labeling requirements for the same type of food product or potable liquid when the food product or potable liquid does not contain psilocybin.
Statutory/Other Authority: ORS 475A.235, ORS 475A.626
Statutes/Other Implemented: ORS 475A.626

AMEND: 333-333-2410

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-2410-Amends product information document rule to clarify requirements for providing document to 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 active and inactive ingredients in descending order of predominance by weight or volume.¶
(k) List of potential major food allergens by:¶
(A) Listing the name of the food source of any major food allergen at the end of or immediately adjacent to the ingredient list; or¶
(B) Placing the term for the appropriate major food allergen in parenthesis within the ingredient list after the common or usual name of the ingredient derived from that major food allergen.¶
(l) ~~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~~m) If the psilocybin product is perishable, a statement that the product must be refrigerated or kept frozen.¶
(2) A facilitator must make reasonable efforts to 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. If a client does not receive a product information document during their preparation session, a facilitator must provide the client a product information document for psilocybin products that may be consumed during an administration session and provide the client an opportunity to discuss the document at another time prior to beginning their administration session. ¶
(3) A service center must make reasonable efforts to translate the product information document to languages other than English and otherwise provide the product information document in an accessible format upon the client's request.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-3010

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-3010¬¬-Amends curriculum approval rule to clarify requirements for training programs to be licensed by HECC.

CHANGES TO RULE:

333-333-3010
Psilocybin Training Program Curriculum Approval Process
(1) A training program applicant must submit the following to the ~~Authority~~Oregon Health Authority (Authority) to be considered for curriculum approval to train psilocybin facilitators:¶
(a) A completed application package, including a description of the proposed curriculum that shows the applicant meets the requirements of OAR 333-333-3050, OAR 333-333-3060, OAR 333-333-3070 and OAR 333-333-3090; and¶
(b) A US$500 non-refundable application evaluation fee paid in the form and manner specified by the Authority. ¶
(2) ~~T~~Following receipt of the items described in section (1) of this rule, the Authority will notify a training program applicant ~~if their~~whether its application is ~~incomplete. T~~complete or incomplete. ¶
(a) If an application is incomplete, the training program applicant will have 90 days from the date the notice is issued to submit a complete application. If the training program applicant does not complete their application within 90 days, the Authority will refuse to process the application. If the Authority refuses to process an application, the applicant may submit a new application, including a non-refundable application evaluation fee, for the program to be considered for approval.~~¶~~
(~~3~~b) ~~T~~If an application is complete, the Authority will evaluate the training program application~~s~~ to determine if the c~~ours~~ericulum meets the standards in OAR 333-333-3005 to OAR 333-333-3090. ¶
(4~~3~~) The Authority will notify ~~the training program applicants in writing if the application is approved or denied. ¶~~
~~(5~~a training program applicant in writing if its complete application for curriculum approval is approved or denied. If the application is approved, the approval is effective on the date of notice. The Authority may not retroactively approve or pre-approve training program applications.¶
(4) For training programs that received curriculum approval prior to December 31, 2023, a training program must no later than June 1, 2024, provide documentation that:¶
(a) The program has applied for any approvals required from the Higher Education Coordinating Commission in accordance with applicable law governing the type of school or institution and paid any required application fees; or ¶
(b) The program has requested a determination from the Higher Education Coordinating Commission that approval is not required in accordance with applicable law governing the type of school or institution.¶
(5) For training programs who receive curriculum approval after December 31, 2023, a training program must within 180 calendar days of receiving curriculum approval, provide documentation to the Authority that:¶
(a) The program has applied for any approvals required from the Higher Education Coordinating Commission in accordance with applicable law governing the type of school or institution and paid any required application fees; or ¶
(b) The program has requested a determination from the Higher Education Coordinating Commission that approval is not required in accordance with applicable law governing the type of school or institution.¶
(6) The Authority may deny a training program application for curriculum approval or revoke or suspend approval of a previously approved training program curriculum if:¶
(a) The training program or training program application does not meet the requirements of OAR 333-333-3005 to OAR 333-333-3090; or¶
(b) The program instructors, staff or representatives have made false or misleading statements to the Authority, students or the public.~~¶~~
~~(6~~¶
(c) For training programs that received curriculum approval prior to December 31, 2023, a training program fails to comply with requirements of section (4) this rule.¶
(d) For training programs that received curriculum approval after December 31, 2023, a training program fails to comply with requirements of section (5) this rule.¶
(e) The Higher Education Coordinating Commission denies a training program's application for any approvals required in accordance with applicable law governing the type of school or institution.¶
(f) A training program fails to maintain its approval status with Higher Education Coordinating Commission in accordance with applicable law governing the type of school or institution.¶
(7) If the Authority denies an application or suspends or revokes a curriculum approval, the Authority will provide

notice of the denial, suspension or revocation and the training program has a right to a hearing under ORS chapter 183.¶
(~~7~~8) Training program curriculum approval has a term of five years from the date of initial approval. If the requirements of OAR 333-333-3005 to OAR 333-333-3090 change substantively during the term, the Authority may require training programs to resubmit an application for approval.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3020

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-3020-Amends training program application rule to clarify requirements for mailing address.

CHANGES TO RULE:

333-333-3020
Psilocybin Training Program Application Requirements
For curriculum to be approved, training program applicants must:¶
(1) Demonstrate that its proposed course modules contain the content required by OAR 333-333-3060;-¶
(2) Demonstrate that its proposed hours of instruction meet the requirements of OAR 333-333-3050;¶
(3) Demonstrate that its proposed practicum meets the requirements of OAR 333-333-3070;¶
(4) Identify all instructors, including at least two lead educators and list the instructors' qualifications to teach curriculum modules identified in these rules;-¶
(5) Identify a program director who is responsible for tracking student progress and has authority to confer student enrollment and program completion; and¶
(6) ~~Be located~~Provide an address to receive mail from the Oregon Health Authority at an established physical location within the United States of America or U.S Territories or the freely associated states Republic of Mar~~tia~~shall Islands, Palau, and the Federated States of Micronesia.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3030

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-3030-Amends program performance rule to clarify requirements for making changes to approved curriculum.

CHANGES TO RULE:

333-333-3030
Psilocybin Training Instructor Qualifications and Program Performance
(1) In order for curriculum to be approved, a training program must demonstrate that each instructor and person who trains instructors at a training program has sufficient experience, knowledge, skills and ability to competently train students in their assigned subject matter.¶
(2) Sufficient experience, knowledge, skills and ability can be demonstrated via education, certifications, professional experience, personal narratives and references.¶
(3) Training programs shall treat personal narratives and references as confidential unless an instructor has consented to their publication.¶
(4) Each instructor at a training program must:¶
(a) Understand the objectives of the training program and be able to communicate effectively with students; and¶
(b) Demonstrate skill in instruction and student supervision.¶
(5) Training programs must notify the ~~Authority~~Oregon Health Authority (Authority) of any material changes to the curriculum listed in their application that affect the requirements of OAR 333-333-3005 to OAR 333-333-3090 in a form and manner prescribed by the Authority. A training program must use its previously approved curriculum until its request has been accepted. ¶
(6) Training programs must notify the Authority of any changes of instructors, lead educators ~~and~~, program director, registered agent or responsible party identified in the application in a form and manner prescribed by the Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3035

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-3035-Amends curriculum reapproval rule to clarify requirements for making changes to approved curriculum.

CHANGES TO RULE:

333-333-3035
Psilocybin Training Curriculum Reapproval
(1) A training program that wishes for ~~their~~its curriculum to be reapproved upon expiration of ~~their~~its initial approval term must submit a completed reapproval application, including proof that the program has received and continues to hold any approvals required from the Higher Education Coordinating Commission in accordance with applicable law governing the type of school or institution and a non-refundable US$500 reapproval fee.¶
(2) The ~~Authority~~Oregon Health Authority (Authority) must receive the reapproval application and fee at least 30 days prior to the date that the training program's approval is set to expire.¶
(3) If a training program files a reapproval application and fee at least 30 days prior to the date that the training program's approval is set to expire, the training program's curriculum approval remains valid while the Authority considers their reapproval application. A training program must use its previously approved curriculum until the reapproval application is approved. ¶
(4) If a training program does not file a reapproval application and fee at least 30 days prior to the date that the training program's approval is set to expire, the training program's curriculum approval will expire, and the training program must submit a new application.¶
(5) If the Authority approves reapproval, the reapproval is valid for five years.¶
(6) The Authority may deny the application for reapproval if:¶
(a) The training program has not complied with these rules; or¶
(b) The training program instructors, staff or representatives have made false or misleading statements to the Authority, students or the public.¶
(7) If the Authority denies reapproval, the Authority will provide notice of the denial and the program has a right to a hearing under ORS chapter 183.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3060

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-3060-Amends rule to correct drafting error.

CHANGES TO RULE:

333-333-3060
Psilocybin Training Curriculum Modules
(1) "Historical, Traditional, and Contemporary Practices and Applications" module shall include:¶
(a) Current and historical use of plant and fungal medicines in indigenous and western cultures;¶
(b) The Controlled Substances Act and its effect on psilocybin research and drug policy; and¶
(c) Overview of historical and recent academic research.¶
(2) "Cultural Equity in relation to Psilocybin Services" module shall include the following subjects and their application during preparation, administration, and integration sessions:¶
(a) Cultural equity, its relationship to health equity and social determinants of health;¶
(b) Racial justice, including the impact of race and privilege on health outcomes and the impact of systemic racism on individuals and communities;¶
(c) The impact of drug policy on individuals and communities;¶
(d) History of systemic inequity, including systemic inequity in delivery of healthcare, mental health and behavioral health services;¶
(e) Intergenerational trauma; and¶
(f) Responsible Referral and Support¶
(3) "Safety, Ethics, Law and Responsibilities" module shall include the following subjects and their application during preparation, administration, and integration sessions:¶
(a) Awareness of facilitator's personal bias, including examination of facilitator's motives;¶
(b) Training on the Oregon Psilocybin Services Act and related laws, regulations, and professional standards for facilitators; including facilitator scope of practice and expectation of referral when scope of practice is exceeded.¶
(c) Training in ethical issues related to psilocybin facilitation, including:¶
(A) ~~Oregon's Facilitator Code of Ethics;¶~~
~~(B)~~ Ethical considerations relating to equity, privilege, bias and power;¶
(~~C~~B) Awareness of increased vulnerability associated with altered states of consciousness;¶
(~~D~~C) Appropriate use of touch and client consent to physical contact;¶
(~~E~~D) Appropriate emotional and sexual boundaries between facilitators and clients both during provision of psilocybin services and at other times, potential harm to clients and consequences for facilitators of breaching those boundaries;¶
(~~F~~E) Historical and contemporary abuse of power associated with psychedelics, including sexual, emotional and physical abuse, and implications for facilitators;¶
(~~G~~F) Financial conflicts of interest and duties to clients; and¶
(~~H~~G) Reasonable expectations regarding client outcomes.¶
(d) Accurate record keeping and client confidentiality.¶
(e) Awareness of new research related to safety and ethics of providing psilocybin services and resources for professional development following program completion.¶
(f) Appropriate measures to mitigate risks associated with psilocybin services, including harm reduction, de-escalation, and conflict resolution.¶
(4) "Psilocybin Pharmacology, Neuroscience, and Clinical Research" module shall include:¶
(a) Pharmacodynamics and pharmacokinetics of psilocybin;¶
(b) Drug and supplement interaction;¶
(c) The metabolism of psilocybin and psilocybin products including concentration of psilocybin and psilocin in available psilocybin products;¶
(d) The primary effects and mechanisms of action of psilocybin on the brain, including connectivity in the brain and activation of serotonin receptors;¶
(e) Key areas of psilocybin research; and¶
(f) Models of substance use, addiction, and recovery.¶
(5) "Core Facilitation Skills" module shall include the following subjects and their application during preparation, administration, and integration sessions:¶
(a) Client communication, empathy and rapport, including a nondirective facilitation approach, cultural attunement and a nonjudgmental disposition;¶

(b) Response to psychological distress and creating a safe space for difficult emotional experiences;¶
(c) Physical reactions and side effects of psilocybin;¶
(d) Trauma informed care, including physiology of trauma, vicarious trauma, empathic stress and compassion fatigue;¶
(e) Active monitoring of client-facilitator boundaries specifically boundaries related to consent and touch;¶
(f) Identification and facilitation of a variety of subjective psilocybin experiences, including experiences relating to physiological sensations, cognitive, emotional and mystical states, and traumatic memories;¶
(g) Appropriate modes of intervention, understanding when intervention is necessary, and when a client may need a higher level of care;-¶
(h) Recognizing and addressing adverse behavioral reactions and adverse medical reactions; and¶
(i) Identification of the unique health, psychological and socio-cultural presented by persons with terminal illness; and awareness of the appropriate knowledge, skills and approach needed to provide safe facilitation to such persons in a manner consistent with client goals, values, heritage, and spiritual practices.-¶
(6) "Preparation and Orientation" module shall include:-¶
(a) Informed consent;-¶
(b) Client information form and intake interview, including discussion of client's reasons for seeking psilocybin services;¶
(c) Using the client information form to assist clients in identifying benefits of referral to specialized treatment services;¶
(d) Facilitator role and the limits of facilitator's scope of practice;-¶
(e) Trauma informed communication skills;¶
(f) Identification of client safety concerns, including medical history, contra-indicated medication and psychological instability;¶
(g) Appropriate strategies to discuss client safety concerns, including but not limited to identification of client's support system;¶
(h) Determination of whether a client should participate in an administration session;-¶
(i) Client directed safety planning to address identified safety concerns;¶
(j) Boundaries between the facilitator and the client including use of touch;-¶
(k) Understanding of how racial and cultural dynamics affect interactions between client and facilitator; and¶
(l) Historical and indigenous modalities of preparation.¶
(7) "Administration" module shall include:¶
(a) Dosing strategies and considerations, including:¶
(A) Experiential differences relating to differing dosages;¶
(B) Physiological considerations in relation to dosage;-¶
(C) Delivery mechanisms of psilocybin; and¶
(D) Use of secondary doses.¶
(b) Effectively working with challenging behaviors during an administration session, including:¶
(A) Unexpected client disclosures;¶
(B) Substance-induced psychosis; and¶
(C) Suicidality.¶
(c) Traumatic stress and its manifestation during a psilocybin experience and appropriate facilitator response, including:¶
(A) Trauma's relationship to the body;¶
(B) Repressed trauma emerging during a psilocybin experience;¶
(C) Trauma and traumatic stress resulting from systemic oppression;¶
(D) Safety for trauma resolution and risks associated with re-traumatization; and¶
(E) Protocols for ensuring facilitator safety and responding to emergencies.¶
(d) "Set and Setting" including environmental considerations for administration session such as lighting sound and temperature; and¶
(e) Completion of administration session.-¶
(8) "Integration" module shall include:-¶
(a) Identification of appropriate resources that may assist client with integration, including resources for:¶
(A) Interpreting feelings and emotions experienced during administration session;¶
(B) Facilitation of positive internal and external changes;¶
(C) Enhancement of existing supportive relationship.-¶
(b) Identification of client safety concerns;¶
(c) Facilitator scope of practice; and¶
(d) Discussion of appropriate intervals between administration sessions and related safety concerns.-¶
(9) "Group Facilitation" module shall include:-¶

(a) Skills required to facilitate psilocybin group sessions, including, but not limited to:¶
(A) Assessing client's compatibility with group format;¶
(B) Set and setting for group facilitation;-¶
(C) Facilitating group communications and dynamics, including strategies for working with multiple facilitators;¶
(D) Group agreements, including confidentiality and safety; and¶
(E) Identifying when a client within a group requires individual support, removal from a group, or additional intervention.¶
(b) Group Preparation Sessions;¶
(c) Group Integration Sessions; and¶
(d) Regulatory requirements for group facilitation.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3070

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-3070-Amends practicum rule to clarify requirements for training programs that offer alternative practicum

CHANGES TO RULE:

333-333-3070
Psilocybin Facilitator Practicum Requirements
(1) Programs shall require students to complete practicum training that provides an opportunity to ~~facilitate and~~ observe the facilitation of non-ordinary states of consciousness.¶
(2) If a practicum site is available, practicum training shall include placement at a practicum site where students can observe ~~and facilitate~~ psilocybin services under the supervision of a practicum site supervisor.¶
(3) Any licensed Service Center can function as practicum site. If a training program uses a Service Center as a practicum site to satisfy the requirements of this rule, the training program shall notify the ~~Authority~~Oregon Health Authority (Authority) in a form and manner prescribed by the Authority.¶
(4) A practicum site must obtain written client consent prior to allowing a client to be observed by practicum students and prior to sharing any client information with practicum students or a training program.¶
(5) The practicum site supervisor is ~~primarily~~ responsible for developing students' practicum skills and evaluating students' practicum performance, ~~focusing on services with client~~related to psilocybin service~~s~~.¶
(6) If a practicum site is not reasonably available or accessible to students, a training program may identify alternative practicum in ~~their~~its application for approval that reasonably approximates training at a practicum site. For alternative practicum, the lead educator or program director is responsible for developing students' alternative practicum skills and evaluating students' alternative practicum performance, focusing on services with clients.¶
(7) Alternative practicum may include but is not limited to observation of taped facilitation sessions that were recorded with participants' consent, participating in psychedelic peer support organization, role playing, and experience with altered states of consciousness that are not drug-induced, for example breath work, meditation or spiritual journeys.¶
(8) Students shall complete a minimum of 40 hours of practicum training, including at least 30 hours of direct practice in which students directly observe clients receiving psilocybin services or directly participate in alternative practicum activity as described in section (7), and at least 10 hours of consultation relating to the student's direct practice.¶
(9) All practicum training, including direct practice, consultation and alternative practicum, must be conducted in person.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3080

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-3080-Amends accelerated training hours rule to clarify requirements for delivering training that does not qualify for accelerated training hours.

CHANGES TO RULE:

333-333-3080
Accelerated Training Hours
(1) Programs may ~~confer upon~~grant qualified students accelerated training hours not to exceed 40 percent of the total number of core training hours required by OAR 333-333-3050.¶
(2) Accelerated training hours may be awarded based on students' professional credentialing, prior training and education, or relevant experiences such as practicing in established plant or fungi-based healing traditions.¶
(3) Training programs that offer accelerated training hours must establish and document criteria for conferring accelerated hours to qualifying students.¶
(4) Student transcripts and other records shall document the number and type of accelerated training hours conferred to each student.¶
(5) Training programs may not offer accelerated training hours for the following modules:¶
(a) "Cultural Equity in relation to Psilocybin Services;"¶
(b) "Safety, Ethics and Responsibilities;"¶
(c) "Preparation and Orientation;"¶
(d) "Administration;" or¶
(e) "Integration."¶
(6) Training programs may not offer accelerated training hours for practicum.¶
(7) Programs that grant accelerated training hours to qualifying students are required to comply with the requirements of OAR 333-333-3050 for remaining core training hours, including but not limited to delivering at least 50 percent of the training through online synchronous learning for training that is not conducted in person, required training modules, and conducting in-person practicum and consultation.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-3090

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-3090¬-Amends training program completion rule to clarify programs responsibilities to ensure student completion.

CHANGES TO RULE:

333-333-3090
Training Program Completion and Exams
(1) Training programs shall maintain a level of training for students such that students who successfully complete the program's training could reasonably expect to possess the knowledge and skills required to practice as a facilitator.¶
(2) Training programs must administer a comprehensive skills-based exam and e~~very~~ach student must receive a passing score, established by the training program, as a condition of completing the training program.¶
(3) The exam required by section (2) of this rule is in addition to the exam required by ORS 475A.330.¶
(4) A lead educator or program director must ensure completion of core curriculum, practicum and comprehensive skills exam and must endorse each student as qualified to provide psilocybin services as a condition of completing the training program.¶
(5) Training programs shall provide every student written confirmation of program completion, including the endorsement described in section (4) of this rule, signed by a lead educator or program director upon the student's successful completion of the program, that includes:¶
(a) Student's full legal name;¶
(b) Date of completion; and¶
(c) ~~Name and location of the training program~~Approved training program name and training program number issued by the Oregon Health Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.380
Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

AMEND: 333-333-4000

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4000-Amends application process rule to clarify requirements for applications and inspections.

CHANGES TO RULE:

333-333-4000
Application Process
(1) Applications must be submitted to the ~~Authority~~Oregon Health Authority (Authority) in the form and manner prescribed by the Authority.¶
(2) The application fee specified in OAR 333-333-4060(1) must be submitted at the time of application in the form and manner prescribed by the Authority.¶
(3) An application must include the following:¶
(a) The names and required information for all individuals and legal entities who are applicants as required by OAR 333-333-4030.¶
(b) 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~~and diagram of the proposed license premises, including the boundaries of the licensed premises relative to its location, identification of any unlicensed areas within the building where the licensed premises is located including suite numbers if applicable, identification of any residence or other unlicensed structures located on the same tax lot as the premises proposed to be licensed, a scaled floor plan identifying all points of ingress and egress, camera locations, limited access areas, client administration areas and areas where psilocybin products will be stored within the licensed premises~~.~~ as required by OAR 333-333-4510. The Authority may request additional documents or information related to the proposed licensed premises, including but not limited to photographs of the premises.¶
(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 must be satisfied by using the designated form published by the Authority on its website.¶
(g) For service center applicants, a service center emergency plan as described in OAR 333-333-4460.¶
(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 t~~he training and passed the exam required by ORS 475A.325.~~raining at a training program with curriculum that has been approved by the Authority and that meets the requirements of OAR 333-333-3005 to OAR 333-333-3090.¶
(k) For facilitator applicants, documentation that the applicant has passed the exam required by ORS 475A.325.¶
(l) For laboratory applicants, documentation that the applicant has received accreditation as described in ORS 475A.606. ¶
(4) In addition to submitting an application form and the items described in section (3) of this rule, the Authority may require:¶
(a) Information or fingerprints required to perform a criminal background check in accordance with OAR 333-333-4100.¶
(b) Any additional information that is reasonably required to determine the merits of the license application.¶
(5) The Authority must review an application to determine if it is complete. An application may be considered incomplete if the form is not complete, the application or license fee has not been paid, or additional information or documentation required under this rule has not been submitted, included but not limited to:¶
(a) Documentation that an applicant for a facilitator license has completed the training required by ORS 475A.325.¶
(b) Documentation that an applicant for a facilitator license has passed the exam required by ORS 475A.325.¶
(c) Results of required criminal background checks completed pursuant to OAR 333-333-4100.¶
(d) A land use compatibility statement from the city or county that authorizes land use in the city or county where the premises of a manufacturer or service center proposed to be licensed is located.¶
(e) Other required forms and documents identified in the training, licensing and compliance system.¶

(6) The Authority will notify an applicant in writing if their application is determined to be incomplete. The applicant will have 90 days from the date the notice is issued to submit a complete application. If the applicant does not complete their application within 90 days, the Authority will ~~deactivat~~close the application. If the Authority ~~deactivat~~closes an application, the applicant may submit a new application, including a non-refundable application fee, at any time.¶
(7) An applicant may submit a written request for reconsideration of an application that is ~~deactivat~~closed as incomplete. Such a request must be received by the Authority within 10 calendar days of the date the ~~deactivation~~closure 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~~will notify the applicant of the results of their request following receipt of the requ~~irements for contested case proceedings under ORS 183.310 to 183.550~~est for reconsideration.
Statutory/Other Authority: ORS 475A.235, ORS 475A.245, ORS 475A.255
Statutes/Other Implemented: ORS 475A.235, ORS 475A.245, ORS 475A.255, ORS 475A.594

AMEND: 333-333-4010

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4010-Amends communication rule to clarify requirements for designating a primary point of contact for communication with the Oregon Health Authority.

CHANGES TO RULE:

333-333-4010
Communication with the Oregon Health Authority
(1) If an applicant or licensee is required to or elects to submit anything in writing to the ~~Authority~~Oregon Health Authority (Authority), unless otherwise prescribed by the Authority, the applicant or licensee may submit the writing to the Authority via:¶
(a) Mail; or¶
(b) Electronic mail.¶
(2) If a written notification must be submitted by a particular deadline it must be received, regardless of the method used to submit the writing, by 5:00 p.m. Pacific Time.~~¶~~
~~(3) Applicants must designate an applicant who will serve as the primary point of contact for communication with~~ on the date specified in the notification.¶
(3) Applicants must designate an individual applicant in their license application who will serve as the primary point of contact for communication with the Authority. If a license is issued, the designated primary point of contact listed in the application continues to serve as primary point of contact unless the licensee provides written notice in the form and manner proscribed by the Authority.¶
(4) The primary point of contact ~~requir~~identifi~~ed by~~in section (3) of this rule is responsible for ensuring all persons identified as licensees or applicants are aware of relevant communications from the Authority, during the license application process and after the license is issued, including but not limited to notices issued under ORS chapter 183.
Statutory/Other Authority: ORS 475A.235, ORS 475A.245
Statutes/Other Implemented: ORS 475A.235, ORS 475A.245

AMEND: 333-333-4020

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4020-Amends social equity plan rule to clarify that confidentiality requirements apply to all information related to the plan.

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, service center, facilitator or laboratory 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.¶
(5) If a facilitator is an employee of a licensed service center, the social equity plan requirements identified in sections (1), (2) and (3) of this rule can be fulfilled by submitting a statement to the Authority that references the service center's social equity plan. If a facilitator is an employee of more than one service center, the statement must identify each service center that employs the facilitator. If a facilitator contracts with a service center, they must submit their own social equity plan.¶
(6) Licensees must maintain confidentiality of any information collected related to their social equity plan that may be used to identify a client, or disclose any communication made by a client, as required by OAR 333-333-4810.
Statutory/Other Authority: ORS 475A.235, ORS 475A.245
Statutes/Other Implemented: ORS 475A.235, ORS 475A.245

AMEND: 333-333-4060

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4060-Amends license fee rule to clarify requirements for receiving reduced license fees, corrects drafting error.

CHANGES TO RULE:

333-333-4060
License Fees
(1) At the time of initial license application:¶
(a) An applicant for a service center, manufacturer or laboratory license must pay a US$500 non-refundable application fee.¶
(b) An applicant for a facilitator license must pay a US$150 non-refundable application fee.¶
(2) If the ~~Authority~~Oregon Health Authority (Authority) approves an initial license application or renewal and grants an annual license, the following non-refundable fees must be paid, except as provided in sections (3) and (4) of this rule:¶
(a) Manufacturer US$10,000.¶
(b) Service Center US$10,000.¶
(c) Facilitator US$2,000.¶
(d) Laboratory US$10,000.¶
(3) Notwithstanding section (2) of this rule, if the Authority approves an initial license application or renewal and grants an annual license to a non-profit entity the following non-refundable fees must be paid:¶
(a) Manufacturer US$5,000.¶
(b) Service Center US$5,000.¶
(4) Notwithstanding section (2) of this rule, if the Authority approves an initial license application or renewal and grants an annual license ~~solely to an individual person~~ the following non-refundable fees must be paid, if ~~the~~every individual ~~satisfies any~~applicant identified in the application satisfies one or more of the requirements of section (5) of this rule:~~¶~~
(a) Manufacturer US$5,000.¶
(b) Service Center US$5,000.~~¶~~
(c) Facilitator US$1,000.~~¶~~
(5) In order to qualify for the reduced fees ide~~scrib~~ntified in section (4) of this rule, an individual applicant must qualify under one of the following circumstances:~~¶~~
(a) ~~B~~Have receiv~~ing Soci~~ed Supplemental Security Income benefits within the 12 months prior to the application date. To qualify for the reduced fee, the applicant must submit at the time of application a copy of a current monthly S~~oci~~upplemental Security Income benefit statement showing dates of coverage.~~¶~~
~~(b) Be enrolled in Oregon Health Plan~~ The Authority may require additional information to verify eligibility upon request.¶
(b) Be enrolled in or have qualified for the Oregon Health Plan within the 12 months prior to the application date. To qualify for the reduced fee the applicant must submit a copy of the applicant's ~~curr~~recent eligibility statement or card.~~¶~~
~~(c) Be receiving food stamp~~ including a date that shows they were eligible for or received benefits within the 12 months prior to the application date. The Authority may require additional information to verify eligibility upon request. ¶
(c) Have received food benefits through the Oregon Supplemental Nutrition Assistance Program within the 12 months prior to the application date. To qualify for the reduced fee the applicant must submit ~~at the time of application current proof of their food stamp benefits~~proof of receiving food benefits within the 12 months prior to the application date. The Authority may require additional information to verify eligibility upon request.¶
(d) Has served in the Armed Forces of the United States. To qualify for the reduced fee, the applicant must provide proof of having served in the Armed Forces, such as but not limited to, submitting a Veteran's Administration form DD-214.¶
(6) The Authority will charge a change fee of US$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 US$250 per inspection for any change to a previously approved license that requires an inspection of the licensed premises, or any inspection of a premises proposed to be licensed that takes place pursuant to OAR 333-333-4~~1~~210(2). This change fee applies regardless of whether the licensee requests the change at renewal or during the term of their license.

Statutory/Other Authority: ORS 475A.235, ORS 475A.290, ORS 475A.305, ORS 475A.325, ORS 475A.594
Statutes/Other Implemented: ORS 475A.235, ORS 475A.290, ORS 475A.305, ORS 475A.325, ORS 475A.594

AMEND: 333-333-4070

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4070-Amends worker permit rule to specify that an application will be considered incomplete if the fee is not paid timely.

CHANGES TO RULE:

333-333-4070
Worker Permit Term and Fees
(1) An individual who is a licensee representative must have a valid worker permit if the individual participates in:¶
(a) The provision of psilocybin services at a licensed premises.¶
(b) The possession, manufacturing, securing or selling of psilocybin products at a licensed premises.¶
(c) The recording of the possession, manufacturing, securing or selling of psilocybin products at a licensed premises.¶
(d) The verification of any document described in ORS 475A.445.¶
(2) An individual person who holds a manufacturer, service center or laboratory license due to their ownership or control of a licensed legal entity, must have a valid worker permit if they perform any of the activities listed in subsections (1)(a) through (d) of this rule.¶
(3) If the ~~Authority~~Oregon Health Authority (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 US$25 fee to receive the permit.¶
(5) If an applicant for a worker permit fails to pay the fee within 180 calendar days of receiving notice of the Authority's determination to grant an application, the application will be considered incomplete.
Statutory/Other Authority: ORS 475A.235, ORS 475A.483, ORS 475A.480
Statutes/Other Implemented: ORS 475A.235, ORS 475A.483, ORS 475A.480

AMEND: 333-333-4120

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4120¬-Amends license application rule to clarify requirements and timing of fee payment.

CHANGES TO RULE:

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

AMEND: 333-333-4130

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4130-Amends license denial rule to clarify factors used to determine if there is a physical or geographical barrier that qualifies for the exception under ORS 475A.310.

CHANGES TO RULE:

333-333-4130
Application Denial
(1) The ~~Authority~~Oregon Health Authority (Authority) shall deny an application if:¶
(a) An applicant is under the age of 21.¶
(b) The applicant for a facilitator license is not an individual person.¶
(c) The applicant's land use compatibility statement shows that the proposed land use is prohibited if a land use compatibility statement is required by these rules.¶
(d) The proposed licensed premises is located on state or federal land.¶
(e) If required, the applicant does not have an approved fitness determination in accordance with OAR 333-333-4100.¶
(f) The application identifies more than one licensed premises.¶
(g) The application identifies a licensed premises that fails to comply with the requirements of OAR 333-333-4300~~(2)~~.¶
(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 shares, membership interests, partnership interests, or other ownership interests in the entity proposed to be licensed are held by individuals who 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)(a) An applicant for a service center is ineligible for a license and the Authority shall deny an application if any portion of the proposed licensed premises for a service center applicant is located:¶
~~(a)~~ E, except as provided in ORS 475A.310, within 1,000 feet of:¶
(A) A public elementary or secondary school for which attendance is compulsory under ORS 339.020; or¶
(B) A private or parochial elementary or secondary school, teaching children as described in ORS 339.030(1)(a).¶
(b) For purposes of determining the distance between a service center and a school, "within 1,000 feet" means a straight--line measurement in a radius extending for 1,000 feet or less in any direction from the closest point anywhere on the boundary line of the real property comprising a school to the closest point of the licensed premises of a service center.¶
(c) In order for the Authority to determine whether there is a physical or geographical barrier that qualifies for the exception under ORS 475A.310, the applicant must demonstrate, in a form and manner prescribed by the Authority, that a physical or geographic barrier exists, and the barrier is capable of preventing children from traversing to a proposed licensed premises. Examples of physical barriers include prisons or interstate highways. Examples of geographic barriers include rivers and mountains. Private properties, shallow streams, locked doors or property fences do not qualify for a school exclusion exception request.¶
(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.¶
(7) The Authority may deny an application for any reason identified in ORS 475A.250.
Statutory/Other Authority: ORS 475A.235, ORS 475A.250
Statutes/Other Implemented: ORS 475A.235, ORS 475A.250, ORS 475A.290, ORS 475A.305, ORS 475A.325, ORS 475A.310

AMEND: 333-333-4200

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4200-Amends notification of changes rule to clarify process and describe circumstances when a new license application will be required.

CHANGES TO RULE:

333-333-4200
Notification of Changes
(1) An applicant or licensee must notify the ~~Authority~~Oregon Health Authority (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) A change in licensee's operational name. ¶
(d) Any closure of the licensed premises lasting more than 30 days.¶
(~~d~~e) Any conviction for any misdemeanor or felony committed by an individual listed as an applicant or licensee.¶
(~~e~~f) Any arrest for conduct that occurred on the licensed premises.¶
(~~f~~g) 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 be submitted in a form and manner prescribed by the Authority and must include:¶
(A) For changes to manufacturer or service center license location, a land use compatibility statement from the city or county that authorizes land use in the city or county where the new licensed premises will be located.¶
(B) For manufacturer, service center and laboratory license applicants, a map or ~~sketch~~diagram of the new location's licensed premises including the boundaries of the licensed premises relative to its location, identification of any residence or other structures located on the same tax lot as the premises proposed to be licensed that will not be included in the licensed premises, and a scaled floor plan identifying all limited access areas and client administration areas. The Authority may request additional documents or information related to the new locations, including but not limited to photographs of the premises to be licensed.¶
(C) For a manufacturer license, if the licensee is not the owner of the real property where the new location will be located, a written statement on a form prescribed by the Authority and signed by the property owner that shows that the owner consents to manufacturing of psilocybin products on the property. The form will be published by the Authority on its website.¶
(5) 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.¶
(6) The Authority may require a licensee to submit a new application including all required forms and documents and the fee specified in OAR 333-333-4060 for a change in ownership structure if the change in ownership structure results in changing the licensee's status from a non-profit entity to another type of entity.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4210

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4210-Amends modification of license premises rule to clarify requirements and exclude unlicensed structures.

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~~Oregon Health Authority's (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~~recording cameras or a change to the security system.¶
(d) Any change~~s~~ to ~~limited access areas or client administration areas on the licensed premises;¶~~
~~(e) Any addition or change to~~the premises plan that alters limited access ~~a residence or other un~~as or c~~licensed structure located on the same tax lot as the licensed premises i~~t administration areas ~~that~~on the license~~e controls or has the right to access~~d premises.~~¶~~
(4) Emergency repairs to the licensed premises made to ensure safety and security do not require prior approval under section (1) of this rule. ~~L~~A 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

AMEND: 333-333-4250

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4250-Amends license renewal rule to make the fee payable on issuance of 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.~~ Oregon Health Authority (Authority) to be complete.¶
(b) For facilitator applicants, a renewal application must include documentation that the applicant has completed training at a training program with curriculum that has been approved by the Authority and that meets the requirements of OAR 333-333-3005 to OAR 333-333-3090.¶
(~~b~~c) A renewal application will be considered timely if a complete renewal application is received by the Authority at least 60 calendar days before the date the license expires. Applications received less than 60 days before the date the license expires will be considered untimely.¶
(~~c~~d) A licensee who submits a complete timely renewal application may continue to operate after the stated license expiration date, pending a decision by the Authority on the renewal application.¶
(~~d~~e) A licensee who submits an untimely or incomplete renewal application or who does not submit a renewal application must cease engaging in the licensed activity when the license expires.¶
(~~e~~f) A person who, while not actively licensed, engages in any activity that would require a license may be subject to administrative and criminal sanctions regardless of their prior licensure status.¶
(2) The Authority may require a licensee with a pending renewal application to submit forms, documents and information described in OAR 333-333-4000 in order to complete an ~~investig~~evaluation 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 being considered incomplete.¶
(3) If upon review of an application the Authority determines the renewal application meets all licensing requirements, the Authority will notify the applicant in writing that the renewal application is pending approval and will request license fee payment.¶
(4) If an applicant for any license type fails to pay the license renewal fee within 30 calendar days of the notice described in section (3) of this rule, the renewal application will be considered incomplete. ¶
(5) The Authority will not renew the license until it has confirmed that payment of the license renewal fee has cleared and processing the renewal application is complete. When the license is renewed, the Authority will notify the applicant and provide the applicant updated proof of licensure that includes a unique license number, the licensee name(s), the operational name, the effective date of the license, and address of the licensed premises.
Statutory/Other Authority: ORS 475A.235, ORS 475A.483
Statutes/Other Implemented: ORS 475A.235, ORS 475A.483

AMEND: 333-333-4300

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4300-Amends license location rule to clarify requirements for temporary uses of licensed premises.

CHANGES TO RULE:

333-333-4300
Licensed Premises Location Requirements
(1) A licensed premises may not be located on state or federally owned land.¶
(2) The interior and exterior areas of a licensed premises may not overlap with:¶
(a) An area that is licensed with 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 is licensed with 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) An area that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited-service restaurant, single event temporary restaurant, commissary, mobile unit, bed and breakfast, or warehouse licensed under ORS chapter 624.¶
(h) A residence.¶
(i) An area that has been issued another license under ORS chapter 475A. ¶
(3) The licensed premises of a service center may not be located:¶
(a) Except as provided in ORS 475A.310 and OAR 333-333-4130(4), within 1,000 feet of:¶
(A) A public elementary or secondary school for which attendance is compulsory under ORS 339.020; or¶
(B) A private or parochial elementary or secondary school, teaching children as described in ORS 339.030.¶
(b) In an area that is zoned exclusively for residential use within city limits.¶
(4) A manufacturer with an edible psilocybin production endorsement may not:¶
(a) Engage in processing in an area that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited-service restaurant, single event temporary restaurant, commissary, mobile unit, bed and breakfast, or warehouse licensed under ORS chapter 624;¶
(b) Share a food establishment where psilocybin will be produced, with another person or entity;¶
(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~~¶
(6) A service center 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 plac~~Activities related to the regular operation of the licensed business, such as staff meetings, are not temporary uses. ¶
(a) The requirements of these rules and ORS 475A.210 to 475A.722 remain in effect during authorized temporary uses and licensees are responsible for any violation of these rules and ORS 475A.210 to 475.722 that occurs on the licensed premises during an authorized temporary use. Requirements include but are not limited to prohibiting any person under 21 years of age from being present on the licensed premises, preventing access to limited access areas, ensuring that no alcoholic beverages or other intoxicants are consumed during the temporary use, complying with local time, place and manner regulations and following applicable rules on food service. .¶
(b) A service center must provide advance written notice of temporary uses of the licensed premises for activities unrelated to the exercise of licensed privileges at least five business days prior to the authorized temporary uses in the form and manner prescribed by the Oregon Health Authority. Service centers may use a single written notice to provide advance notice of multiple and reoccurring events occurring within 90 days following the date of the notice.¶
(c) Psilocybin products may not be sold or transferred, and no psilocybin services may be provided, during an authorized temporary use. ¶

(d) A licensee representative must be present at the licensed premises for the duration of the authorized temporary use.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.305, ORS 475A.310

AMEND: 333-333-4400

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4400-Amends operating requirements rule to clarify requirements for employee and visitor logs and other operational issues.

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~~for persons temporarily at the premises to make a service, maintenance, or repair call or for other purposes independent of the premises operations.¶
(b) On-site sale or transfer of a psilocybin product except for sales and transfers to other licensed premises and retail sales by a service center in connection with an administration session.¶
(c) On-site consumption of a psilocybin product except for clients consuming psilocybin products at a service center in connection with an administration session.¶
(d) On-site consumption of any intoxicants by any individual, except for clients consuming psilocybin products during an administration session.¶
(2) A licensee must clearly identify all limited access areas in accordance with OAR 333-333-4000(3)(e).¶
(3) Log. A licensee must keep a daily log of all licensees, licensee representatives and employees and permitted visitors who perform work on the licensed premises, except for ~~Authority~~Oregon Health Authority (Authority) employees and other state or local government officials acting in an official capacity who have jurisdiction over some aspect of the licensed premises or operation. The daily log must contain the license number and worker permit number, if applicable, for all individuals listed in the log. ¶
(a) A licensee must record and retain the following information for each current employee and license representative and make the information available to the Authority upon request:¶
(A) For a~~n~~ licensee, 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 a~~n~~ licensee, 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~~or display an item issued by the licensee that ~~easi~~visually identifies the individual as a~~n employee or~~ permitted visitor. ¶
(c) Upon client request, facilitators, permitted workers and licensee representatives present at a service center must make reasonable efforts to wear, display or carry an item provided by the licensee that identifies their role at the licensed premises. ¶
(~~c~~d) All permitted visitors must be supervised by a licensee representative when they are present in limited access areas or any areas where clients may be present.¶
(~~d~~e) On the daily log, a licensee must record the name and date of birth as this information is displayed on valid government-issued ID for every contractor who performs work on the licensed premises.¶
(~~e~~f) A licensee must maintain a copy of the daily log required by subsection (3)(e) of this rule for a period of at least two years.¶
~~(f) The requirements of subsections (3)(a) through (c) of this rule do not apply when a licensee authorizes temporary use of a licensed premises for purposes unrelated to the exercise of license privileges as described by section (6) of this rule.¶~~
(4) Permitted Visitors. The general public is not permitted in limited access areas on a licensed premises. In addition to licensee representatives, the following visitors are permitted to be present in limited access areas on a licensed premises, subject to the requirements of th~~is rule and other pertinent~~ese rules:¶
(a) Laboratory personnel if the laboratory is licensed by the Authority.¶
(b) A contractor, vendor or ~~service provider~~individual or entity providing professional services to a licensee, including media authorized by a licensee representative to be on the licensed premises.¶
(c) Another licensee or that licensee's representative.¶
(5) Nothing in this rule is intended to prevent or prohibit Authority employees or contractors, or other state or local government officials that have jurisdiction over some aspect of the licensed premises or licensee from being on the licensed premises.¶
(6) A licensee may not sublet any portion of a licensed premises. A ~~licensee~~service center may authorize the temporary use of a licensed premises subject to OAR 333-333-4300(6), excluding limited access areas, for activities that are unrelated to the exercise of license privileges. The requirements of these rules and ORS

475A.210 to 475A.722 remain in effect when such activities take place.¶
(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~~9) If the licensed premises contains outdoor areas, the boundaries of the licensed outdoor areas must be clearly marked with visible signage or barriers.¶
(1~~1~~0) Licensees that are required to be registered with the Oregon Secretary of State must register prior to receiving a license and maintain registration, including registration of an Assumed Business Name (ABN) if applicable that is used as an operational name.¶
(11) Licensee representatives who are not licensees under ORS 475A are prohibited from exercising control over the license. ¶
(12) Licensees must construct and maintain floors, walls, ceilings counters and surface areas within a licensed premises in a manner that reduces the potential development of microbials, molds and unintended fungi.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.460

AMEND: 333-333-4450

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4450¬-Amends client administration area rule to clarify requirements for location and construction of indoor areas where client will consume psilocybin products during and administration session.

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 client 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) Indoor client administration areas must be constructed and used in a manner that effectively maintains confidentiality for clients participating in an administration session. ¶
(~~3~~4) 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 licensee representatives who are present to deliver psilocybin products to clients to be consumed during an administration session~~.~~ or otherwise assist with operations subject to the requirements of OAR 333-333-5200.¶
(4~~5~~) A client may leave a~~n~~ client administration area briefly during an administration session for reasons including accessing a restroom, moving to a separate client administration area or retrieving personal belongings. A client who leaves a~~n~~ client 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 client 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~~6) 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~~.~~ without assistance.¶
(~~6~~7) 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

AMEND: 333-333-4480

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4480-Amends service center rule to describe requirements for food service and sale of merchandise at licensed service centers.

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 firearms and other weapons on the licensed premises.¶
(5) A service center may not:¶
(a) Discount a psilocybin product or offer a psilocybin product for free 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 licensee representative of a service center may not assist a client with any of the activities required to be performed by a client support person pursuant to OAR 333-333-5070.¶
(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.¶
(8) Service centers may provide packaged food and beverages to clients and food that was prepared offsite at a restaurant or other facility licensed under ORS chapter 624. If food will be provided during an administration session, service centers must discuss client's dietary needs, restrictions and preferences prior to beginning the administration session. ¶
(9) Service centers may not provide food items or beverages to clients that were prepared on the licensed premises. This rule does not prevent a service center from providing heated or unheated water to clients.¶
(10) Licensed service centers may not promote unregulated cultivation and processing of psilocybin products by offering for sale spores, mycelium or materials used to cultivate and process psilocybin products.
Statutory/Other Authority: ORS 475A.235, ORS 475A.305
Statutes/Other Implemented: ORS 475A.235, ORS 475A.305

AMEND: 333-333-4510

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4510-Amends storage rule to clarify requirements for product storage.

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~~n area within a limited access area of the licensed premises that is enclosed on all sides with permanent walls and 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~~. ¶~~
~~(c) A locked refrigerator or freezer located within a limited access area of the licensed premises.~~ that is not located within an area that meets the requirements of subsection (2)(a).¶
(c) For products that require refrigeration, a locked refrigerator or freezer located within a limited access area of the licensed premises that is not located within an area that meets the requirements of subsection (2)(a).¶
(3) The requirements of section (2) of this rule do not prevent a licensee from designating the entirety of a limited access area as an area for product storage if doing so is consistent with other requirements of these rules.¶
(~~3~~4) The requirements of section (2) of this rule do not apply to fungi and mycelium stored at a manufacturer's licensed premises that has not been harvested or is undergoing a drying process.¶
(4~~5~~) The requirements of section (2) of this rule do not apply to secondary doses of psilocybin products that have been purchased by a client and are stored pursuant to OAR 333-333-5240. ¶
(6) Psilocybin products that require refrigeration must be stored in appropriate, temperature-controlled environments.¶
(~~5~~7) Psilocybin products offered for sale by a service center must be stored in such a manner that the items are only accessible to licensee 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 licensee representative.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4520

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4520-Amends Client Bill of Rights to include provisions regarding service center employees and choice of facilitators.

CHANGES TO RULE:

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

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

AMEND: 333-333-4550

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4550-Amends security rule to clarify requirements to prevent unauthorized access to the licensed premises.

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 from the licensed premises, including providing adequate safeguards against theft or diversion of psilocybin products. ¶
(2) A service center, manufacturer or laboratory licensee is responsible for taking adequate measures to prevent unauthorized access to the licensed premises. Adequate measures include but are not limited to locking or monitoring exterior doors to the licensed premises during business hours. The exterior walls, doors and roof of the licensed premises must be constructed of materials that effectively prevent unauthorized entry. Any measures taken by a service center to prevent unauthorized access must be consistent with the requirements for client administration areas in OAR 333-333-4450. ¶
(3) A service center, manufacturer or laboratory licensee is responsible for taking adequate measures to prevent unauthorized access to records and maintain client confidentiality. ¶
(4) 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~~5) Licensees must ensure that all limited access areas of a licensed premises are accessible only to licensee representatives and other personnel authorized to be present under these rules. ¶
(4~~2~~6) 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

AMEND: 333-333-4620

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4620-Amends rule to clarify requirements for placement of video monitors and recording audio.

CHANGES TO RULE:

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

AMEND: 333-333-4640

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4640-Amends rule to clarify requirements for video recording of administration session, including allowable equipment, retention of recordings and client consent.

CHANGES TO RULE:

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

AMEND: 333-333-4650

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4650-Amends video recording rule to clarify requirements for accessing video.

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~~video recordings for a minimum of 30 calendar days.¶
(d) Maintain ~~surveillance~~video recordings in a format approved by the ~~Authority~~Oregon Health Authority (Authority) that can be easily accessed for viewing and easily reproduced.¶
(e) Upon request of the Authority, keep ~~surveillance~~video recordings for periods exceeding the retention period specified in subsection (2)(c) of this rule.¶
(f) Have the date and time embedded on all ~~surveillance~~video recordings without significantly obscuring the picture.¶
(g) Archive video recordings in a format that ensures authentication of the recording and guarantees that no alteration of the recorded image has taken place.¶
(h) Make video ~~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 regardless of whether the recordings are stored on the licensed premises or on a cloud-based platform.¶
(i) Ensure that only authorized licensee representatives, Authority employees and contractors, and other state or local government officials that have jurisdiction over some aspect of the licensed premises or licensee have access to video recordings. ¶
(3) Notwithstanding the requirements in section (1) of this rule a service center, manufacturer or laboratory licensee may stop recording in areas where psilocybin products are not present due to seasonal closures or periods of inactivity.¶
(a) At least 24 hours before stopping recording, a licensee must submit written notice to the Authority by electronic mail using a designated form as published by the Authority on its website and the notice must include:¶
(A) A description of the total number and location of cameras that will be deactivated.¶
(B) The date and time recording will stop.¶
(C) An explanation for why recording will be stopped.¶
(D) The date and time recording will resume.¶
(b) A licensee must resume all required recording no later than the date and time specified in the notice submitted under subsection (a) of this section.¶
(c) A licensee may not engage in any licensed privileges in any areas where recording was stopped under this section.¶
(4) Recordings made under this rule are not subject to OAR 333-333-4640.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-4660

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4660-Amends rule to clarify that video recording equipment must be located on the licensed premises.

CHANGES TO RULE:

333-333-4660
Location and Maintenance of ~~Surveillance~~Video Equipment
(1) ~~A~~Except as provided in OAR 333-333 4620(3), a service center, manufacturer or laboratory licensee must house the ~~surveillance~~ recording equipment in a designated, locked, and secured room or other enclosure within the licensed premises with access limited to:¶
(a) The licensee, licensee representatives, and authorized personnel.¶
(b) Employees of the ~~Authority~~Oregon Health Authority (Authority).¶
(c) Service personnel or contractors.¶
(2) A service center, manufacturer or laboratory licensee must keep a current list of all authorized employees and service personnel who have access to the ~~surveillance~~video recording system and room on the licensed premises.¶
(3) Service center, manufacturer or laboratory licensees must keep a ~~surveillance~~video recording 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~~video recording system.¶
(4) Service center, manufacturer or laboratory licensees must keep a ~~surveillance~~video recording 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

AMEND: 333-333-4810

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4810-Amends client confidentiality rule to clarify requirements for accessing and amending client records.

CHANGES TO RULE:

333-333-4810
Client Confidentiality
(1) A service center or facilitator may not disclose any information that may be used to identify a client, or disclose any communication made by a client related to psilocybin services or selling psilocybin products to a client, except with a client's consent or otherwise as allowed by ORS 475A.450. Service centers may allow facilitators to access records related to services a facilitator provided to clients at the service center without the client's consent. A licensed facilitator may only access client records for clients to whom they have provided preparation, administration, or integration sessions. A licensed facilitator may not access the client records of any other client unless the client has provided prior written consent and the facilitator accesses the records for the purpose of providing services to the client. ¶
(2) A service center 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 ~~pat~~client.¶
(e) An expiration date when the consent to use or disclose is withdrawn.¶
(3) A service center or facilitator must use the client written consent form provided by the ~~Authority~~Oregon Health Authority (Authority) to meet the requirements of section (2) of this rule. The consent form is available ~~at~~ on the Authority's website.¶
(4) ~~T~~If a client consents to disclose their identifiable client information the client consent form described in section (2) of this rule must be completed at least 24 hours prior to the client's administration session or at least 724 hours after the conclusion of the client's administration session. If a client chooses to withdraw their consent form described in section (2), they may do so by providing written notice to the service center or facilitator in a form and manner prescribed by the Authority. ¶
(5) A service center or facilitator must provide a client with a disclosure form during or prior to a preparation session if the facilitator or service center intends to share de-identified data related to the client's receipt of psilocybin product or services. ¶
(a) The disclosure form must contain:¶
(~~a~~A) The name of the person or organization that will receive de-identified data.¶
(~~b~~B) The specific purpose for which the de-identified data will be used or disclosed.¶
(~~c~~C) The date the form was provided to the client and client signature acknowledging receipt.¶
(~~d~~D) An option that allows the client to opt out of having their de-identified data disclosed to third parties.¶
(b) The disclosure form is not required when reporting required data to the Authority pursuant to OAR 333-333-4910 and may not be used for clients to request that their data be withheld from the Authority as described in OAR 333-333-4900(4).¶
(6) A service center or facilitator must use the disclosure form provided by the Authority to meet the requirements of section (5) of this rule. The disclosure form is available on the Authority's website.¶
(7) ~~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 information~~If a client chooses to withdraw their disclosure form described in section (5), they may do so by providing written notice to the service center or facilitator in a form and manner prescribed by the Authority. ¶
(8) Service centers and facilitators may not alter client records after the completion of preparation, administration or integration sessions. Service centers and facilitators may create an addendum to existing records.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.450, OL 2023, ch. 150

AMEND: 333-333-4820

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4820-Amends record retention rule to require that client records are stored at service centers, clarifies requirements for accessing client records.

CHANGES TO RULE:

333-333-4820
Record Retention
(1) Licensees shall store, maintain and destroy records, including client records, in a manner that prevents unauthorized access ~~and protects client confidentiality.~~ , protects client confidentiality and prevents alteration of client records. ¶
(a) All client records and copies of client records, including records created by facilitators, must be stored at the service center where the client participates or intends to participate in an administration session. ¶
(b) Service centers may store electronic records on cloud-based platforms that use security measures to effectively prevent unauthorized access and protect client confidentiality. Electronic records must be accessible at the licensed premises. Electronic records stored pursuant to this subsection are considered to be stored at the service center.¶
(2) Unless otherwise specified in these rules, licensees must retain required records for a period of five years. For example, licensees must retain security video required by OAR 333-333-4650 for a period of 30 calendar days.¶
(3) ~~Licensed facilitators and s~~Service centers must allow current and former clients to access and examine their own client records and request ~~corrections~~an addendum 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.¶
(4) Service centers must allow facilitators who will provide or have provided psilocybin services at the service center to access and examine client records related to those services. Facilitators may not access the records of other clients without the client's prior written consent and may not alter the records. ¶
(5) Licensee representatives of a service center may not access client records, without the client's prior written consent, unless doing so is necessary to support operations of the service center where the client has received or will receive psilocybin services. ¶
(6) If a service center license is revoked, surrendered or expired the Oregon Health Authority may address in an order the manner and condition under which client records held by the licensee must be maintained, destroyed or transferred to other licensees.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-4900

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4900-Describes requirements for service centers to collect and store data required by SB 303 and offer clients an opportunity to request that their data is not submitted to the Authority.

CHANGES TO RULE:

333-333-4900
Collection and Maintenance of 303 Client Data
(1) On and after January 1, 2025, service centers must collect 303 client data in a manner prescribed by the Oregon Health Authority (Authority), consistent with OAR chapter 950, division 30, by using the form published by the Authority on its website prior to beginning an administration session for every client who will participate in an administration session at the licensed premises. ¶
(2) Service centers must store, maintain and destroy 303 client data, in a manner that prevents unauthorized access and protects client confidentiality. ¶
(3) 303 client data may only be accessed by licensee representatives of a service center and only for the purposes of aggregating and reporting the data to the Authority as required by OAR 333-333-4910.¶
(4) Prior to beginning an administration session, every client must provide written confirmation, in a form and manner prescribed by the Authority, that the client has had an opportunity to request that 303 client data related to their receipt of psilocybin services be withheld from data submitted to the Authority.¶
(5) A service center must collect 303 client data by using the form described in section (1) from every client, even if a client requests their information be withheld from data submitted to the Authority.¶
(6) Failure to comply with this rule is a violation.
Statutory/Other Authority: OL 2023, ch. 150
Statutes/Other Implemented: OL 2023, ch. 150

ADOPT: 333-333-4910

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4910-Describes requirements for service centers to report data to the Authority required by SB 303.

CHANGES TO RULE:

333-333-4910
Required Reporting of Data
(1) Beginning March 31, 2025, all data required to be submitted under this rule must be submitted in a form and manner prescribed by the Oregon Health Authority (Authority) on a quarterly basis no later than 15 days after the last day of the quarter. The last days of each quarter are March 31, June 30, September 30 and December 31 of every calendar year. ¶
(2) A service center must aggregate and submit the following aggregated 303 client data that pertains to the previous quarter for clients who participated in an administration session at the licensed premises, except for clients who have requested that their data be withheld from being submitted to the Authority:¶
(a) The race, ethnicity, preferred spoken and written languages, disability status, sexual orientation, gender identity, income, age and if applicable the county of residence. ¶
(b) The reasons, or reasons, for which clients requested psilocybin services. ¶
(3) A service center must aggregate and submit the following aggregated 303 service center data that pertains to the previous quarter for psilocybin services provided at the licensed premises.¶
(a) The number of clients served by participating in an administration session.¶
(b) The number of individual administration sessions provided.¶
(c) The number of group administration sessions provided.¶
(d) The number of individuals to whom the psilocybin service center denied psilocybin services by declining to allow the individual to participate in an administration session and the reasons for which psilocybin services were denied.¶
(4) A service center must compute and submit the following averaged 303 service center data that pertains to the previous quarter for psilocybin services provided at the licensed premises.¶
(a) The average number of times per client that a client participated in an administration session.¶
(b) The average number of clients participating in each group administration session. ¶
(c) The average dose of psilocybin per client per administration session measured in milligrams of psilocybin analyte.¶
(5) A service center must compile records of adverse reactions required by OAR 333-333-5100(1)(g) and aggregate and submit the following aggregated data that pertains to the previous quarter:¶
(a) The number of severe adverse behavioral reactions experienced by clients who participated in an administration session at the licensed premises.¶
(b) The number of adverse behavioral reactions experienced by clients who participated in an administration session at the licensed premises.¶
(c) The number of severe adverse medical reactions experienced by clients who participated in an administration session at the licensed premises.¶
(d) The number of adverse medical reactions experienced by clients who participated in an administration session at the licensed premises.¶
(6) Service centers must report data in a manner that prevents unauthorized access and protects client confidentiality. ¶
(7) Failure to comply with this rule is a violation.
Statutory/Other Authority: OL 2023, ch. 150
Statutes/Other Implemented: OL 2023, ch. 150

ADOPT: 333-333-4920

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-4920-Prohibits licensees from selling or otherwise monetizing client records.

CHANGES TO RULE:

333-333-4920
Sale of Records
Licensees may not sell, monetize, or otherwise profit from client records, 303 client data or 303 service center data.
Statutory/Other Authority: ORS 475A.235, OL 2023, ch. 150
Statutes/Other Implemented: ORS 475A.235, OL 2023, ch. 150

AMEND: 333-333-5000

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5000-Amends preparation session rule to address timing of form completion, include opt-out form for SB 303, and address other requirements related to alternate facilitators and other individuals who may be present during the client's session.

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

administration session.¶
(d) Video or audio recording of an administration session pursuant to requirements of OAR 333-333-4640.¶
(e) Presence of an interpreter or client support person allowed by OAR 333-333-5070, in the administration area during an administration session.¶
(f) Sharing of identifiable client data as described in OAR 333-333-4810(2).¶
(g) The use of different facilitators to conduct a client's preparation, administration sessions or integration session.¶
(h) Consuming secondary doses of psilocybin products after the administration session has begun, including the maximum amount of psilocybin analyte that a client has agreed to consume, not to exceed 50 mg of psilocybin analyte.¶
(i) Participating in an administration session where licensee representatives of a service center will be present pursuant to OAR 333-333-5200(9).¶
(j) Disclosure form for de-identified client data required by OAR ~~845-025~~333-333-4810(5).¶
(~~8~~9) If a facilitator or service center intends to share de-identified data related to the client's receipt of psilocybin product or services, a facilitator or service center must provide a disclosure form required by OAR 333-333-4810(5) during the client's preparation session.¶
(~~9~~10) 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.¶
(1~~0~~1) Preparation sessions may be completed in person or virtually using video conferencing technology.¶
(1~~1~~2) The requirements of this rule may be satisfied by conducting multiple preparation sessions.¶
(1~~2~~3) A facilitator must complete an initial preparation session with every client before conducting an administration session with that client for the first time. After a client completes an initial preparation session at a service center, the client is not required to complete additional preparation sessions prior to participating in an administration session at the same service center for a period of 12 months.¶
(1~~3~~4) If a facilitator does not complete additional preparation sessions as allowed by section (1~~2~~3) 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 a~~dditional administration sessions.~~ n administration session. If the previously completed client information form is no longer accurate on the date of the client's proposed administration session, a facilitator must conduct an additional preparation session to complete an updated client information prior to conducting administration sessions.¶
(1~~4~~5) A facilitator must discuss the process for verification of license status and process for making complaints to the Authority during a preparation session.¶
(1~~5~~6) The documents described in sections (~~6~~7), (~~7~~8) and (~~8~~9) of this rule must be provided to a client prior to a preparation session upon the client's request.¶
(17) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.¶
(18) If different facilitators will conduct preparation and administration sessions, the facilitator conducting the administration session must receive and review all forms and documents required to be completed during a preparation session prior to beginning the administration session. ¶
(19) Except for practicum site supervisors, lead educators and students participating in a practicum with the client's prior written consent, only the client, and any facilitators and client support persons who will be present during the client's administration session may be present during a preparation session.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340, OL 2023, ch. 150

AMEND: 333-333-5040

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5040-Amends client informed consent document to include statements regarding activation time and presence of service center employees during an administration session.

CHANGES TO RULE:

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

psilocybin at any time.¶
14. ___ I understand that I have the right to update my client information form prior to beginning an administration session and I have the right to receive a copy of my client information form upon request.¶
15. ____ I understand that if de-identified data collected by facilitators and service centers is shared with people and institutions outside of the facilitator or psilocybin service center, I must be provided with a disclosure form that describes who will receive the data and how it will be used, and that I have the opportunity to opt-out of having my de-identified data provided to third parties .¶
16. ____I understand data that may be used to identify me as a client will only be shared to the extent permitted or required by law. Specifically, ORS 475A.450 allows disclosure in the following circumstances:¶
(1) When the client or a person authorized to act on behalf of the client gives consent to the disclosure;¶
(2) When the client initiates legal action or makes a complaint against the psilocybin service center operator, the psilocybin service facilitator, or the employee;¶
(3) When the communication reveals the intent to commit a crime harmful to the client or others;¶
(4) When the communication reveals that a minor may have been a victim of a crime or physical, sexual or emotional abuse or neglect; or¶
(5) When responding to an inquiry by the Oregon Health Authority made during the course of an investigation into the conduct of the psilocybin service center operator, the psilocybin service facilitator, or the employee under ORS 475A.210 to 475A.722.¶
17. ____I understand that my facilitator may take short restroom breaks during my administration session.¶
18. ____ I understand that for my own safety, leaving a psilocybin service center during an administration session once it has begun is strongly discouraged. Doing so could lead to safety and legal risks.¶
19. ____ I understand and have been informed of the potential benefits, risks, and complications of psilocybin services with my facilitator to the extent that they are known.¶
20. ____ My facilitator has shared 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. ____I understand that activation times for psilocybin products are variable and cannot be accurately predicted.
¶
245. ____I acknowledge that the risks and benefits of consuming doses greater than 35 mg of psilocybin analyte are unknown.¶
256. ____If consuming whole fungi during an administration session, I understand that psilocybin content can vary between individual fruiting bodies.¶
267. ____I understand that the risks and benefits of repeated psilocybin use are unknown.¶
278. ____I understand that a facilitator has a duty to call emergency services if required and a client assumes responsibility for costs of emergency services.¶
289. ____I understand that I will be required to identify an emergency contact and a facilitator or service center may contact this person in the event of a medical or other emergency.¶
29¶
30. ____ I understand that I may be charged a cancellation fee if I cancel a scheduled preparation, administration or integration session.¶
301. ____I understand that I have the right to choose my facilitator and if a facilitator has supervisory, evaluative, or other authority over me, I will be provided an opportunity to receive psilocybin services from another facilitator.¶
32. ____I understand that service center licensee representatives may be present during my administration session to assist licensed facilitators with operations. ¶
_____¶
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.¶
(5) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

AMEND: 333-333-5050

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5050-Amends client information form rule to clarify that the form must be stored at the service center.

CHANGES TO RULE:

333-333-5050
Client Information Form
(1) A client must review and complete a client information form in coordination with a facilitator prior to participating in an administration session. This requirement must be satisfied by using the designated form published by the ~~Authority~~Oregon Health Authority (Authority) on its website.¶
(2) A facilitator must provide a client information form in other languages or accessible formats upon a client's request. If a facilitator is unable to provide a translated or accessible client information form upon a client's request, they may not conduct an administration session with the client.¶
(3) The client information form must include the following questions, and a client must answer each question by indicating "yes" or "no":¶
(a) Have you taken the prescription drug Lithium in the last 30 days?¶
(b) Are you currently being treated by a medical, clinical or other healthcare provider for a medical, mental health, or behavioral health condition?¶
(c) Have you ever had an allergic reaction to consuming mushrooms or other fungi?¶
(d) Are you currently taking any 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) Are you having thoughts of causing harm, or wanting to cause harm, to self or others?¶
(i) Do you have a history of causing harm, or wanting to cause harm, to self or others?¶
(j) Have you ever been diagnosed with active psychosis or treated for active psychosis?¶
(k) Are you pregnant or feeding with breast milk?¶
(l) Do you require any assistive mobility devices?¶
(m) Will you require assistance to consume psilocybin products?¶
(n) Would you like to share any other conditions, sensitivities or health concerns with your facilitator?¶
(4) The client information form must include the following questions, and a client may provide a narrative answer to these questions.¶
(a) Would you like to share anything about your medical history, including current 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 that you feel would be helpful for an administration session?¶
(c) Would you like to share anything about specific behaviors, internal or external stimuli ("triggers") that could cause you to be uncomfortable during an administration session?¶
(d) Would you like to share anything about your history of substance use, including current substance use, that you feel would be helpful for an administration session?¶
(e) Would you like to share any past experiences with psychedelics or altered states of consciousness?¶
(f) Would you like to share any information about your relationships, your living situation, or your educational or work environment that may be affected by your administration session or may require additional safety or support planning?¶
(5) A facilitator must evaluate the answers to questions listed in section (3) of this rule to determine whether the client should participate in an administration session.¶
(a) If a client answers yes to question (3)(a), the client may not participate in an administration session.¶
(b) If a client answers yes to question (3)(b), a facilitator shall encourage the client to consult a medical, clinical or other healthcare provider regarding the risk of consuming psilocybin.¶
(c) If a client answers yes to question (3)(c), the client should be encouraged to consume an alternative psilocybin product rather than whole fungi or homogenized fungi during the administration session.¶
(d) If a client answers yes to question (3)(d), a facilitator should encourage the client to schedule their administration session at a time that allows them to participate without taking 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~~and 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), the client may not participate in an administration session.¶
(i) If a client answers yes to question (3)(i), a facilitator shall encourage the client to consult with a medical or clinical provider regarding the risk of consuming psilocybin.¶
(j) If a client answers yes to question (3)(j), the client may not participate in an administration session.¶
(k) If a client answers yes to question (3)(k), the facilitator must inform the client that the risks of consuming psilocybin while pregnant or feeding with breast milk are unknown.¶
(l) If a client answers yes to question (3)(l), the client and facilitator must work together to create a written plan that describes how the client will safely exit the service center in the event that an emergency occurs during their administration session.¶
(m) If a client answers yes to question (3)(m), the client and facilitator must work together to identify an appropriate client support person who will be present to assist the client with consuming psilocybin products during their administration session.¶
(n) If a client answers yes to question (3)(n), the client and facilitator must work with the client to create a written plan that describes how the facilitator will take reasonable steps to accommodate the conditions, sensitivities or health concerns identified by the client. For example, if a client has a compromised immune system, the written plan will describe efforts to prevent the transmission of viruses and bacteria.¶
(6) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

AMEND: 333-333-5070

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5070-Amends rule on client support persons to clarify that plans must be stored at the service center.

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~~Oregon Health Authority (Authority) that contains the following information:¶
(a) The name of the interpreter or client support person who will attend the session.¶
(b) The specific purpose for which the interpreter or client support person will be present, including but not limited to identifying any 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.¶
(6) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.¶
(7) Facilitators and licensee representatives of a service center are prohibited from acting as client support person during an administration session for which they are acting as a facilitator or licensee representative. ¶
(8) Service centers and facilitators may not:¶
(a) Provide nor compensate client support persons who attend client administration sessions. ¶
(b) Require a client to a use a specific client support person.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

AMEND: 333-333-5080

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5080- Amends rule on safety and support plans to clarify that plans must be stored at the service center.

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 must include contact information for a person to be contacted in the event the client experiences a medical or other emergency.¶
(3) Safety and support plans may not be changed during an administration session.¶
(4) Client records described by this rule must be stored at the service center where the client participates or intends to participate in an administration session or on cloud-based platforms as required by OAR 333-333-4820.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

AMEND: 333-333-5100

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5100-Amends record keeping rule to reference confidentiality standards and correct drafting error.

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 t~~These records must be ~~also~~shared with the service center and stored at the service center where the client received services as required by OAR 333-333-4820:¶
(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~~e) 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~~f) Any deviation from the client's transportation plan.¶
(~~h~~g) Any adverse ~~reactions that required medical attention or emergency service~~behavioral reactions or adverse medical reactions, including a record of severe adverse reactions.¶
(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 as required by OAR 333-333-4820:¶
(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

AMEND: 333-333-5120

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5120-Amends facilitator conduct rule to clarify requirements for using nondirective facilitation.

CHANGES TO RULE:

333-333-5120
Facilitator Conduct
(1) Facilitators have a duty to put clients' interest above their own and to use a standard of care that other reasonable facilitators would use under similar circumstances.¶
(2) A facilitator shall not make any misrepresentations to clients regarding psilocybin products or services, the requirements of ORS 475A.210 to 475A.722 and these rules, or the facilitator's qualifications and experience.¶
(3) A facilitator must use a nondirective facilitation approach to providing psilocybin services to clients during preparation, administration and integration sessions. ¶
(~~3~~4) 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~~5~~) A facilitator shall determine whether they are able to provide psilocybin services to a client. If a facilitator determines that they are unable to provide services to a client for any reason, the facilitator may refer the client to another facilitator.¶
(~~5~~6) If a facilitator has supervisory, evaluative, or other authority over a client, the facilitator shall provide the client an opportunity to receive psilocybin services from another facilitator.¶
(~~6~~7) Facilitators may provide supportive touch during administration sessions when requested by the client and with the client's prior written consent.¶
(a) Supportive touch is limited to hugs or placing hands on a client's hands, feet or shoulders. A facilitator shall not use any other forms of touch, nor permit another person to use any other form of touch during an administration session.¶
(b) Clients participating in a group administration session may provide prior written consent to authorize supportive touch from other clients participating in the administration session. Supportive touch is limited to hugs or placing hands on a client's hands, feet or shoulders.¶
(~~7~~8) 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~~9) 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~~10) A facilitator shall not engage in any romantic relationships, sexual contact, or sexual intimacy with clients, or clients' partners or immediate family members, for a period of one year following the last date that the facilitator provided psilocybin services to the client.¶
(1~~0~~1) A facilitator may not engage in any financial transactions with clients or the client's partners or immediate family members that violate a facilitator's duty to place client's interests above their own as required by section (1) of this rule.¶
(1~~1~~2) If a facilitator is a mandatory reporter of abuse under Oregon law, the facilitator must disclose their status and obligations to a client at the beginning of the client's first preparation session.¶
(1~~2~~3) The requirements of this rule apply to all facilitators, regardless of whether facilitator is also a licensee representative of a service center.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

AMEND: 333-333-5140

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5140-Amends rule to correct drafting error.

CHANGES TO RULE:

333-333-5140
Duty to Report Misconduct
(1) Any licensee, licensee 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~~Oregon Health Authority (Authority) within 24 hours.¶
(2) Any licensee, licensee 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 a 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

AMEND: 333-333-5150

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5150-Amends transportation plan rule to clarify that plans must be stored at the service center.

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 make reasonable efforts to resolve the safety issue.¶
(4) If facilitators are unable to resolve safety issues caused by clients failure to follow their transportation plan after making reasonable efforts required by section (3) of this rule, facilitators must contact appropriate emergency services.¶
(5) If a client is unable to follow their transportation plan, a facilitator must make reasonable efforts to arrange for alternative transportation.¶
(6) A facilitator must document in writing and retain documentation for all instances in which a client does not follow their transportation plan.¶
(7) All client records, including any copies of client records, described by this rule must be stored at the service center where the client participates or intends to participate in an administration session as required by OAR 333-333-4820.
Statutory/Other Authority: ORS 475A.235, ORS 475A.340
Statutes/Other Implemented: ORS 475A.340

AMEND: 333-333-5170

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5170-Amends rule to clarify requirements for transferring psilocybin products to clients.

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 licensee representatives of a service center. Licensee representatives of a service center may only sell and transfer products to clients consistent with dosage, product type and method of consumption determined by a facilitator and client during the client's preparation session. ¶
(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 licensee representative of a service center must transfer psilocybin products to clients within a designated administration area and clients must consume psilocybin products following transfer.¶
(4) A licensee representative of a service center must transfer psilocybin products to clients in sealed client packaging. Facilitators who are also licensee representatives of a service center are prohibited from transferring products to clients while acting as a licensed facilitator.¶
(5) A licensee representative of a service center must ensure that a client consumes psilocybin products promptly after psilocybin products are transferred to the client.¶
(6) A licensee 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 licensee 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~~m) and OAR 333-333-5070.¶
(7) Facilitators are prohibited from transferring, preparing or otherwise handling psilocybin products, unless the facilitator is also a licensee 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 licensee representative of a service center.¶
(9) Clients may mix psilocybin products with packaged food or packaged beverages prior to consuming, as long as the packaged food or packaged beverage was unopened prior to mixing. Potable water is not required to be packaged.¶
(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

AMEND: 333-333-5200

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5200-Amends client administration session rule to clarify requirements for service center representatives who will be present during an administration session.

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 licensee representative is available to monitor clients.¶
(6) In addition to a facilitator conducting the administration session, at least one licensee representative of a service center license must be present on the licensed premises at all times when an administration session is taking place at a service center. ~~If the additional~~The licensee representative required by this rule may take restroom breaks of approximately five minutes or less during an administration session as long as they remain on the licensed premises and adequate measures to prevent unauthorized access to the licensed premises are in place as required by OAR 333-333-4550. Licensee representatives may traverse through client administration areas to access restrooms as long as they do not interfere with client administration sessions. If the licensee representative required by this rule holds a facilitator licensee, they are prohibited from transferring, selling or otherwise handling any psilocybin product while they are facilitating a preparation, administration or integration session.¶
(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 licensee representatives of a service center may be present during an administration session.¶
(9) Licensee representatives of a service center who are present during an administration session: ¶
(a) May not provide psilocybin services.¶
(b) May only be present to assist with operations and shall not interfere or otherwise participate in the administration session.¶
(c) May not share or disclose any information regarding clients' participation in psilocybin services without the client's prior written consent.¶
(10) If licensee representatives of a service center are scheduled to be present during an administration session, every client participating in the administration session must receive notice of the names of the licensee representatives and have an opportunity to meet the licensee representatives who may be present prior to the administrative session beginning. ¶
(11) A service center may not host administrative sessions for more than 100 clients at any given time regardless of whether the clients are participating in separate individual or group administration sessions.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.340

AMEND: 333-333-5240

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5240-Amends rule on consumption limits to clarify that psilocybin products may be transferred in multiple packages and revises requirements for sale and transfer of secondary doses.

CHANGES TO RULE:

333-333-5240
Consumption Limits
(1) A service center licensee or licensee representative may not allow a client to consume more than a total of 50 mg of psilocybin analyte during an administration session. Both initial doses and secondary doses described in this rule may be transferred and consumed in multiple packages. For example, a dose consisting of 20 mg of psilocybin analyte could be transferred to a client in the form of two packages containing 10 mg of psilocybin of analyte. ¶
(2) A service center licensee or licensee representative may permit a client to consume ~~a~~ secondary doses 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) If a client wants the option to consume ~~a~~ secondary doses during their administration session, up to a total of 50 mg of psilocybin analyte, a service center must:¶
(a) Receive written consent from the client prior to the beginning of their administration session.¶
(b) Require the client to purchase and take possession of ~~the~~ secondary doses prior to beginning their administration session.¶
(c) Require the client to store ~~the~~ secondary doses at a designated secured location outside of a limited access area and within the service center's licensed premises.¶
(d) Require the client, or a client support person, to retrieve ~~the~~ secondary doses from the designated location and consume without assistance ~~if they~~from a licensee representative or facilitator if the client chooses to consume the secondary dose.¶
(e) Ensure that secondary doses remain in sealed client packaging until consumed. ¶
(~~e~~f) Require the client to return the secondary dose to the service center at the conclusion of their administration if they do not consume it during their administration session.¶
(4) A service center licensee or licensee representative may decline to make secondary doses available for purchase for any reason. ¶
(5) During an administration session, a service center licensee representative, in consultation with the client's facilitator, may decline to make a secondary dose available to a client who has purchased the secondary dose pursuant to section (3) of this rule. A service center must provide clients a refund for the purchase price of any secondary dose that is not made available to clients. ¶
(6) A service center must provide clients a refund for the purchase price of any secondary dose that is not consumed and remains in its original sealed client packaging. After providing a refund, a service center may make the product in its original sealed client packaging available for sale to other clients.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.340, ORS 475A.504

AMEND: 333-333-5250

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5250-Amends duration of administration session rule to clarify requirements for sessions that extend beyond a service center's hours of operation.

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 less than 2.5 mg of psilocybin analyte, the minimum duration of the administration session shall be one hour for the client's initial administration session at a service center. Except as described in section (2) of this rule, after completing an initial administration session at the service center, the minimum duration shall be 30 minutes when the client participates in any subsequent administration session at the same service center within a period of 12 months following the initial administration session.¶
(b) For clients consuming equal or greater than 2.5 mg and less than 5 mg of psilocybin analyte, the minimum duration of the administration session shall be one hour.¶
(c) 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.¶
(d) 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.¶
(e) 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.¶
(f) For clients consuming equal or greater than 35 mg and up to 50 mg of psilocybin analyte, the minimum duration of the administration session shall be six hours.¶
(2) Notwithstanding subsection (1)(a) of this rule, the minimum duration of an administration session shall be one hour for clients consuming whole ~~dried~~ fungi that contains less than 2.5 mg of psilocybin analyte.¶
(3) Upon or after the conclusion of the minimum duration period described in sections (1) and (2) of this rule, a facilitator, in consultation with the client, shall determine whether the administration session should be concluded. If the facilitator and client determine that continuing the administration session is not required to ensure the safety of the client and the public, the administration session may be concluded.¶
(4) If following the consultation described in section (3) of this rule, a facilitator determines that it is appropriate to continue the administration session beyond 11:59 PM local time, the ~~facilitator and~~ service center where the client received services ~~shall notify the Authority~~, in consultation with the facilitator, shall notify the Oregon Health Authority (Authority) in a form and manner prescribed by the Authority no later than ~~11~~4:00 ~~AM~~PM local time the next calendar day. Notices required by this section must include:¶
(a) Start and end time of the administration session.¶
(b) Amount each client consumed during the administration session, including any secondary doses. ¶
(c) Minimum duration of the administration session required by OAR 333-333-5250.¶
(d) Whether the administration session was a group session or an individual session. ¶
(e) For group sessions, the number of clients participating in the administration session. ¶
(f) The names and worker permit numbers, if applicable, of all facilitators, licensee representatives and other authorized individuals who were present at the licensed service center after 11:59 PM. ¶
(5) A facilitator shall record and retain the time and date that each administration session began and concluded.¶
(6) 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.¶
(7) 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

AMEND: 333-333-5260

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-5260-Amends integration session rule to clarify who may be present during an integration session.

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 facilitation approach to an integration session and comply with OAR 333-333-5130 during an integration session.¶
(3) Except practicum site supervisors, lead educators and students participating in a practicum with the client's prior written consent, only clients, facilitators and client support persons may be present during an integration session. ¶
(~~3~~4) 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.¶
(5) Integration sessions may be offered in person or virtually using video conferencing technology.
Statutory/Other Authority: ORS 475A.235
Statutes/Other Implemented: ORS 475A.235, ORS 475A.340

AMEND: 333-333-6000

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-6000-Amends prohibited conduct rule to clarify prohibition of permitting disorderly conduct.

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 licensee 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, licensee 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~~Oregon Health Authority (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, licensee representative, or permittee may consume any intoxicants while on duty.¶
(b) No licensee, licensee 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, licensee 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. "Intoxicants" does not include caffeine and nicotine.¶
(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 and is responsible for addressing disorderly activity or activity that is unlawful under Oregon state law on the licensed premises ~~or in areas adjacent to or outside~~. This section applies to all disorderly or unlawful activity that occurs on the licensed premises ~~under the control of the licensee.~~regardless of whether the activity was caused by a licensee representative, a client, a facilitator or other individuals. ¶
(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, religion, language, disability, age, gender, gender identity, sexual orientation, or social class.¶
(C) "Permitting" means that the licensee or permittee is aware of the activity and failed to take reasonable steps to address it. ¶
(~~C~~D) "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.¶
(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

AMEND: 333-333-6030

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-6030-Amends rule to clarify that laboratory licenses may not receive psilocybin products from unlicensed sources.

CHANGES TO RULE:

333-333-6030
Laboratory Licensee Prohibited Conduct
(1) In addition to the prohibitions set forth in OAR 333-333-6000, a laboratory licensee may not:¶
(a) Perform any required psilocybin sampling or testing using any sampling or testing methods or equipment not permitted under the laboratory's accreditation through the Oregon Environmental Laboratory Accreditation Program.¶
(b) Perform any required psilocybin sampling or testing for any licensed psilocybin manufacturer in which the laboratory licensee has a financial interest.¶
(c) Receive, possess or perform sampling and testing of psilocybin products from any source other than a licensed premises as allowed by these rules. ¶
(d) Engage in any activity that violates any provision of ORS chapter 475A, OAR chapter 333, division 64 as applicable, or these rules.¶
(2) Nothing in these rules prohibits testing laboratory licensees from possessing psilocybe cubensis for purposes of method validation ~~and testing. ¶~~
~~(3) The~~.¶
(3) The Oregon Health Authority may suspend or revoke a laboratory license for any violation of ORS chapter 475A, OAR chapter 333, division 64, or these rules. The licensee has a right to a hearing under the procedures of ORS chapter 183.
Statutory/Other Authority: ORS 475A.235, ORS 475A.594
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-6040

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-6040-Amends dishonest conduct rule to clarify exception for statements that are supported by scientific evidence.

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~~Oregon Health Authority (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 or services 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 effect~~or services have curative or therapeutic effects unless the representation or claim is 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.¶
(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

AMEND: 333-333-7020

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-7020¬-Amends rule on ordering compliance tests to reflect product tracking system functionality.

CHANGES TO RULE:

333-333-7020
Ordering Tests
(1) A manufacturer must provide to a laboratory, prior to the laboratory taking samples, the following information:¶
(a) The manufacturer's license number and endorsement type;-¶
(b) The manufacturer's name, address and contact information;¶
(c) Type of psilocybin product;¶
(d) ~~Batch numbers to be sampled;¶~~
~~(e) Harvest lot~~Unique identification numbers ass~~ociated with the batch number, if applicable;¶~~
~~(f) Process lot number associated with the batch number, if applicab~~igned to products that will be sampled;¶
(g~~e~~) Total mass or volume of each batch to be sampled; and¶
(~~h~~f) Identification of tests requested.¶
(2) If the manufacturer informs a laboratory that a psilocybin product is being re-sampled after a failed test, the manufacturer must provide the laboratory with documentation of the failed test.-¶
(3) A manufacturer is responsible for ordering the compliance tests necessary to comply with these rules.-¶
(4) A manufacturer may not order more than one compliance test for the same harvest lot, process lot or psilocybin product except as allowed under OAR 333-333-7120.-¶
(5) A manufacturer violates these rules if they:¶
(a) Fail to provide information required in these rules to a laboratory.¶
(b) Submit false or misleading information to a laboratory.-¶
(6) Tests ordered under these rules expire after one year. If a test has expired, the psilocybin product must be tested again before it can be sold to a client, transferred to another licensee, or converted to another product type.
Statutory/Other Authority: ORS 475A.235, ORS 475A.590
Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

AMEND: 333-333-7030

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-7030-Amends species testing rule to correct drafting error and clarify frequency of required testing.

CHANGES TO RULE:

333-333-7030
Speciation Testing
(1) A manufacturer must order a test for a batch taken from the first harvest lot recorded in a calendar year to ensure that the lot con~~sists only of~~tains Psilocybe cubensis. This test must be performed prior to transferring the harvest lot to another licensee or converting the harvest lot to a~~nother~~ psilocybin extract or edible psilocybin product ~~type.~~.¶
(2) Following the test described in section (1) of this rule, a manufacturer must order tests for ~~one~~the first batch harvested in each calendar month that a harvest lot is recorded to ensure that the lot con~~sists only of~~tains Psilocybe cubensis.¶
(3) A batch fails speciation testing if the test demonstrates that the ~~fungi is a speci~~batch does not~~her tha~~ contain Psilocybe cubensis.¶
(4) If a batch fails speciation testing, a manufacturer must order tests for every harvest lot for a period of 12 months following the failed test to ensure that batches con~~sist only of~~tain Psilocybe cubensis. This test must be performed prior to transferring the harvest lot to another licensee or converting the harvest lot to a~~nother~~ psilocybin extract or edible psilocybin product ~~type.~~.¶
(5) In addition to the requirements of section (1) of this rule, a manufacturer must submit one or more batches from a harvest lot or process lot for speciation testing upon written request by the Oregon Health Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.590
Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

AMEND: 333-333-7040

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-7040-Amends potency testing rule to correct drafting error.

CHANGES TO RULE:

333-333-7040
Potency Testing
(1) A manufacturer must order tests for every batch of finished psilocybin product from a harvest lot or process lot to determine the concentration (potency) of psilocybin and psilocin in the product.¶
(2) A process lot of homogenized fungi, psilocybin extract or edible psilocybin product fails potency testing if the amount of psilocybin or psilocin between primary and duplicate samples taken from the batch exceeds 20 percent relative ~~standard deviation~~percent difference between sample~~ increments~~.¶
(3) In addition to the requirements of section (1) of this rule, a manufacturer must submit one or more batches from a harvest lot or process lot for potency testing upon written request by the Oregon Health Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.590
Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

AMEND: 333-333-7060

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-7060-Amends pesticide testing rule to correct drafting error.

CHANGES TO RULE:

333-333-7060
Pesticide Testing
(1) A ~~manufacturer~~licensee must submit one or more batches from a harvest lot or process lot for pesticide testing upon written request by the Oregon Health Authority.¶
(2) A batch fails pesticide testing if the test detects the presence of a pesticide above action levels in any sample, including a field duplicate:¶
(a) During an initial test where no reanalysis is requested; or¶
(b) Upon reanalysis as described in OAR 333-333-7120.¶
(3) If a sample from a harvest lot or process lot fails pesticide testing, the batch may not be remediated and must be destroyed.
Statutory/Other Authority: ORS 475A.235, ORS 475A.590
Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

AMEND: 333-333-7070

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-7070-Amends contaminant testing rule to correct drafting error.

CHANGES TO RULE:

333-333-7070
Contaminant Testing
(1) A ~~manufacturer~~licensee must submit one or more batches from a harvest lot or process lot for contaminant testing upon written request by the Oregon Health Authority.¶
(2) A psilocybin product required to be tested for contaminants under these rules must be sampled using appropriate aseptic technique and tested for total coliform count.¶
(3) If the presence of any fecal coliforms is detected the sample must be assessed for Escherichia coli (E. Coli)¶
(4) A batch fails microbial contaminant testing if the presence of E. Coli at more than 100 colony forming units per gram is detected in a sample.¶
(5) A psilocybin product required to be tested for contaminants may also be tested for aflatoxins and other harmful mycotoxins.¶
(6) A psilocybin product fails testing for aflatoxins and other harmful mycotoxins if the tests detect mycotoxins at levels that are unsafe for human consumption.¶
(7) If a sample from a batch of psilocybin product fails contaminant testing, the batch may not be remediated and must be destroyed.
Statutory/Other Authority: ORS 475A.235, ORS 475A.590
Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

AMEND: 333-333-7080

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-7080-Amends heavy metals testing rule to correct drafting error.

CHANGES TO RULE:

333-333-7080
Heavy Metals Testing
(1) A ~~manufacturer~~licensee must submit one or more batches from a harvest lot or process lot for heavy metal testing upon written request by the Oregon Health Authority. ¶
(2) A harvest lot or process lot required to be tested for heavy metals may be tested for lead, cadmium, mercury and arsenic. ¶
(3) A batch fails heavy metal testing if the presence of metals above the limits in section (4) of this rule are detected in any sample, including a field duplicate:¶
(a) During an initial test where no reanalysis is requested; or¶
(b) Upon reanalysis as described in OAR 333-333-7120.¶
(4) The limits for heavy metal testing are:¶
(a) Lead (Pb) above .5 g/g.¶
(b) Cadmium (Cd) above .2 g/g.¶
(c) Arsenic (As) above .2 g/g.¶
(d) Mercury (Hg) above .1 g/g.¶
(5) If a sample from a batch of psilocybin product fails heavy metal testing, the batch may not be remediated and must be destroyed.
Statutory/Other Authority: ORS 475A.235, ORS 475A.590
Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

AMEND: 333-333-7090

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-7090-Amends batch requirement rule to reflect product tracking system functionality.

CHANGES TO RULE:

333-333-7090
Psilocybin Batch Requirements
(1) A manufacturer must separate each harvest lot of dried whole fungi into batches no larger than one kilogram.~~.~~¶
(2) A process lot for psilocybin extracts, homogenized fungi or edible psilocybin products is considered a batch.¶
(3) A manufacturer must ass~~ign~~ociate each batch with a unique ~~batch~~identification number and that unique ~~batch~~identification number must be:~~.~~¶
(a) ~~Documented and maintained in the manufacturer's records for at least three years and available to the Authority upon request; ¶~~
~~(b)~~ Provided to the individual responsible for taking samples; and¶
(~~c~~b) Included in the batch labels required by OAR 333-333-7110.~~¶~~
~~(4) A manufacturer may not reuse a unique batch number.~~
Statutory/Other Authority: ORS 475A.235, ORS 475A.590
Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

AMEND: 333-333-7120

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-7120-Amends failed test rule to correct drafting error.

CHANGES TO RULE:

333-333-7120
Failed Test Samples
(1) If a sample or a field duplicate sample (collectively referred to as "sample" for purposes of this rule) fails any initial test, the laboratory that did the testing may reanalyze the sample. The laboratory that did the initial test may not subcontract the reanalysis. If a primary sample or a field duplicate sample fails, both must be reanalyzed. If the sample passes, another laboratory must resample the batch and confirm that result for the batch to pass testing.¶
(a) If a manufacturer wishes to have a sample reanalyzed, the manufacturer must request a reanalysis within seven calendar days from the date the laboratory sent notice of the failed test to the manufacturer. The reanalysis must be completed by the laboratory within 30 days from the date the reanalysis was requested.¶
(b) If a manufacturer has requested a reanalysis in accordance with subsection (1)(a) of this rule and the sample passes, the manufacturer has seven calendar days from the date the laboratory sent notice of the passed test to request that another laboratory resample the batch and confirm the passed test result. The retesting must be completed by the second laboratory within 30 days from the date the retesting was requested.¶
(c) A manufacturer must inform the ~~Authority~~Oregon Health Authority (Authority) immediately, of the following, in a manner prescribed by the Authority:¶
(A) A request for reanalysis of a sample;¶
(B) The testing results of the reanalysis;¶
(C) A request for retesting; and¶
(D) The results of retesting.¶
(2) If a sample fails a test or a reanalysis under section (1) of this rule the batch:¶
(a) May be remediated in accordance with these rules; or¶
(b) If it is not or cannot be remediated under this rule, must be destroyed in a manner specified by the Authority.¶
(3) If a manufacturer is permitted to remediate under this rule, the manufacturer must provide notice to the Authority of the registrant's intent to remediate.¶
(4) A psilocybin extract that is permitted to undergo remediation cannot be further processed into a psilocybin product during the remediation process.¶
(5) Failed microbiological contaminant testing. If a sample from a batch psilocybin product fails microbial contaminant testing the batch may not be remediated and must be destroyed as ordered by the Authority. ¶
(6) Failed solvent testing. ¶
(a) If a sample from a batch fails solvent testing the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.¶
(b) A batch that is remediated in accordance with subsection (a) of this section must be re-sampled and re-tested in accordance with these rules and must be tested if not otherwise required for that product under these rules~~,~~ for solvents ~~and pesticides~~.¶
(c) A batch that fails solvent testing that is not remediated or that if remediated fails testing must be destroyed in a manner specified by the Authority.¶
(7) Failed pesticide testing. If a sample from a batch of psilocybin product fails pesticide testing the batch may not be remediated and must be destroyed as ordered by the Authority¶
(8) Failed heavy metal testing. If a sample from a batch of psilocybin product fails heavy metal testing the batch may not be remediated and must be destroyed as ordered by the Authority¶
(9) Failed potency testing. A psilocybin product that fails potency testing under OAR 333-333-7040 may be re-mixed in an effort to meet the standards in OAR 333-333-7040. A psylocibin product that is re-mixed must be re-sampled and re-tested in accordance with these rules.¶
(10) If a sample fails a test after undergoing remediation as permitted under this rule the batch must be destroyed in a manner approved by the Authority.¶
(11) A manufacturer must inform a laboratory prior to samples being taken that the batch has failed a test and is being retested after undergoing remediation.¶
(12) A manufacturer must document all sampling, testing, remediation and destruction that are a result of failing a test under these rules.¶
(13) If a batch fails a test under these rules a manufacturer:¶
(a) Must store and segregate the batch in a secure area and label the batch clearly to indicate it has failed a test

and the label must include a test batch number.¶
(b) May not remove the batch from the registered premises without permission from the Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.590
Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

AMEND: 333-333-7150

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-7150-Amends rule on quality control testing to clarify that test results may not be used on labels.

CHANGES TO RULE:

333-333-7150
Quality Control and ~~Research and~~Product Development Testing
(1) A manufacturer may request that a laboratory conduct testing for the purpose of assuring quality control or ~~research and~~product development, except as provided in section (2) of this rule.¶
(2) A manufacturer may not request that a laboratory conduct pesticide testing on psilocybin products for the purpose of quality control or ~~for research and~~product development. A pesticide test is always a compliance test.¶
(3) A manufacturer that submits a psilocybin product for quality control or ~~research and~~product development testing is not subject to OAR 333-333-7010 to OAR 333-333-7120.¶
(4) A laboratory result from a quality control or ~~research and~~product development test cannot be used as a compliance test result and may not be displayed on client packaging or labels. A psilocybin product that has undergone a quality control or ~~research and~~product development test may not be transferred or sold without undergoing required compliance tests.¶
(5) Manufacturers must retain all quality control and ~~research and~~product development test results for at least two years and provide copies of such results upon request to the Oregon Health Authority.
Statutory/Other Authority: ORS 475A.235, ORS 475A.590
Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

AMEND: 333-333-8000

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-8000-Amends waste management rule to clarify requirements for storing and disposing of psilocybin waste.

CHANGES TO RULE:

333-333-8000
Waste Management
(1) A manufacturer, service center or laboratory licensee must:¶
(a) S 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:¶
(Aa) Solid waste requirements in ORS chapter 459 and OAR chapter 340, divisions 93 to 96.¶
(Bb) Hazardous waste requirements in ORS chapter 466 and OAR chapter 340, divisions 100 to 106.¶
(Cc) Wastewater requirements in ORS chapter 468B and OAR chapter 340, divisions 41 to 42, 44 to 45, 53, 55 and 73.¶
(b2) Store pPsilocybin 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 harveconsisting of psilocybin products that have not been rendered unfit for human consumption must be securely st-or process lot has been recorded and disposed, or if on the waste was previously designated as a finished psilocybin product, licensed premises or transferred to another licensee must document: ¶
(a) A reason for the waste in thfor disposal. Licensees must store 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 itemswaste in either a limited access area or a locked waste receptacle located on the licensed premises until it is disposed.¶
(3) Psilocybin waste consisting of psilocybin products must bethat have been rendered unfit for consumption, securely stored, and disposed of on may be stored prior to final disposal in a locked dumpster or other locked receptable outside of the licensed premises or transferred to another licensee for disposalmay be stored pursuant to section (2) of this rule. Psilocybin products may be rendered unusable by composting, mixing with inactive ingredients, or any other method which renders the product unfit for consumption but does not pose a safety risk for accidental consumption. If waste consisting¶
(4) Manufacturers may dispose of waste that is a byproduct of cultivation ofr psilocybin products has been rendered unfit for consumption and is placed in a dumpster or other receptable outside of the licensed premises prior to final disposal, the area or receptacle must be locked to prevent unauthorized access. rocessing by composting that waste in a secured area on the licensed premises subject to the requirements of OAR 333-333-2010.¶
(5) If a licensee generates psilocybin waste after a harvest or process lot has been recorded, or if psilocybin waste was previously designated as a finished psilocybin product, the licensee must document:¶
(a) A reason for the waste in the product tracking system.¶
(b) The exact time and method of destruction in the product tracking system.¶
(46) All psilocybin waste must be disposed of in a manner that effectively prevents spontaneous growth of fruiting bodies or mycelium containing psilocybin. For example, through a controlled composting process or by placing waste in a sealed container.¶
(57) Material that has been designated as psilocybin 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

AMEND: 333-333-8100

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-8100-Amends product transportation rule to clarify requirements for unscheduled stops.

CHANGES TO RULE:

333-333-8100
Product Transportation
(1) Psilocybin products transferred by licensees.¶
(a) Psilocybin products transferred between licensed premises may only be transported by a licensee or licensee representative of the originating or receiving licensee.¶
(b) Samples of psilocybin products obtained by a laboratory licensee pursuant to OAR 333-333-7100 may only be transported by the laboratory licensee or a laboratory licensee representative of the receiving laboratory.¶
(c) Every manufacturer, service center and laboratory licensee must maintain a list of licensee representatives authorized to transport product or travel in vehicles transporting product.¶
(d) Psilocybin products transferred between licensed premises must not exceed possession quantities described in OAR 333-333-2200.¶
(2) Physical transport requirements for licensees.¶
(a) A licensee representative of a manufacturer, service center or laboratory license who transports psilocybin products on behalf of a licensee must have a valid driver license.¶
(b) A manufacturer, service center or laboratory licensee must:¶
(A) Store psilocybin products in the delivery vehicle within a locked, secured area, shielded from view from the exterior of the vehicle.¶
(B) When transporting perishable psilocybin products, provide appropriate temperature control within the delivery vehicle.¶
(C) Use a delivery vehicle that is equipped with an alarm system and is insured at or above the legal requirements in Oregon.¶
(D) Deliver psilocybin products to all destinations and return any remaining psilocybin products to the licensed premises of origin within 60 hours of initial departure and notify the ~~Authority~~Oregon Health Authority (Authority) immediately in the manner prescribed by the Authority if they are unable to satisfy this requirement due to inclement weather, mechanical failure, or other unforeseen circumstances.¶
(E) Document all overnight stops in the planned route of the manifest and include the address, estimated arrival time at, and estimated departure time from the location of each overnight stop.¶
(F) Package all psilocybin products for transport in shipping receptacles and assign and affix a unique identification ~~tag~~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 p~~silocybin~~roduct 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~~as soon as it is safe to do so of every stop at an unlicensed location that exceeds two hours in duration and is not already listed in the manifest route.¶
(K) Upon the Authority's request, make the vehicle and its contents available for inspection if the delivery vehicle is stopped at an unlicensed location.¶
(c) A licensee may not:¶
(A) Make any unnecessary stops in between the originating and destination locations except to other licensed premises receiving inventory as described on the manifest;¶
(B) Remove psilocybin products from the vehicle until they arrive at the destination recorded in the manifest. Licensees or laboratory licensees may not transfer psilocybin products to, nor store psilocybin products in or at any unlicensed premises;¶
(C) Void or change a manifest after departing the originating licensed premises; or¶
(D) Travel with any persons not listed on the manifest.¶
(d) Any vehicle that meets the requirements of this rule may be used as a delivery vehicle.¶
(3) P~~silocybin~~roduct 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 p~~silocybin~~roduct 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 p~~silocybin~~roduct tracking system.¶
(B) The destination location's license number and address as it appears in the p~~silocybin~~roduct tracking system.¶
(C) The unique identification number, product type, and quantity of each psilocybin product.¶
(D) The actual date and estimated time of departure.¶
(E) Location and duration of time for any overnight stop.¶
(F) The arrival date and estimated time of arrival or completion of delivery.¶
(G) The delivery vehicle make, model, and license plate number.¶
(H) The name, contact information, worker permit number and signature of any licensee representatives accompanying the transport.¶
(b) A physical, printed copy of the generated manifest must accompany every transport of psilocybin products.¶
(4) P~~silocybin~~roduct tracking system requirements when receiving psilocybin products. Upon receipt of a delivery of psylocibin products, the receiving licensee must:¶
(a) Record each applicable unique identification number as accepted and received or rejected in the p~~silocybin~~roduct 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 p~~silocybin~~roduct 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 p~~silocybin~~roduct tracking system.
Statutory/Other Authority: ORS 475A.235, ORS 475A.400
Statutes/Other Implemented: ORS 475A.235

AMEND: 333-333-8200

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-8200-Amends product tracking rule to reflect product tracking system functionality.

CHANGES TO RULE:

333-333-8200
Product Tracking - General Requirements
(1) A service center, manufacturer or laboratory licensee must:~~¶~~
~~(a) U~~ use the p~~silocybin~~roduct tracking system as an inventory and record~~ing~~ keeping system.¶
(b2) ~~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 licensee 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 licensee 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~~Each individual service center, manufacturer and laboratory licensee will have access to the product tracking system. A licensee may authorize additional licensee representative~~s~~ to ~~attend and successfully complete required psilocybin tracking system training so long as both~~use the product tracking system for the~~ir~~ license~~e and the designated re~~premi~~sentative obtain psilocybin tracking system administrator account~~s~~.¶
(5~~3~~) Each service center, manufacturer and laboratory licensee must:¶
(a) Maintain an accurate and complete list of all p~~silocybin tracking system administrators and psilocybin~~roduct tracking system users for each licensed premises and must update the list when a new p~~silocybin~~roduct tracking system user is ~~train~~added.¶
(b) Train and authorize any new p~~silocybin~~roduct tracking system users before those users are permitted to access the p~~silocybin~~roduct tracking system or input, modify, or delete any information in the p~~silocybin~~roduct tracking system.¶
(c) ~~Cancel any psilocybin tracking system administrator or~~Remove access for any product tracking system user from an associated p~~silocybin~~roduct tracking system account if that individual is no longer a licensee representative.¶
(d) Correct any data that is entered into the p~~silocybin~~roduct tracking system in error.¶
(6~~4~~) Each service center, manufacturer and laboratory licensee is ~~accounta~~responsible for all actions licensee representatives take while logged into the p~~silocybin~~roduct tracking system or while otherwise conducting inventory tracking activities.¶
(7~~5~~) Nothing in this rule prohibits a service center, manufacturer or laboratory licensee from using secondary separate software applications to collect information to be used in its operation including secondary inventory tracking or point of sale systems. ~~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~~¶
(6) If at any point a service center, manufacturer or laboratory licensee loses access to the p~~silocybin~~roduct 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 p~~silocybin~~roduct 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 p~~silocybin~~roduct tracking system unless the ~~Authority~~Oregon

Health Authority (Authority) has provided written authorization to do so.¶
(~~9~~7) The Authority may issue a temporary waiver of any requirements of these rules if the ~~Psilocybin T~~product tracking ~~S~~system is unable to perform required functions. Any temporary waiver issued under this section will be published on the Authority's website and will identify the specific rule sections affected and the duration of the waiver.
Statutory/Other Authority: ORS 475A.235, ORS 475A.400
Statutes/Other Implemented: ORS 475A.235, ORS 475A.400

AMEND: 333-333-8210

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-8210-Amends reconciliation of inventory rule to reflect product tracking system functionality.

CHANGES TO RULE:

333-333-8210
Product Tracking - Reconciliation of Inventory
(1) Each service center, manufacturer and laboratory licensee must:¶
(a) Use the p~~silocybin~~roduct 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 p~~silocybin~~roduct tracking system to reflect the prior day's activity.¶
(c) For psilocybin products that have completed potency testing, use the p~~silocybin~~roduct tracking system to record the total amount of psilocybin analyte contained in psilocybin products by weight, measured in grams or milligrams.¶
(2) The requirements of subsection (1)(b) of this rule do not apply~~t~~:¶
(a) 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, d~~b) During the first 15 days following the harvest of fruiting bodies or mycelium, daily reconciliation by a manufacturer of the weight of moisture lost to evaporation is not required. The weight of moisture loss must be reconciled by a manufacturer prior to transferring, processing, selling, or packaging the fungi and no later than 15 days after the harvest, whichever comes first.¶
~~(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 t~~c) To psilocybin products held by a laboratory licensee that are undergoing analytical testing required by these rules so long as the psilocybin products do not leave the laboratory's licensed premises and are reconciled on the same day that the analytical testing concludes.¶
(~~6~~3) 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 p~~silocybin~~roduct 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

AMEND: 333-333-8220

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-8220-Amends unique identification number rule to reflect product tracking system functionality.

CHANGES TO RULE:

333-333-8220
Product Tracking - Unique Identification Numbers
(1) A service center, manufacturer or laboratory licensee must:¶
(a) U 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 numbers generated by the product tracking system for invendtor fees.¶
(b) Have an adequate supply of unique identification tags at all y tracking activitimes, 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. required by these rules. ¶
(2) A manufacturer licensee must:¶
(ca) Assign and affix a unique identification tagnumber to each separated area containing a cultivation batch of mycelium or fruiting bodies as described in OAR 333-333-8230.¶
(db) After harvest, assign and affix a unique identification tagnumber to all psilocybin products or receptacles containing psilocybin products.¶
(ec) Assign and affix unique identification tagnumbers 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 tagnumber each time a psilocybin product is added to a quantity of psilocybin products grouped together under a pre-existing unique identification tag. number.¶
(fd) Place tagAffix unique identification numbers in a position that can be clearly read by an individual standing next to the item.¶
(g) Keep tags free from dirt and debris.¶
(23) To allow for a drying period, the requirements of subsection (12)(ec) of this rule do not apply to harvested mycelium or fruiting bodies in the first 15 days after harvest.¶
(34) The requirements of section (12) of this rule do not apply to psilocybin spores or mycelium that are in a preproduction process at a manufacturer's licensed premises.¶
(45) A manufacturer licensee may not combine psilocybin products of different package or serving size, potency, or type under a single unique identification tagnumber, except for:¶
(a) M mixed lots of homogenized fungi.¶
(b) P or psilocybin extracts that will undergo further processing.¶
(6) A service center, manufacturer or laboratory licensee may not reuse unique identification numbers.
Statutory/Other Authority: ORS 475A.235, ORS 475A.400
Statutes/Other Implemented: ORS 475A.235, ORS 475A.400

AMEND: 333-333-8230

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-8230-Amends cultivation batch rule to reflect product tracking system functionality.

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~~create a batch name for each cultivation batch ~~name~~ and record the cultivation batch name and location in the p~~silocybin~~roduct tracking system ¶
~~(3) Batch names and u~~with the unique identification number assigned to the cultivation batch.¶
(3) Unique identification ~~tag~~numbers 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

AMEND: 333-333-8240

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-8240-Amends inventory audit rule to reflect product tracking system functionality.

CHANGES TO RULE:

333-333-8240
Product Tracking - Inventory Audits
(1) The Oregon Health 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.¶
(2) A variance between the physical audit and the inventory reflected in the p~~silocybin~~roduct 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

AMEND: 333-333-8250

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-8250-Amends user requirement rule to reflect product tracking system functionality.

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~~product tracking system user shall enter data into the p~~silocybin~~roduct 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 p~~silocybin~~roduct tracking system.¶
(3) ~~An~~Each individual ~~entering data into the psilocybin tracking system may only use~~ who accesses the product tracking system must have log in credentials, which may not be shared or used by any other ~~own individual psilocybin tracking system account. ¶~~
~~(4) Each~~person. ¶
(4) An individual entering data into the psilocybin tracking system ~~administrator and~~may only use their own 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~~log in credentials. ¶
(5) Every individual who accesses the product tracking system 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

REPEAL: 333-333-8260

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: 333-333-8260-Repeals rule on system notifications because this rule is no longer consistent with product tracking system functionality.

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~~