

Definitions (333-333-1010)

(1) “Adulterant” means chemicals, drugs, plants or substances that alter the potency, intoxicating effect, duration of effect, toxicity or potential for excessive use when added to psilocybin products. Adulterant does not include naturally occurring substances contained in food items such as, but not limited to chocolate

(2) “Adverse behavioral reaction” means client behavior that a facilitator reasonably believes may endanger the safety of the client, facilitator, or others.

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

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

(5) “Applicant” means an individual or legal entity who:

(a) Holds or controls an interest of more than 10 percent in the business proposed to be licensed;

(b) Is entitled to receive 10 percent or more of revenue, profits or proceeds from the business proposed to be licensed; or

(c) Is entitled to exercise control over the business which can be indicated by, but is not limited to, authority to bind the business to contracts, obligations or debt.

(6) “Attractive to minors” means:

(a) Cartoons;

(b) A design, brand or name that resembles a non-psilocybin consumer product of the type that is typically marketed to minors;

(c) Symbols or celebrities that are commonly used to market products to minors;

(d) Images of minors; or

(e) Words that refer to products that are commonly associated with minors or marketed by minors.

(7) “Authority” means the Oregon Health Authority.

(8) “Authorized Authority representative” means an employee of the Authority who is authorized to conduct inspections or investigations and otherwise enforce ORS chapter 475A and any rules adopted thereunder.

~~(3)~~(9) “Batch” means a quantity of whole fungi from a harvest lot, or a quantity of psilocybin product from a process lot.

(10) “Billboard” means a large outdoor advertising structure.

(11) “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.

~~(4)~~ (12) “Capsule” means a small soluble pill, tablet or container that contains liquid or powdered psilocybin product and is intended for human consumption.

~~(5)~~(13) “Chemical synthesis” means the production of psilocybin using precursor ingredients rather than cultivation of fruiting bodies and mycelium.

(14) “Client administration area” means any area within the licensed premises of a service center where:

- (a) Psilocybin products are transferred to a client;
- (b) Psilocybin products are consumed by a client; and
- (c) Administration sessions take place.

(15) “Client information form” means the form required by ORS 475A.350.

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

(17) “Cultural equity” means values, policies, and practices that ensure all people, especially those who have been historically marginalized based on race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances are considered in the development of social pathways to health equity.

(18) “Cultivation batch” means a quantity of unharvested fruiting body or mycelium that is grown together under the same conditions.

(19) “Curriculum” means the topics, subjects, and activities that make up courses taught by a training program.

(20) “De-identified data” means client information from which the Authority or other entity has deleted, redacted, or blocked identifiers so the remaining information cannot reasonably be used to identify an individual.

~~(6)~~(21) “Edible psilocybin product” means psilocybin extract or homogenized fungi that has been incorporated into a food item or potable beverage.

(22) “Elementary school”:

- (a) Means a learning institution containing any combination of grades kindergarten through 8.
- (b) Does not mean a learning institution that includes only pre-kindergarten, kindergarten, or a combination of pre-kindergarten and kindergarten.

~~(7)~~ (23) “Extraction” means:

- (a) The process of separating psilocybin from fungi by using a solvent; and
- (b) Manufacturing psilocybin extracts.

(24) “Financial interest”:

- (a) Means a membership interest, partnership interest or other ownership interest in a business that is proposed to be licensed.
- (b) Does not include an investment that the investor does not control in nature, amount or timing.

(25) “Facilitation” means the provision of services to a client by a licensed facilitator during a preparation, administration, or integration session.

~~(8)~~ (26) “Fruiting bodies” means the spore producing organs of the fungi *Psilocybe cubensis*.

~~(9)~~ (27) “Fungi” means the fruiting bodies or mycelium of the fungi *Psilocybe cubensis*.

(28) “Harvest” means the act of removing mycelium or fruiting bodies from a production environment for drying or processing.

~~(40)~~ (29) “Harvest lot” means a specifically identified quantity of fungi that is cultivated and dried under the same conditions and harvested within a 24-hour period at the same location within the licensed premises.

(30) “Health equity” means the opportunity for all people to reach their full health potential and well-being without being disadvantaged by their race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities or other socially determined circumstances.

~~(44)~~ (31) “Homogenized fungi” means dried fruiting bodies or mycelium that have been mixed by powdering or other techniques which uniformly distribute psilocybin throughout the product. Homogenized products may contain inactive ingredients such as binders, dilutants and carrying agents.

(32) “Intervention” means taking proactive steps to respond to the client’s behavior, experience, or condition during an administration session.

(33) “Intoxicant” means any substance that has intoxicating effects, and includes alcohol, prescription drugs, non-prescription drugs and any other controlled substances.

~~(42)~~ (34) “Laboratory” means a laboratory licensed under ORS 475A.594.

(35) “Lead educator” means a person affiliated with a training program who is responsible for tracking the progress of students throughout the program.

(36) “License representative” means an owner, director, officer, manager, employee, agent or other representative of a manufacturer, service center, or laboratory licensee, to the extent that the person acts in a representative capacity.

(37) “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.

(38) “Limited access area” means any area of a license premises where psilocybin products or waste are stored or produced.

(39) “Location” means a building, suite or designated outdoor area with its own postal address where a service center, manufacturer, or laboratory is located.

~~(43)~~ (40) “Manufacturer” means a manufacturer licensed under ORS 475A.290.

~~(44)~~ (41) “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.

(42) “Marijuana” has the meaning given that term in ORS 475C.009.

~~(45)~~ (43) “Mycelium” means the fungal threads or hyphae of *Psilocybe cubensis*.

(44) “Nondirective facilitation” means an approach to facilitation in which the facilitator maintains a consistent disposition with a client, while avoiding giving the client direct advice or directly interpreting a client’s statements or behaviors.

(45) “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.

(46) “Oregon Psilocybin Services Act” means ORS 475A.210 to ORS 475A.722.

~~(46)~~ **(47) “Pesticide” means any substance or mixture of substances included in ORS 634.006(8).**

(48) “Practicum site” means a designated service center that provides practicum training.

(49) “Practicum site supervisor” means an onsite practicum supervisor of assigned trainees, affiliated with a practicum site.

(50) “Premises”:

(a) Means all areas of a location that are licensed under ORS chapter 475A, including:

(A) All public and private enclosed areas at the location that are used in the licensed business operated at the location, including offices, kitchens, rest rooms and storerooms;

(B) All areas outside a building that are used in the licensed business operated at a location for which the Authority has issued a license for a manufacturer or service center;

(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.

(51) “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.

~~(47)~~ **(52) “Process lot” means homogenized fungi, psilocybin extract or edible psilocybin product of the same type that was processed at the same time using the same processing method, ingredients, and standard operating procedures.**

(53) “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.

~~(48)~~ **(54) “Psilocybin” means psilocybin or psilocin.**

~~(49)~~ **(55) “Psilocybin extract” means:**

(a) A substance consisting entirely of solid or liquid psilocybin and may include other compounds which were simultaneously extracted from fruiting bodies or mycelium of *Psilocybe cubensis*; and

(b) A substance consisting of solid or liquid psilocybin and may include other compounds which were simultaneously extracted from fruiting bodies or mycelium of *Psilocybe cubensis* and inactive ingredients that are used to form capsules, tinctures and other oral preparations.

~~(20)~~ **(56) “Psilocybin Tracking System” or “PTS” means the system for tracking psilocybin products required by ORS 475A.400.**

~~(24)~~ **(57) “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.**

(58) “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.

(59) “Responsible referral and support” means supporting the personal needs, growth, and wellbeing of others, particularly those going through temporal crises such as homelessness, illness or marginalization.

(60) “Residence” means real property inhabited by an owner, renter or tenant, including manufactured homes and vehicles used as domiciles.

(61) “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.

(62) “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.

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

(64) “Service center” means a premises licensed under ORS 475A.305.

(65) “Sublet” means to sublease or otherwise allow a person who is not a licensed representative to exercise license privileges on the premises of a service center, manufacturer or laboratory license.

(66) “Synchronous learning” means that students learn from their instructor at the same time as their fellow students.

(67) “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.

~~(22)~~ **(68) “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.

(69) “Training, Licensing and Compliance System (TLC)” means the online training, license and compliance portal maintained by the Authority to receive applications, communicate with applicants, licensees, permittees and training programs, and track compliance actions.

(70) “Training program applicant” means a program that has applied to offer training to psilocybin facilitators as described in ORS 475A.380.

(71) “Training program” means a program that has been approved to offer training to psilocybin facilitators as described in ORS 475A.380.

(72) “Unique identification number” means a unique number generated by the Authority’s designated vendor for the psilocybin tracking system for the purpose of tracking psilocybin products within the psilocybin tracking system.

(73) “Unique identification tag” means a tag that contains a unique identification number that was ordered and received from the Authority’s designated vendor for the psilocybin tracking system for the purpose of tracking psilocybin products in the psilocybin tracking system.

~~(23)~~ **(74) “Whole fungi” means dried fruiting bodies of *Psilocybe cubensis*, or portions thereof, that have not been homogenized.**

~~(24)~~ **(75) “Wood chips” mean substrates consisting primarily of wood products that have not been composted.**

(76) “Worker permit” means a permit required by ORS 475A.480.

RAC Table #1: Packaging, Labeling, Product Transportation, Tracking and Miscellaneous

Statutory Authority: ORS 475A.235(2)(c)

Statutes Implemented: ORS 475A.235(2)(c)

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Allowable Species (333-333-2015)

- (1) A Manufacturer may only cultivate or possess fruiting bodies of the fungi species *Psilocybe cubensis* on the licensed premises.
- (2) A manufacturer may not possess mycelium or spores of any species other than *Psilocybe cubensis* that contain or are capable of producing psilocybin.

Statutory Authority: ORS 475A.235(2)(c)

Statutes Implemented: ORS 475A.235(2)(c)

Psilocybin Product Quantity Limits (333-333-2200)

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

Statutory Authority: ORS 475A.235(2)(c), ORS 475A.300

Statutes Implemented: ORS 475A.300

Packaging for Sale to Client (333-333-2300)

- (1) Containers or packaging for psilocybin products must protect the packaged item 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 a sealed package 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) Psilocybin product packaging may not contain any untruthful or misleading content.

Statutory Authority: ORS 475A.235(2)(c), ORS 475A.634

Statutes Implemented: ORS 475A.634

Packaging and Serving Size (333-333-2310)

- (1) A serving of a psilocybin product may not contain more than 25 mg of psilocybin.
- (2) A package of a psilocybin product may not contain more than one serving.

Statutory Authority: ORS 475A.235(2)(c), ORS 475A.642

Statutes Implemented: ORS 475A.642

Labeling for Sale to Client (333-333-2400)

- (1) A label required by these rules must:
 - (a) Be printed on or affixed to the container holding the psilocybin product and printed on or affixed to any outer package or container that is used to display psilocybin product for sale or transfer to a client.
 - (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) Contain 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. Every container that holds a psilocybin product for sale to a client must display:
 - (a) The manufacturer's business or trade name and license number.
 - (b) 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) Quantity of psilocybin contained in the product, expressed in milligrams, and calculated using laboratory test results for tests required by OAR 333-333-7040.
 - (f) Species of fungi.
 - (g) Harvest date for whole fungi.
 - (h) Date of manufacture for all products other than whole fungi.
 - (i) Unique identification number as defined in OAR 333-333-1010.
 - (j) List of all ingredients in descending order of predominance by weight or volume.
 - (k) List of potential major food allergens by:
 - (A) Listing the name of the food source of any major food allergen at the end of or immediately adjacent to the ingredient list; or
 - (B) Placing the term for the appropriate major food allergen in parenthesis within the ingredient list after the common or usual name of the ingredient derived from that major food allergen.

- (l) Estimated activation time, expressed in minutes.
- (m) “Best by” date indicating the time that the manufacturer has determined that their product will retain its original quality.
- (n) If the psilocybin product is perishable, a statement that the product must be refrigerated or kept frozen.

Statutory Authority: ORS 475A.235(2)(c), ORS 475A.626

Statutes Implemented: ORS 475A.626

Product Information Document (333-333-2410)

- (1) All of the information required by OAR 333-333-2400 must also be listed in English on a printed or electronic product information document in 12-point font or larger.
- (2) The product information document for any psilocybin products to be consumed during an administration session must be provided to a client during their preparation 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 Authority: ORS 475A.235(2)(c)

Statutes Implemented: ORS 475A.235(2)(c)

Sale of Psilocybin Services (333-333-5160)

- (1) A facilitator must list fees separately for preparation, administration and integration sessions and must specify whether those fees will be paid directly to the facilitator or to the service center where the client receives psilocybin services.
- (2) If a client notifies a facilitator 24 hours or more prior to their scheduled preparation, administration or integration session that they will not participate in a scheduled session, a facilitator must refund or credit any fees collected for the session.

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

Statutes/Other Implemented: ORS 475A.340

Sale and Transfer of Psilocybin Products to Clients (333-333-5170)

- (1) Psilocybin products may only be sold and transferred to clients by license representatives of a service center.
- (2) License representatives of a service center must transfer psilocybin products to clients within a designated administration area located indoors.
- (3) License representatives of a service center must transfer psilocybin products to clients in the products’ sealed original packaging.
- (4) A license representative of a service center must observe a client consume any psilocybin products transferred to that client. Any portion of a product that is not consumed must be returned to a license representative and must be destroyed at the conclusion of the client’s administration session. If a client is unable to open or consume a psilocybin product without

assistance, they may identify a client support person to assist them subject to the requirements of OAR 333-333-5050(5)(j) and OAR 333-333-5070.

(5) Facilitators are prohibited from transferring, preparing or otherwise handling psilocybin products, unless the facilitator is also a license representative of a service center.

(6) Clients may mix psilocybin products with unopened packaged food or unopened beverages prior to consuming.

(7) 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(c)

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

Collection of Taxes (333-333-5180)

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

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

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

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

Statutory/Other Authority: ORS 475A.235(c)

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

Prohibited Conduct (333-333-6000)

(1) Sale to a person under 21 years of age. A licensee or permittee may not sell, deliver, transfer or make available any psilocybin product to a person under 21 years of age.

(2) Services to a person under 21 years of age. A facilitator may not provide psilocybin services to a person under 21 years of age.

(3) Identification for Products. A licensee or license representative must require a person to produce identification as required by ORS 475A.445 before selling or providing a psilocybin product to that person.

(4) Identification for Services. A facilitator must require a person to produce identification before providing psilocybin services to that person.

(5) Access to Premises.

(a) A licensee, license representative or permittee may not:

- (A) During regular business hours for the licensed premises, refuse to admit or fail to promptly admit an authorized Authority representative who identifies themselves and who enters or wants to enter a licensed premises to conduct an inspection to ensure compliance with ORS 475A.210 to 475A.722 or these rules;
- (B) Outside of regular business hours or when the 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. If the licensee has psilocybin products in physical inventory at the licensed premises or in the psilocybin tracking system, failure to retain such control or right of access is a Category I violation and may be grounds for immediate suspension or revocation of the license.
- (6) Use or Consumption of Intoxicants on Duty and Under the Influence on Duty.
- (a) No licensee, license representative, or permittee may consume any intoxicating substances while on duty.
- (b) No licensee, license representative, or permittee may be under the influence of intoxicating substances while present on a licensed premises.
- (c) As used in this section “intoxicants” means any substance that has intoxicating effects, and includes alcohol, prescription drugs, non-prescription drugs and any other controlled substances.
- (7) Import and Export. A licensee or permittee may not import psilocybin products into this state or export psilocybin out of this state.
- (8) Permitting, Disorderly or Unlawful Conduct. A licensee or permittee may not permit disorderly activity or activity that is unlawful under Oregon state law on the licensed premises or in areas adjacent to or outside the licensed premises under the control of the licensee.
- (a) If the prohibited activity under this section results in death or serious physical injury, or results in a sexual offense the violation is a Category I violation and could result in license or permit cancellation.
- (b) As used in this section:
- (A) “Disorderly activities” means activities that harass, threaten or physically harm oneself or another person.
- (B) “Disorderly activities” include offensive conduct towards another person based on race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, or social class.
- (C) “Unlawful activity” means activities that violate the laws of this state, including but not limited to any activity that violates a state criminal statute.
- (c) The Authority does not require a conviction to establish a violation of this section.
- (9) Psilocybin as a Prize, Premium or Consideration. No licensee or permittee may give or permit the giving of any psilocybin product as a prize, premium, or consideration for any lottery, contest, game of chance or skill, exhibition, or any competition of any kind on the licensed premises.

(10) Visibly Intoxicated Persons. No licensee or permittee may sell, give, or otherwise make available any psilocybin products or provide psilocybin services to any person who is visibly intoxicated.

(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(c)

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

Laboratory Licensee Prohibited Conduct (333-333-6030)

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

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

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

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

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

Statutory/Other Authority: ORS 475A.235(c), ORS 475A.594

Statutes/Other Implemented: ORS 475A.235(c), ORS 475A.594

Dishonest Conduct (333-333-6040)

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

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

(a) Misrepresenting the contents of a psilocybin product.

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

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

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

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

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

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

Statutory/Other Authority: ORS 475A.235(c)

Statutes/Other Implemented: ORS 475A.235(c)

Advertising Restrictions (333-333-6100)

(1) Psilocybin advertising may not:

- (a) Contain statements that are deceptive, false, or misleading.
 - (b) Contain any content that can reasonably be considered to target individuals under the age of 21, including but not limited to images of minors, cartoons, toys, or similar images and items typically marketed towards minors, or references to products that are commonly associated with minors or marketed by minors.
 - (c) Encourage activity that is illegal under state law.
 - (d) Assert that psilocybin products are safe because they are regulated by the Authority or have been tested by a certified laboratory or otherwise make claims that any government agency endorses or supports psilocybin.
 - (e) Make claims that psilocybin products and services have curative or therapeutic effects or make other health claims that are not supported by the totality of publicly available scientific evidence (including evidence from studies conducted in a manner that is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims.
- (2) A licensee may not make any deceptive, false, or misleading assertions or statements on any informational material, any sign, or any document provided to a consumer.

Statutory/Other Authority: ORS 475A.235(c), (e) and (f)

Statutes/Other Implemented: ORS 475A.235(c), (e) and (f)

Advertising Media, Coupons, and Promotions (333-333-6110)

- (1) A licensee may not utilize television, radio, billboards, print media or internet advertising unless the licensee has reliable evidence that no more than 30 percent of the audience for the program, publication or Internet website in or on which the advertising is to air or appear is reasonably expected to be under the age of 21.
- (2) A licensee who advertises via webpage must utilize appropriate measures to ensure that individuals visiting the webpage are over 21 years of age.
- (3) A licensee may not engage in advertising via marketing directed towards location-based devices, including but not limited to cellular phones, unless the marketing is a mobile device application installed on the device by the owner of the device who is 21 years of age or older and includes an opt-out feature.

Statutory/Other Authority: ORS 475A.235(c), (e) and (f)

Statutes/Other Implemented: ORS 475A.235(c), (e) and (f)

Removal of Objectionable and Non-Conforming Advertising (333-333-6120)

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

Statutory/Other Authority: ORS 475A.235(c), (e) and (f)

Statutes/Other Implemented: ORS 475A.235(c), (e) and (f)

Waste Management (333-333-8000)

- (1) A manufacturer, service center or laboratory licensee must:
 - (a) Store, manage and dispose of solid and liquid wastes generated during production and processing of psilocybin products in accordance with applicable state and local laws and regulations which may include but are not limited to:
 - (A) Solid waste requirements in ORS chapter 459 and OAR chapter 340, divisions 93 to 96.
 - (B) Hazardous waste requirements in ORS chapter 466 and OAR chapter 340, divisions 100 to 106.
 - (C) Wastewater requirements in ORS chapter 468B and OAR chapter 340, divisions 41 to 42, 44 to 45, 53, 55 and 73.
 - (b) Store psilocybin waste in a locked waste receptacle or limited access area in the possession of and under the control of the licensee.
- (2) If a licensee generates the waste after a harvest or process lot has been recorded, or if the waste was previously designated as a finished psilocybin product, the licensee must document:
 - (a) A reason for the waste in the psilocybin tracking system.
 - (b) The exact time and method of destruction in the psilocybin tracking system.
- (3) In addition to the requirements of sections (1) and (2) of this rule, waste items consisting of psilocybin products must be rendered unusable and disposed of on the licensed premises or transferred to another licensee for disposal. Psilocybin products may be rendered unusable by composting, mixing with inactive ingredients, or any other method which renders the product unfit for consumption but does not pose a safety risk for accidental consumption.
- (4) All psilocybin waste must be disposed of in a manner that effectively prevents spontaneous growth of fruiting bodies or mycelium containing psilocybin.
- (5) Material that has been designated as waste must be disposed of pursuant to this rule and may not be used in the production of psilocybin products.

Statutory/Other Authority: ORS 475A.235(c)

Statutes/Other Implemented: ORS 475A.235(c)

Product Transportation (333-333-8100)

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

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

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

(2) Physical transport requirements for licensees.

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

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

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

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

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

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

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

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

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

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

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

(J) Notify the Authority in advance of every stop at an unlicensed location that exceeds two hours in duration and is not already listed in the manifest route.

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

(c) A licensee may not:

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

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

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

- (D) Travel with any persons not listed on the manifest.
- (d) Any vehicle that meets the requirements of this rule may be used as a delivery vehicle.
- (3) Psilocybin tracking system manifest requirements.
 - (a) Prior to removing a psilocybin product from the originating licensed premises for the purposes of transport or delivery, the originating licensee must use the psilocybin tracking system to generate a printed transport manifest containing the following information:
 - (A) The originating location's license number and address as it appears in the psilocybin tracking system.
 - (B) The destination location's license number and address as it appears in the psilocybin tracking system.
 - (C) The unique identification number, product name, and quantity of each psilocybin product.
 - (D) The actual date and estimated time of departure.
 - (E) Location and duration of time for any overnight stop.
 - (F) The arrival date and estimated time of arrival or completion of delivery.
 - (G) The delivery vehicle make, model, and license plate number.
 - (H) The name, contact information, worker permit number and signature of any license representatives accompanying the transport.
 - (b) A physical, printed copy of the generated manifest must accompany every transport of psilocybin products.
- (4) Psilocybin tracking system requirements when receiving psilocybin products. Upon receipt of a delivery of psilocybin products, the receiving licensee must:
 - (a) Record each applicable unique identification number as accepted and received or rejected in the psilocybin tracking system as applicable.
 - (b) Verify the psilocybin products received are as described on the manifest and record receipt of the psilocybin products in the psilocybin tracking system if accepted.
 - (c) Separately and for each unique identification number document any differences between the quantities specified on the manifest and the quantities received in the psilocybin tracking system.

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

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

Product Tracking — General Requirements (333-333-8200)

- (1) A service center, manufacturer or laboratory licensee must:
 - (a) Use the psilocybin tracking system as an inventory and recording keeping system.
 - (b) Have a psilocybin tracking system account activated and functional within three 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 license holder who is a psilocybin tracking system administrator. A licensee may authorize additional license holders or license representatives to obtain psilocybin tracking system administrator accounts.
- (3) In order to obtain a psilocybin tracking system administrator account, a license holder must attend and successfully complete all required psilocybin tracking system training, except as

provided in section (4) of this rule. The Authority may also require additional ongoing, continuing education for individual administrators to retain his or her psilocybin tracking system administrator account.

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

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

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

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

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

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

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

(7) Nothing in this rule prohibits a service center, manufacturer or laboratory licensee from using secondary separate software applications to collect information to be used by the business including secondary inventory tracking or point of sale systems. If a licensee uses a separate software application that links to the psilocybin tracking system, it must get approval from the psilocybin tracking system vendor contracting with the Authority and the software application must:

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

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

(8) If at any point a service center, manufacturer or laboratory licensee loses access to the psilocybin tracking system for any reason, the licensee must keep and maintain comprehensive records detailing all tracking inventory activities that were conducted during the loss of access.

(a) Once access is restored, all inventory tracking activities that occurred during the loss of access must be entered into the psilocybin tracking system.

(b) A licensee must document when access to the system was lost and when it was restored.

(c) A licensee may not transport any psilocybin product to another licensed premises until such time as access is restored and all information is recorded into the psilocybin tracking system unless the Authority has provided written authorization to do so.

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

Product Tracking - Reconciliation with Inventory (333-333-8210)

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

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

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

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

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

(3) Notwithstanding subsection (1)(b) of this rule, 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 ten calendar days of licensure for a service center, manufacturer or laboratory licensee so long as the licensee, has ordered unique identification tags and unique identification tags are in transit to the receiving party.

(5) The requirements in subsection (1)(b) of this rule do not apply to psilocybin products held by a laboratory licensee that are undergoing analytical testing required by these rules so long as the psilocybin products do not leave the laboratory's licensed premises and are reconciled on the same day that the analytical testing concludes.

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

(7) Information that is not required to be recorded and reconciled daily pursuant to section (3) 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(c), ORS 475A.400

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

Product Tracking - Unique Identification Numbers (333-333-8220)

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

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

- (b) Have an adequate supply of unique identification tags at all times, except during the first 10 calendar days of licensure so long as unique identification tags have been ordered and are in transit to the premises.
- (c) Assign and affix a unique identification tag to each separated area containing a cultivation batch of mycelium or fruiting bodies as described in OAR 333-333-8230.
- (d) After harvest, assign and affix a unique identification tag to all psilocybin products or receptacles containing psilocybin products.
- (e) Assign and affix unique identification tags in a manner that:
 - (A) Establishes an accurate record of cultivation, harvest and drying of fungi, including documentation of harvest lots and batches as described in OAR 333-333-2020 and OAR 333-333-7090.
 - (B) Establishes an accurate record when one psilocybin product is converted to another product type.
 - (C) Uses a new unique identification tag each time a psilocybin product is added to a quantity of psilocybin products grouped together under a pre-existing unique identification tag.
- (f) Place tags in a position that can be clearly read by an individual standing next to the item.
- (g) Keep tags free from dirt and debris.
- (2) To allow for a drying period, the requirements of subsection (1)(e) of this rule do not apply to harvested mycelium or fruiting bodies in the first 15 days after harvest.
- (3) The requirements of section (1) of this rule do not apply to psilocybin spores or mycelium that are in a preproduction process at a manufacturer's licensed premises.
- (4) A manufacturer licensee may not combine psilocybin products of different size, potency, or type under a single unique identification tag, except for:
 - (a) Mixed lots of homogenized fungi.
 - (b) Psilocybin extracts that will undergo further processing.

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

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

Product Tracking — Cultivation Batches (333-333-8230)

- (1) Within 72 hours of beginning a production process, a manufacturer must create a cultivation batch that will contain all fruiting bodies and mycelium produced by that production process.
- (2) A manufacturer must assign each cultivation batch a unique user-generated sequential batch name and record the batch name and location in the psilocybin tracking system
- (3) Batch names and unique identification tags must be physically affixed to the cultivation batch or the separated area where the cultivation batch is physically located as required by OAR 333-333-8220.
- (4) A manufacturer may have an unlimited number of cultivation batches at any one time.

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

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

Product Tracking — Inventory Audits (333-333-8240)

- (1) The Authority may perform a physical audit of the inventory of any service center, manufacturer or laboratory licensee at the agency's discretion and with reasonable notice to the licensee.
- (2) A variance between the physical audit and the inventory reflected in the psilocybin tracking system at the time of the audit, which cannot be attributed to normal moisture variation psilocybin products, is a violation.

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

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

Product Tracking - User Requirements (333-333-8250)

- (1) A service center, manufacturer or laboratory licensee and any designated psilocybin tracking system administrator or user shall enter data into the psilocybin tracking system that fully and transparently accounts for all inventory tracking activities.
- (2) A service center, manufacturer or laboratory licensee is responsible for the accuracy of all information entered into the psilocybin tracking system.
- (3) An individual entering data into the psilocybin tracking system may only use their own individual psilocybin tracking system account.
- (4) Each psilocybin tracking system administrator and psilocybin tracking system user must have a unique log-on and password, which may not be used by any other person.
- (5) Every psilocybin tracking system user and administrator must hold a valid worker permit as required by ORS 475A.480.

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

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

Product Tracking - System Notifications (333-333-8260)

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(c), ORS 475A.400

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