OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 333

PSILOCYBIN

333-333-1010
Definitions
For purposes of chapter 333, division 333 the following definitions apply:
(1) "Adulterant" means chemicals, drugs, plants or substances that alter the potency, intoxicating effect, duration of effect, toxicity or potential for excessive use when added to psilocybin products. Adulterant does not include naturally occurring substances contained in food items such as, but not limited to chocolate.
(2) "Authority" means the Oregon Health Authority.
(3) "Batch" means a quantity of whole fungi from a harvest lot, or a quantity of psilocybin product from a process lot.
(4) "Capsule" means a small soluble pill, tablet or container that contains liquid or powdered psilocybin product and is intended for human consumption.
(5) "Chemical synthesis" means the production of psilocybin using precursor ingredients rather than cultivation of fruiting bodies and mycelium.
(6) "Edible psylocibin product" means psilocybin extract or homogenized fungi that has been incorporated into a food item or potable beverage.
(7) "Extraction" means:
(a) The process of separating psilocybin from fungi by using a solvent; and
(b) Manufacturing psilocybin extracts.
(8) "Fruiting bodies" means the spore producing organs of the fungi *Psilocybe cubensis.*
(9) "Fungi" means the fruiting bodies or mycelium of the fungi *Psilocybe cubensis*
(10) "Harvest lot" means a specifically identified quantity of fungi that is cultivated and dried under the same conditions and harvested within a 24-hour period at the same location within the licensed premises.
(11) "Homogenized fungi" means dried fruiting bodies or mycelium that have been mixed by powdering or other techniques which uniformly distribute psilocybin throughout the product. Homogenized products may contain inactive ingredients such as binders, dilutants and carrying agents.
(12) "Laboratory" means a laboratory licensed under ORS 475A.594.
(13) "Manufacturer" means a manufacturer licensed under ORS 475A.290.
(14) "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.
(15) "Mycelium" means the fungal threads or hyphae of *Psilocybe cubensis*.
(16) "Pesticide" means any substance or mixture of substances included in ORS 634.006(8).

(17) "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.
(18) "Psilocybin" means psilocybin or psilocin.
(19) "Psylocibin 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) "Psilocybin Tracking System" means the system for tracking psilocybin products required by ORS 475A.400.
(21) "Psilocybin product" means psilocybin-producing fungi, mycelium and mixtures or substances containing a detectable amount of psilocybin, including whole fungi, homogenized fungi, psilocybin extract and edible psilocybin products.
(22) "These rules" mean Oregon Administrative Rules, chapter 333, division 333.
(23) "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.
(24) "Whole fungi" means dried fruiting bodies of *Psilocybe cubensis*, or portions thereof, that have not been homogenized.
(25) "Wood chips" mean substrates consisting primarily of wood products that have not been composted.
Statutory Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235

333-333-2010
Psilocybin Production
A manufacturer is prohibited from:
(1) Using manure in cultivation or production of psilocybin products.
(2) Using wood chips as a growing medium in cultivation or production of psilocybin products.
(3) Producing psilocybin by using genetically modified organisms such as bacteria.
(4) Producing psilocybin by chemical synthesis.
Statutory Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235 and ORS 475A.290

333-333-2020
General Manufacturer Requirements
(1) A manufacturer must:
(a) Use equipment, counters and surfaces for processing that are food-grade and do not react adversely with any solvent being used.

(b) Construct and maintain 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) Assign every process lot and harvest lot a unique identification number and enter this information into the Psilocybin Tracking 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 Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235 and ORS 475A.290

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 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 processor has a right to a hearing under ORS chapter 183.
Statutory Authority: ORS 475A.235 and ORS 475A.295
Statutes Implemented: ORS 475A.235 and ORS 475A.295

333-333-2040
Pesticides
Manufacturers are prohibited from applying pesticides to fungi or growing medium.
Statutory Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235 and ORS 475A.290

333-333-2050
Adulterants
(1) A licensee may not add to psilocybin products 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 effect, toxicity or addictiveness is considered adulterated.
(2) A licensee may not produce, store or transfer adulterated psilocybin products. In addition to the provisions of section (1) 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.
(3) Psilocybin products that are intended for research and development and will not be made available for consumption may be stored in states that are unfit for human consumption.
Statutory Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235

333-333-2060
Psilocybin Extract Manufacturing Requirements
(1) A manufacturer with a psilocybin extraction endorsement may use only water, vegetable glycerin, acetic acids, 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) A manufacturer with a psilocybin extraction endorsement may not apply pressure or heat over 140 degrees Fahrenheit when manufacturing psilocybin extracts.

(4) 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) If a manufacturer with a psilocybin extraction endorsement produces a psilocybin extract that will be used in an edible psilocybin product, 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 Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235

333-333-2070
Psilocybin Extract Manufacturing Safety Procedures
(1) A manufacturer with an extraction endorsement must:
(a) Work in an environment with proper ventilation, controlling all sources of ignition where flammable vapors may be present;
(b) Use only potable water in processing;
(c) Have an emergency eye-wash station, rinse kit and emergency shower in any room in which solvents other than water are used; and
(d) Make appropriate personal protective equipment available to employees.
(2) A manufacturer with a psilocybin extraction endorsement must create and maintain a comprehensive training program that includes the hazards presented by all solvents used at the licensed premises as described in the material safety data sheet for each solvent.
Statutory Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235

333-333-2080
Psilocybin Edible Manufacturing Requirements
(1) A manufacturer with an edible psilocybin production endorsement may only process in a food establishment licensed by the Oregon Department of Agriculture (ODA) and must comply with the applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28.
(2) A manufacturer with an edible psilocybin production endorsement may not use a psilocybin product to produce edible psilocybin products unless that psilocybin product was processed or cultivated in a food establishment licensed by the ODA in compliance with the applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28.
Statutory Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235

333-333-2100
Psilocybin Manufacturing Records
A manufacturer with a psilocybin extraction, or edible psilocybin production endorsement must create and maintain standard policies and procedures that include but are not limited to:
(1) Instructions and ingredients for making each psilocybin product;

(2) The procedure for making each process lot homogenous;
(3) If applicable, the procedure for purging and disposing of any solvent or other unwanted product from a psilocybin extract;
(4) Procedures for conducting necessary safety checks prior to commencing production of psilocybin products;
(5) Procedures for cleaning all equipment, counters and surfaces;
(6) Procedures for preventing growth of pathogenic organisms and toxin formations;
(7) Proper handling and storage of any solvent or other chemical used in processing in accordance with material safety data sheets and other applicable laws;
(8) Proper disposal of any waste produced during processing in accordance with applicable laws, rules and regulations;
(9) Appropriate use of any necessary safety or sanitary equipment; and
(10) Emergency procedures to be followed in case of fire, chemical spill or other emergencies.
Statutory Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235

333-333-2110
Allowable Psilocybin Product Types
(1) A manufacturer with a fungi cultivation endorsement may produce and dry whole fungi, mycelium and homogenized fungi. A manufacturer with a fungi cultivation endorsement may produce fungi in aquatic environments in addition to any substrates and growing mediums allowed by these rules.
(2) A manufacturer with a psilocybin extraction endorsement may produce psylocibin extract.
(3) A manufacturer with an edible psilocybin production endorsement product may produce edible psilocybin products.
(4) A manufacturer may only produce those psilocybin products for which they hold an endorsement.
(5) Psilocybin products not included in this rule are prohibited and may not be manufactured, nor possessed by any licensee.
Statutory Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235

333-333-2120
Psilocybin Product Delivery Methods
(1) All psilocybin products must be designed to be consumed by a client orally or delivered via another enteral method.
(2) Psilocybin products designed to be delivered to clients through any method other than orally, including but not limited to, transdermal patches, inhalers, nasal sprays, suppositories and injections, are prohibited.
Statutory Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235

333-333-3005

Psilocybin Training Definitions

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

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

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

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

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

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

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

(7) "Health equity" means 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.

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

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

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

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

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

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

(14) "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.

(15) "Service Center" means a premises licensed under ORS 475A.305.

(16) "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.

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

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

(19) "Training program" means a program that has been approved to offer training to psilocybin facilitators as described in ORS 475A.380.
Statutory Authority: ORS 475A.235
Statutes Implemented: ORS 475A.235 and ORS 475A.380

333-333-3010
Psilocybin Training Program Approval Process
(1) A training program applicant must submit the following to the Authority to be considered for 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 $500 non-refundable application evaluation fee paid in the form and manner specified by the Authority.
(2) The Authority will notify a training program applicant if their application is incomplete. The training program applicant will have 90 days from the date the notification 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 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) The Authority will evaluate training program applications to determine if the course meets the standards in OAR 333-333-3060 and OAR 333-333-3070.
(4) The Authority will notify the training program applicants in writing if the application is approved or denied.
(5) The Authority may deny a training program application for approval or revoke approval of a previously approved training program if:
(a) The training program application does not meet the requirements of OAR 333-333-3050, OAR 333-333-3060 and OAR 333-333-3070; or
(b) The program instructors, staff or representatives have made false or misleading statements to the Authority, students or the public.
(6) If the Authority denies an application or revokes an approval, the Authority will provide notice of the denial and the training program has a right to a hearing under ORS chapter 183.
(7) Training program approval has a term of five years from the date of initial approval. If the requirements for training program approval change substantively during the term, the Authority may require training programs to resubmit an application for approval.
Statutory Authority: ORS 475A.235 and ORS 475A.380
Statutes Implemented: ORS 475A.235 and ORS 475A.380

333-333-3020
Psilocybin Training Program Application Requirements
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 within the United States of America or U.S Territories.
Statutory Authority: ORS 475A.235 and ORS 475A.380
Statutes Implemented: ORS 475A.235 and ORS 475A.380

333-333-3030
Psilocybin Training Instructor Qualifications and Program Performance
(1) In order to be approved, a training program must demonstrate that each instructor and person who trains instructors at a training program must have 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) Personal narratives and references must be treated 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 of any material changes to the curriculum and staff identified in their application in a form and manner prescribed by the Authority.
Statutory Authority: ORS 475A.235 and ORS 475A.380
Statutes Implemented: ORS 475A.235 and ORS 475A.380

333-333-3035
Psilocybin Training Reapproval
(1) A training program that wishes to be reapproved upon expiration of their initial approval term must submit a completed reapproval application and a non-refundable $500 reapproval fee.
(2) The 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 the Authority approves reapproval, the reapproval is valid for five years.
(4) 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.
(5) 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 Authority: ORS 475A.235 and ORS 475A.380

Statutes Implemented: ORS 475A.235 and ORS 475A.380

333-333-3040

Psilocybin Training Program Record Keeping

(1) Training programs shall maintain records for each class, including course curriculum, location, date and student attendance for every online and in-person class. These records must be maintained for five years. Training programs shall provide these records to current and former students upon request. Training programs shall provide these records to the Authority upon request.

(2) Training programs shall maintain enrollment records, including the name of each student enrolled, their date of completion and examination results. These records must be maintained for five years.

(3) Training programs shall provide records required to be maintained under this rule to the Authority upon request, and in the manner requested.

(4) Except as required by sections (1) and (3) of this rule, student records shall not be released without the student's written consent.

Statutory Authority: ORS 475A.235 and ORS 475A.380

Statutes Implemented: ORS 475A.235 and ORS 475A.380

333-333-3050

Psilocybin Training Program Core Requirements

(1) Programs shall provide core training that consists of at least 120 hours of instruction. At least 25 percent of core training hours shall take place in an in-person teaching format.

(2) For training that is not conducted in person, at least 50 percent of the training shall be conveyed through online synchronous learning.

(3) The in-person teaching requirements in section (1) of this rule may be waived by the Authority during a Governor declared emergency or Governor declared public health emergency.

(4) Applicants for training programs must demonstrate that their curriculum consists of the following minimum hours of instruction, in the following areas consistent with the requirements of OAR 333-333-3060:

(a) Historical, Traditional, and Contemporary Practices and Applications: 12 hours.

(b) Cultural Equity in relation to Psilocybin Services: 12 hours.

(c) Safety, Ethics and Responsibilities: 12 hours.

(d) Psilocybin Pharmacology, Neuroscience, and Clinical Research: 8 hours.

(e) Core Facilitation Skills: 16 hours.

(f) Preparation and Orientation: 16 hours.

(g) Administration: 20 hours.

(h) Integration; 12 hours.

(i) Group Facilitation: 12 hours.

(5) Training programs must comply with the requirements specified in these rules to maintain approved status.

(6) The requirements listed in these rules are minimum requirements. Nothing in these rules prevents a training program from offering additional modules or hours of instruction.
Statutory Authority: ORS 475A.235 and ORS 475A.380
Statutes Implemented: ORS 475A.235 and ORS 475A.380

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) Awareness of increased vulnerability associated with altered states of consciousness;
(D) Appropriate use of touch and client consent to physical contact;
(E) 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) History of abuse of power associated with psychedelics;
(G) Financial conflicts of interest and duties to clients; and
(H) 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) Scope of practice, including using the client Information form to identify clients in need of referral to specialized treatment services;
(d) Facilitator role and the limits of facilitator’s scope of practice;
(e) Trauma informed interview techniques;
(f) Evaluation of client safety concerns, including medical history, contra-indicated medication and psychological instability;
(g) Appropriate mitigation strategies to address client safety concerns, including but limited to assessment of client’s support system;
(h) Client’s suitability for psilocybin services;
(i) Safety planning to address client 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;
(D) Use of secondary doses.
(b) Effectively working with challenging behaviors during session, including:
(A) Unexpected client disclosures;
(B) Substance-induced psychosis;
(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;
(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 administrative session.
(8) "Integration" module shall include:
(a) Identification of appropriate resources and referrals to assist client with integration, including:
(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) Facilitating group communications and dynamics;
(C) Group agreements, including confidentiality and safety; and
(D) 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 Authority: ORS 475A.235 and ORS 475A.380
Statutes Implemented: ORS 475A.235 and ORS 475A.380

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 practicum sites to satisfy the requirements of this rule, the training program shall notify the Authority in a form and manner proscribed 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 administrator is primarily responsible for developing students' practicum skills and evaluating students' practicum performance, focusing on direct services with clients.

(6) If a practicum site is not reasonably available or accessible to students, a training program may identify alternative practicum in their application for approval that reasonably approximates training at a practicum site.

(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, and at least 10 hours of consultation relating to the student's direct practice.

(9) Practicum may not include participating in unregulated administration of psilocybin or other unregulated substances where it is unlawful to do so.

Statutory Authority: ORS 475A.235 and ORS 475A.380

Statutes Implemented: ORS 475A.235 and ORS 475A.380

333-333-3080

Accelerated Training Hours

(1) Programs may confer upon 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 for the following modules:

(a) "Cultural Equity in relation to Psilocybin Services;"
(b) "Safety, Ethics and Responsibilities;" or
(c) "Preparation and Orientation."
Statutory Authority: ORS 475A.235 and ORS 475A.380
Statutes Implemented: ORS 475A.235 and ORS 475A.380

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 every 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) Training programs shall provide every student written confirmation of program completion signed by a lead educator upon the student's successful completion of the program, including:
(a) Student's full name;
(b) Date of completion; and
(c) Name and location of the training program.
Statutory Authority: ORS 475A.235 and ORS 475A.380
Statutes Implemented: ORS 475A.235 and ORS 475A.380

333-333-7010
Psilocybin Testing: Purpose
(1) The purpose of these rules is to establish minimum compliance testing standards for psilocybin products.
(2) A person licensed under ORS 475A.290, 475A.305, or 475A.325 may not transfer, accept or provide a psilocybin product unless it has been sampled and tested in accordance with these rules.
Statutory Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

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 number associated with the batch number, if applicable;

(f) Process lot number associated with the batch number, if applicable;
(g) Total mass or volume of each batch to be sampled; and
(h) 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 Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

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 consists only of *Psilocybe cubensis.* This test must be performed prior to transferring the harvest lot to another licensee or converting the harvest lot to another product type.
(2) Following the test described in section (1) of this rule, a manufacturer must order tests for one batch harvested in each month that a harvest lot is recorded to ensure that the lot consists only of *Psilocybe cubensis.*
(3) A batch fails speciation testing if the test demonstrates that the fungi is a species other than *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 consist only of *Psilocybe cubensis.* This test must be performed prior to transferring the harvest lot to another licensee or converting the harvest lot to another 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 Authority.
Statutory Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

333-333-7040
Potency Testing

(1) A manufacturer must order tests for every batch of finished psilocybin product from a harvest lot or process lot to determine the concentration (potency) of psilocybin and psilocin in the product.
(2) A process lot of homogenized fungi, psilocybin extract or edible psilocybin product fails potency testing if the amount of psilocybin or psilocin between samples taken from the batch exceeds 20 percent relative standard deviation 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 Authority.
Statutory Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

333-333-7050
Solvent Testing
(1) If methanol or acetic acid are used to manufacture psilocybin extract, a manufacturer must order tests for methanol or acetic acid for every process lot of psilocybin extract prior to selling or transferring the psilocybin extract or converting to another product type.
(2) A batch fails solvent testing if a laboratory detects the presence of methanol above 3000 μg/g or acetic acid above 5000 μg/g in any sample.
(3) If a sample from a batch fails solvent testing, the batch may be remediated using procedures that would reduce the concentration of solvents to less that than the action level.
(4) A batch that is remediated in accordance with section (3) of this rule, must be re-sampled and re-tested for solvents in accordance with these rules.
(5) In addition to the requirements of section (1) of this rule, a manufacturer must submit one or more batches from a process lot for solvent testing upon written request by the Authority.
Statutory Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

333-333-7060
Pesticide Testing
(1) A manufacturer must submit one or more batches from a harvest lot or process lot for pesticide testing upon written request by the 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 Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

333-333-7070
Contaminant Testing

(1) A manufacturer must submit one or more batches from a harvest lot or process lot for contaminant testing upon written request by the 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 Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

333-333-7080
Heavy Metals Testing
(1) A manufacturer must submit one or more batches from a harvest lot or process lot for heavy metal testing upon written request by the 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 µg/g.
(b) Cadmium (Cd) above .2 µg/g.
(c) Arsenic (As) above .2 µg/g.
(d) Mercury (Hg) above .1 µg/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 Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

333-333-7090
Psilocybin Batch Requirements
(1) A manufacturer must separate each harvest lot of dried whole fungi into batches no larger than one kilogram.
(2) A process lot for psilocybin extracts, homogenized fungi or edible psilocybin products is considered a batch.

(3) A manufacturer must assign each batch a unique batch number and that unique batch 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) Included in the batch labels required by OAR 333-333-7110.
(4) A manufacturer may not reuse a unique batch number.
Statutory Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

333-333-7100
Psilocybin Product Sampling Requirements
(1) Whole fungi.
(a) Whole fungi may only be sampled after it is dried, regardless of whether the whole fungi will be processed into another product type.
(b) Sample increments taken must in total represent a minimum of 2.0 percent of the batch, consistent with the laboratory's accredited sampling policies and procedures.
(2) Other product types.
(a) Samples of psilocybin extracts, homogenized fungi, and edible psilocybin products intended for use by a client must be taken from the finished product.
(b) Sufficient sample increments from a batch must be taken to determine whether the batch is homogenous and must be taken in a manner consistent with the laboratories sampling policies and procedures.
(c) A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests.
(3) Sufficient sample increments must be taken for analysis of all required tests and the quality control performed by the testing laboratory for these tests.
(4) Only individuals employed by a laboratory with an ORELAP accredited scope item for sampling under these rules may take samples.
(5) Sampling may be conducted at a manufacturer's licensed premises, or the manufacturer may transport the batch to a laboratory with an ORELAP accredited scope item for sampling under these rules.
Statutory Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

333-333-7110
Requirements for Pre-Tested Psilocybin Products
(1) Following samples being taken from a harvest or process lot a manufacturer must:
(a) Label the batch with the following information:
(A) The harvest or process lot unique identification number;
(B) The name of the laboratory that took samples and the name of the laboratory responsible for testing, if different;
(C) The test batch or sample unique identification numbers supplied by the laboratory;

(D) The date the samples were taken: and
(E) In bold, capital letters, no smaller than 12-point font, "PRODUCT NOT TESTED."
(b) Store and secure the batch in a manner that prevents the product from being tampered with or transferred prior to test results being reported; and
(c) Be able to easily locate a batch stored and secured under subsection (1)(b) of this rule and provide that location to the Authority or a laboratory upon request.
(2) If the samples pass testing, the product may be sold or transferred in accordance with applicable rules.
(3) If the samples do not pass testing, the manufacturer must comply with OAR 333-333-7120.
Statutory Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

333-333-7120
Failed Test Samples
(1) If a sample or a field duplicate sample (collectively referred to as "sample" for purposes of this rule) fails any initial test, the laboratory that did the testing may reanalyze the sample. The laboratory that did the initial test may not subcontract the reanalysis. If a primary sample or a field duplicate sample fails, both must be reanalyzed. If the sample passes, 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 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 Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590

333-333-7150
Quality Control and Research and Development Testing
(1) A manufacturer may request that a laboratory conduct testing for the purpose of assuring quality control or research and 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 quality control or for research and development. A pesticide test is always a compliance test.
(3) A manufacturer that submits a psilocybin product for quality control or research and 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 development test cannot be used as a compliance test result. A psilocybin product that has undergone a quality control or research and development test may not be transferred or sold.
(5) Manufacturers must retain all quality control and research and development test results for at least two years and provide copies of such results upon request to the Authority.
Statutory Authority: ORS 475A.235 and ORS 475A.590
Statutes Implemented: ORS 475A.235 and ORS 475A.590