



# Oregon Psilocybin Services Guidance on Administrative Rules

Public Health Division  
Center for Health Protection  
Oregon Psilocybin Services (OPS)  
[www.oregon.gov/psilocybin](http://www.oregon.gov/psilocybin)

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## Table of Contents

<b>Introduction</b> .....	7
<b>Training Programs</b> .....	8
<b>Licensing and Approval Requirements</b> .....	<b>8</b>
HECC License Requirements .....	8
<b>Practicum Requirements</b> .....	<b>9</b>
Practicum – Accelerated Training Hours .....	9
Practicum – Client Disclosure Forms .....	9
Practicum – Consumption by Practicum Students .....	9
Practicum – Hours of Instruction .....	10
Practicum – Material Changes to Curriculum .....	10
Practicum—Practicum Site Supervisor .....	10
Practicum – Practicum Sites and Alternative Practicum .....	11
Practicum - Site Supervisors .....	12
Practicum – Students are not Facilitators .....	12
Practicum - Timing of Completion .....	13
<b>License Applicants</b> .....	15
<b>General OPS License Information</b> .....	<b>15</b>
Number of Licenses OHA Will Issue .....	15
Individuals Holding Multiple Licenses .....	15
Business License Requirements .....	15
Liability Insurance for Licensees .....	15
<b>License Application Process</b> .....	<b>15</b>
Residency Requirements .....	15
Background Checks .....	16
Operational Name .....	17
Conviction Guidance for Licensees .....	17
Annual License Fees .....	17
Site Inspections .....	19
Worker Permits .....	19
Proof of Licensure or Worker Permit .....	20
<b>Facilitator Applicant Information</b> .....	<b>20</b>
Holding Other Professional Licenses .....	20

OPS Facilitator Regulations Exam .....	20
<b>Site Location Information.....</b>	<b>21</b>
Local Opt-Out.....	21
Zoning Requirements .....	22
Co-Location of Licensed Premises.....	22
Co-Location with a Cannabis Business .....	22
Co-Location with a Residence.....	23
Service Center School Proximity Requirements and Barrier Exceptions .....	23
Licensing Responsibilities of a Landlord .....	25
<b>General Premises Information.....</b>	<b>25</b>
Premises Plan Requirements.....	25
ADA Requirements .....	25
Restroom Requirements .....	26
Security System Requirements.....	26
Product Storage – General Requirements .....	27
Product Storage - Locked Refrigerators .....	27
<b>Specific to Service Center Premises .....</b>	<b>27</b>
Non-Contiguous or Unlicensed Areas.....	27
Client Administration Areas – Open Stairwells are Safety Hazards.....	28
Overnight Guests .....	28
<b>Specific to Manufacturer Premises.....</b>	<b>28</b>
Licensed Premises – Roof of Structure .....	28
Manufacturing in a Greenhouse.....	29
Manufacturing in a Culinary Facility .....	29
Equipment Requirements for Manufacturing Facilities.....	29
Handwashing .....	30
Potable Water .....	30
Naming “Strains” .....	30
<b>Licensee Operations .....</b>	<b>31</b>
<b>General Operations.....</b>	<b>31</b>
Developing Operational Best Practices .....	31
Approval Status of Worker Permit Applications.....	31
Sharing Applicant Information .....	31

Verifying License Status.....	31
OPS Licensee Directory .....	31
Transferring a License.....	32
Charity Auctions .....	32
Local Government Verification Hotline.....	32
Use of the Term “Therapy”.....	33
Advertising Requirements.....	33
Out-of-State Advertising.....	34
Unlicensed Sales.....	34
Filing a Complaint.....	34
<b>General Client Safety and Confidentiality .....</b>	<b>35</b>
Client Safety – General Considerations.....	35
Consumption Limits – General Considerations .....	35
Client Support Person .....	36
Portability of Client Records .....	36
Disclosure of Information by Clients.....	37
<b>Facilitator Operations .....</b>	<b>37</b>
Facilitator Scope of Practice and Adverse Reactions.....	37
Documenting Client Doses .....	38
Virtual (Video) Preparation Sessions and Digital Signatures on Forms .....	38
Required Client Forms.....	39
Consumption of Supplements and Other Medications During an Administration Session...	39
Accompanying Clients in Restrooms .....	40
“Bad Trips” .....	40
Clients Refusing to Sign the Release Form .....	41
Early Discharge .....	41
Integration Sessions .....	41
<b>Service Center Operations .....</b>	<b>42</b>
Sharing Data with Third Parties .....	42
Communication with Potential Clients at Service Centers.....	43
Presence of Potential Clients at Service Centers .....	43
Authorized Visitors of Limited Access Areas and Client Administration Areas .....	43

Musician, Breath Worker, Other Performer or Service Provider Present During Administration Sessions.....	43
Client Consent for Others to be Present During Administration Sessions .....	44
Requirements for Video Recording Client Administration Sessions .....	44
Media at Service Centers.....	45
Ketamine (and other intoxicants) on a licensed premises .....	45
Food and Beverages at Service Centers.....	45
Secondary Doses .....	46
Secondary Doses - Storage and Retrieval.....	47
Duration of Administration Session .....	50
Service Center Liability for Dosing Decisions .....	50
Service Center Worker Serving as a Translator.....	50
Service Center Worker Serving as a Support Person .....	50
Medical Professionals at Service Centers.....	51
Service Center Forms - Supplementary Forms used Pre-preparation .....	51
Requirements for Notice When Administration Session Goes Beyond 11:59 pm .....	52
Receiving Transfers of Psilocybin Product at a Service Center .....	52
Point-of-Sale Systems.....	53
Restrooms .....	53
Minors on the Licensed Premises.....	53
Requirements for Temporary Use of Licensed Premises .....	53
Local 'Time, Place and Manner' (TPM) Regulations .....	55
<b>Manufacturer Operations .....</b>	<b>55</b>
Detectable Psilocybin - Culture and Spore Requirements.....	55
Cultivation Batches .....	56
Harvest Lots and Process Lots .....	56
Drying Fungi.....	57
Capsules.....	57
Whole and Homogenized Fungi Testing Requirements.....	57
Potency Testing and Product Degradation .....	57
Re-Testing Psilocybin Products .....	58
Rounding Product Weight .....	58
Product Information Document .....	59

<b>Laboratory Operations .....</b>	<b>59</b>
Wasting Test Samples.....	59
Sampling for Required Tests.....	60
<b>Product Testing, Packaging, and Labeling.....</b>	<b>60</b>
Individual Serving Size .....	60
Listing Dosage on Product Labels.....	60
Psilocybin Analyte - Weight .....	60
Psilocybin Analyte - Labeling.....	61
Including Psilocin Analyte on Label.....	61
Products that Require Refrigeration .....	61
Best By Dates – Product Degradation and Label Information.....	61
Best By Dates – Expired Products .....	62
Product Packaging Requirements .....	62
Sealed Client Packaging .....	63
Re-using Product Packaging.....	63
Handwritten Labels .....	64
<b>Product Tracking, Transfer, Storage, and Waste .....</b>	<b>64</b>
Recording Product Price in TLC-PTS .....	64
Trade Samples .....	64
Product and Product Waste Storage.....	64
Psilocybin Product Quantity Limits .....	65

## **Introduction**

Oregon Psilocybin Services (OPS) section is required to adopt administrative rules to administer [ORS chapter 475A](#), the Oregon Psilocybin Services Act. You can read current OPS administrative rules here: [Oregon Administrative Rules 333-333](#).

The content of this document does not cover all sections of the rules and is a compilation of OPS responses to specific requests for guidance. This document was first published on January 2, 2024 and continues to be updated regularly. Please be sure to access the most recent [OPS Guidance on Administrative Rules document posted online](#).

The topics in this document will likely expand over time, as we field more questions about OPS administrative rules. OPS expects to open administrative rules during the fall of each year and the content of this document may change as new or updated administrative rules are adopted.

OPS is the first licensing and regulatory framework for psilocybin services in the nation. Some questions from our regulated community have helped to identify gaps in the rules or the need for technical fixes. We are working together with our regulated community to continuously improve the way we administer the Oregon Psilocybin Services Act.

Each section in the table of contents is hyperlinked to help navigate the topics, however users can also perform a word search using the “Find” tool (Ctrl+F on PCs or Command+F on Macs) to identify topics of interest.

If you have additional questions about how to comply with OPS administrative rules, which are not addressed in this document, please direct your questions to the general OPS inbox: [OHA.Psilocybin@odhsoha.oregon.gov](mailto:OHA.Psilocybin@odhsoha.oregon.gov).

The date listed in the footer shows when this document was most recently updated. This guidance supersedes any prior guidance. This guidance is not intended to create new or additional requirements not already found in state statute and rule but is intended to explain OHA’s implementation and application of applicable statutes and rules. If the guidance in this document in any way

conflicts with Oregon statute or administrative rule, statute and rule always take precedence.

## **Training Programs**

### **Licensing and Approval Requirements**

#### HECC License Requirements

Facilitator license applicants are required to complete core training, practicum, and pass a comprehensive exam administered by an OPS approved psilocybin training program before applying for a facilitator license. OPS does not license psilocybin training programs. Under ORS 475A, OPS regulation of psilocybin training programs is limited to administrative rules relating to review, approval, denial, or revocation of curriculum. Under Oregon law, the Higher Education Coordinating Commission (HECC) requires licensure of all training programs that meet the statutory definitions of career training schools and/or degree granting programs. HECC also makes determinations on exemption from licensure for all training programs.

OPS rules on psilocybin training program curriculum align with existing Oregon law. The rules do not create new requirements for psilocybin training programs. Instead, they clarify that existing requirements for HECC licensure apply to psilocybin training programs and are necessary to receive and maintain OPS curriculum approval.

A psilocybin training program that received curriculum approval from OPS prior to December 31, 2023, must provide documentation that it has applied for a license from HECC or requested determination from HECC that a license is not required no later than June 1, 2024.

Psilocybin training programs who receive OPS curriculum approval after December 31, 2023, must provide this documentation within 180 calendar days of receiving OPS curriculum approval. Psilocybin training programs who have already been licensed by HECC do not need to re-apply; however, psilocybin training programs are required to maintain their HECC license including renewing the license on an annual basis.



Psilocybin training programs will provide documentation using the [HECC Verification Form](#) published on the OPS website. Failure to provide the required documentation under the timelines described above and in rule may result in revocation of OPS curriculum approval. OPS may also revoke curriculum approval if HECC denies a psilocybin training program's license application. Finally, after a psilocybin training program has received a license or a determination from HECC that approval is not required, the psilocybin training program must maintain that status to ensure that their OPS curriculum approval is not affected.

## **Practicum Requirements**

### **Practicum – Accelerated Training Hours**

Accelerated training hours do not apply to practicum. We encourage training programs to review and understand all accelerated training hours rules outlined in [OAR 333-333-3080](#).

### **Practicum – Client Disclosure Forms**

Clients who agree to allow practicum students to observe their administration session must provide written consent for the students to be present *and* complete an [Authorization to Disclose Personal Identifiable Information](#) that identifies training program and practicum students as the persons receiving the client's information and describes how that information will be used.

### **Practicum – Consumption by Practicum Students**

OAR 333-333-3070 requires that practicum must provide students "an opportunity to observe the facilitation of non-ordinary states of consciousness." This requirement for observation does not apply to scenarios when students are experiencing non-ordinary state of consciousness. Therefore, any hours spent experiencing the effect of psilocybin cannot be credited towards that student's required practicum hours. A training program, however, can offer additional hours for students to access psilocybin services as a client for learning purposes.

To work with a licensed service center on practicum training hours, the training program would need to submit an updated curriculum to OPS for review and approval, as well as update contacts in TLC for practicum site supervisors. Licensed service centers working with training programs will also need to notify

OPS that they are serving as practicum sites for training programs in accordance with OPS administrative rules.

Training programs that offer psilocybin services at licensed service centers to students for learning purposes, in addition to practicum requirements, must submit updated curriculum to OPS for review and approval to ensure they are in compliance with OPS administrative rules.

### **Practicum – Hours of Instruction**

OPS rules define synchronous learning to mean that “students learn from their instructor at the same time as their fellow students” and require that for training that is not conducted in person, at least 50 percent of the training shall be conveyed through online synchronous learning. [OAR 333-333-1010](#), [333-333-3050](#).) The rules do not specifically address the requirements for training hours that are neither in person, nor delivered through online synchronous learning. However, these hours must include instruction. Student directed activities such as reading assignments, reflections and worksheets are not sufficient to qualify as training hours.

### **Practicum – Material Changes to Curriculum**

The OPS Licensing Team must be notified of any material changes to the training program curriculum, which includes practicum, as well as changes to training program contact information and individuals affiliated with the training program, such as instructors and lead educators. If a training program proposes a practicum plan that was not included with its initial application, it must update and submit revised curriculum which will allow the OPS team to evaluate if the practicum plan meets rule requirements. These updates can be submitted through the TLC System. [OAR 333-333-3030\(5\) and \(6\)](#)

### **Practicum—Practicum Site Supervisor**

The practicum site supervisor is responsible for developing students’ practicum skills and evaluating practicum performance including ensuring that students are prepared to take the required exam upon completion of the training program. [See 333-333-3070\(2\) and \(5\)](#). In order to fulfill this requirement, the practicum site

supervisor must be familiar with the training program’s curriculum and requirements for completion. The practicum site supervisor is defined as someone who is affiliated with the service center that is acting as a practicum site for training programs. “Affiliated” does not mean that the practicum site supervisor must be an employee of the service center acting as a practicum site. Instead, it means that the training program and the service center acting as a practicum site must have agreements in place that identify the practicum site supervisor and allow the training program to use licensed premises as a practicum site. The practicum site supervisor must be on-site and in attendance during the entire practicum.

A licensed facilitator may not act as a practicum site supervisor while providing psilocybin services to clients because doing so would be outside of their scope of practice. Scope of practice is defined in [OAR 333-333-1010](#). The practicum site supervisor should not facilitate any psilocybin services while acting in that role because it is not feasible for the same person to simultaneously provide educate to students while fulfilling their duties to monitor and provide client-centered psilocybin services to clients. [See 333-333-5200\(3\)](#).

### **Practicum – Practicum Sites and Alternative Practicum**

Facilitator practicum requirements are described in [OAR 333-333-3070](#). If a practicum site is available, practicum training will take place at a licensed service center serving as a practicum site where students can observe the facilitation of psilocybin services (preparation, administration, and integration sessions) by a licensed facilitator. Students will be trained under the supervision of a practicum site supervisor at a practicum site. As OPS continues to approve service center applications, there may be more opportunities for training programs to partner with service centers to create practicum sites around the state. We encourage training programs to review the OPS Licensee Directory to connect with licensed service centers for practicum site opportunities.

If a practicum site is not reasonably available or accessible to students, a training program may identify alternative practicum in their application for approval. Alternative practicum may include, but is not limited to, observation of taped

facilitation sessions that were recorded with participant consent, participating in psychedelic peer support activities, role playing, and experience with altered states of consciousness that are not drug-induced (for example breath work, meditation or spiritual journeys). Alternative practicum can also take place outside of the U.S. All activity that takes place at an alternative practicum location should be lawful under the applicable laws and regulations for that location. In addition, a lead educator or program director is responsible for developing student practicum skills and evaluating student practicum performance for alternative practicum, with a focus on services with clients. As a reminder, all practicum training must be conducted in person, and no accelerated hours are available for practicum students.

Alternative practicum may include, but is not limited, to the options described in OPS rules. [OAR 333-333-3070\(7\)](#). Students must receive 30 hours of direct practice where they directly participate in alternative practicum activities as well as 10 hours of consultation. Alternative practicum can also take place outside of the U.S. All activity that takes place at an alternative practicum location should be lawful under the applicable laws and regulations for that location. If a training program has a practicum plan update that needs review and approval, it needs to submit a curriculum update.

### **Practicum - Site Supervisors**

[OAR 333-333-1010](#) defines the following: (57) “Practicum site” means a designated service center that provides practicum training. (58) “Practicum site supervisor” means an onsite practicum supervisor of assigned trainees, affiliated with a practicum site. A practicum site supervisor is affiliated with the licensed service center that serves as a practicum site. If a practicum site supervisor provides psilocybin services (preparation, administration, and integration sessions) to a client, they must be a licensed facilitator.

### **Practicum – Students are not Facilitators**

Under ORS 475A, only licensed facilitators may provide psilocybin services to clients. [OAR 333-333-3070\(2\)](#) states that students may be placed at a practicum site where they “can observe and facilitate psilocybin services under the supervision of a practicum site supervisor.” OPS interprets the language in [333-](#)

[333-3070](#) to mean that students will observe facilitation and participate in consultation, rather than providing services directly to clients. Practicum students may not be considered facilitators for any purpose under OPS administrative rules. For example, practicum students may not be left unattended with clients during an administration session. This interpretation is supported by the statute, which requires that psilocybin services must be provided by a licensed facilitator and the rule itself which states that students will be under the supervision of a practicum site supervisor. Training program students are not licensed as facilitators and, therefore, cannot conduct administration sessions nor provide any other psilocybin services.

#### Practicum – Students Who Receive Psilocybin Services in Practicum

Under ORS 475A, students in practicum may only consume psilocybin as clients. A licensed service center and licensed facilitators must treat all students of OHA approved psilocybin facilitator training programs that are receiving psilocybin services as clients. All rules, regulations and requirements must be followed. Facilitators must conduct a preparation session, administration session, and integration session with clients and ensure all required paperwork, including client consent forms, are filled out appropriately. If any client is not an appropriate fit for the facilitator or service center, a licensed facilitator has a duty to make a responsible referral. If a client is not appropriate for psilocybin services, a licensed facilitator must decline services in accordance with ORS 475A and OAR 333-333.

#### **Practicum - Timing of Completion**

A practicum can take place at any time during the training program. While OPS rules do not require a specific timeframe for practicum to take place, practicum is meant to provide students with experience in observation of psilocybin services and preparing them for providing psilocybin services once they have received a facilitator license. Practicum provides students with opportunities to apply what they have learned in the training program, which includes any final core training if practicum is staggered.



## **License Applicants**

### **General OPS License Information**

#### **Number of Licenses OHA Will Issue**

Under [ORS 475A](#), Oregon Psilocybin Services (OPS) does not have the authority to limit the number of licenses issued for any of the four license types.

#### **Individuals Holding Multiple Licenses**

Individuals may hold multiple licenses if they meet the requirements for each of the license types. Separate license applications and license fees are required for each of the license types. Licensed premises may be adjacent to each other, but they may not have overlapping footprints (for instance, the boundaries of a licensed manufacturing site may not overlap with the boundaries of a licensed service center). An individual may not hold an interest in more than one manufacturer license or more than five service center licenses.

#### **Business License Requirements**

OPS rules state licensees that are required to be registered with the Oregon Secretary of State must register prior to receiving a license and maintain registration. Any questions regarding business registration requirements must be directed to the [Oregon Secretary of State](#).

#### **Liability Insurance for Licensees**

Oregon Psilocybin Services (OPS) is unable to offer advice on insurance and liability. Although ORS475A states that the Oregon Health Authority (OHA) may require liability insurance, Oregon Psilocybin Services Administrative Rules do not require liability insurance for any of the license types at this time. This could change in the future with any changes to ORS 475A or administrative rules.

### **License Application Process**

#### **Residency Requirements**

There are residency requirements for facilitator, manufacturer, and service center licenses. The requirements vary by license type and applicants are responsible for ensuring all residency requirements outlined in [OAR 333-333-4050](#) are met. These residency requirements will be in place until January 1, 2025.

Applicants and licensees must retain documentation that demonstrates they meet the residency requirement. Proof of residency may be demonstrated by providing:

- A valid Oregon driver license or Oregon identification card issued at least two years prior to the date of application
- Oregon full-year resident tax returns for the last two years
- Proof of Oregon voter registration issued at least two years prior to the date of application
- Utility bills, lease agreements, rental receipts, mortgage statements or similar documents that contain the name and address of the applicant dated at least two years prior to the date of application and from the most recent month
- Letter from a homeless shelter, nonprofit entity, employer, or government agency attesting that applicant has been an Oregon resident for at least two years
- Any other documentation that the Authority determines to reliably demonstrate proof of Oregon residency for the last two years

Non-profit applicants for a manufacturer or service center license must complete the Residency Questionnaire for Non-Profit Entities as part of their license application.

Oregon residency is not required, however, to [access psilocybin services](#).

### **Background Checks**

All license types will have an identical background check fitness determination. If an applicant has passed a background check for a license and then applies for another license within thirty days of the background check, OPS can apply the first result directly to the second license application without running a second background check.

Oregon Administrative Rules [\(OAR\) 333-333-4100](#) outlines the background check rules for Oregon Psilocybin Services (OPS) license and worker permit applicants. To create a safety, equity, and justice centered criminal background check process, background checks are conducted by a certified third party and assessed by the Oregon Department of Human Services (ODHS) and the Oregon Health Authority Background Check Unit (BCU).



An applicant who has completed a background check for an OPS license application is not required to complete a new background check for a worker permit application if the person completed the background check within 12 months of their worker permit application.

However, you must still complete a new background check for any new license application. New fingerprints are not required if the previous fingerprints were completed within 30 days of submitting a previous application. If it has been longer than 30 days since you submitted your fingerprints for previous application, you may be required to undergo a new background check and provide new fingerprints for your license application.

The [Overview of the Oregon Psilocybin Services Background Check Process](#) provides more details about the process.

### **Operational Name**

“Operational Name” means an individual, legal entity, or business name listed on an application and license certificate of a service center, manufacturer, or laboratory license that the licensee(s) will use for purposes of advertising and business with the public. An individual applying for a service center, manufacturer, or laboratory license may use a business name as the operational name in the license application.

### **Conviction Guidance for Licensees**

Licensees and applicants are required to notify the Authority in writing if convicted of a felony or misdemeanor See OAR 333-333-4200. Reporting may initiate an additional background check. When reporting a new conviction, please send a message to the OPS Licensing Program in TLC with the subject line, “Conviction Reporting.” The OPS Licensing Program will notify the Oregon Background Check Unit (BCU), which may initiate an additional background check. Please do not disclose conviction details to OPS. The Oregon Background Check Unit (BCU) will require conviction details when you complete the BCU Authorization and Disclosure Form.

### **Annual License Fees**

License fees are determined through the state agency budget process and were adopted in final rules in December 2022. The sum of annual license fees collected

must cover the cost of operating the Oregon Psilocybin Services (OPS) section. License fees are required on an annual basis and are part of the license renewal process. License fees are paid online through the Training, Licensing and Compliance (TLC) system or may be paid in person. Applicants will receive instructions on how to pay application and license fees during the application process.

At the time of initial license application, an applicant for a service center, manufacturer, or laboratory license must pay a \$500 non-refundable application fee. An applicant for a facilitator license must pay a \$150 non-refundable application fee.

If the application meets all licensing requirements, psilocybin service facilitators pay a \$2,000 nonrefundable annual fee. Manufacturers, Testing Laboratories and Service Center Operators pay a \$10,000 nonrefundable annual fee.

There are some ways that a licensee can pay a reduced fee. If a manufacturer or service center is a non-profit entity, they can apply to pay a nonrefundable reduced annual fee of \$5,000. An individual applicant may also qualify for a reduced fee if they (1) have received Supplemental Security Income benefits within 12 months prior to the application date, (2) received or were eligible to food stamp benefits within 12 months prior to the application date, (3) are enrolled or eligible to be enrolled in the Oregon Health Plan within 12 months prior to the application date, or (4) have served in the Armed Forces of the United States. If an individual applicant satisfies any of these requirements, manufacturer and service center applicants can pay a \$5,000 nonrefundable annual fee and facilitators pay a \$1,000 nonrefundable annual fee. If an applicant for a manufacturer or service center license application is a non-profit entity, the applicant can pay a \$5,000 nonrefundable annual fee.

An applicant for any license type has 180 calendar days to pay the license fee from the date they are notified that their application is pending approval. If the license fee is not paid within that timeframe, the application is considered incomplete and it may be closed ([OAR 333-333-4120 \(3\)](#)). It's important to know a license application with the status *pending approval* is not approved and cannot exercise privileges associated with the license.

## Site Inspections

Once the Oregon Psilocybin Services (OPS) Licensing Program has reviewed a license application, required documents have been submitted, and background checks and social equity plan requirements are met, the OPS Compliance Program will work with an applicant on preparing for a site inspection.

Photographs of the proposed premises will be requested, and a pre-site inspection will be scheduled. Once applicants have addressed issues identified in the pre-site inspection and the OPS Compliance Program has determined that the applicant is ready for a site inspection, they will work with you on scheduling. For more information on site requirements, please review the Inspection Orientation documents:

[Inspection Orientation for Service Center Applicants](#)

[Inspection Orientation for Manufacturer Applicants](#)

[Inspection Orientation for Laboratory Applicants](#)

For more information about premises requirements, please see the premises sections of this document.

## Worker Permits

Oregon Administrative Rules [\(OAR\) 333-333-4070](#) outlines the requirements for worker permits. The rules require that all individuals who perform work for, or on behalf of, a licensee must have a valid worker permit issued by the Oregon Health Authority (OHA). This also includes any individual/employee (including licensees and licensee representatives) who participate in:

- The provision of psilocybin services at a licensed premises.
- The possession, manufacturing, securing, or selling of psilocybin products at a licensed premises.
- The recording of the possession, manufacturing, securing, or selling of psilocybin products at a licensed premises.
- The verification of any document described in ORS 475A.445.

The [OPS Worker Permit webpage](#) has application information, including a comprehensive [Worker Permit Application Guide](#) to support applicants in the worker permit application process.

General worker permit requirements include:

- Applicants must be 21 years of age or older.
- Must pass a criminal background check (see: [OPS Background Check Process](#)).
- Must pay a non-refundable worker permit fee (\$25).

### **Proof of Licensure or Worker Permit**

If you have submitted an application online through the Training Program, Licensing, and Compliance (TLC) system, the proof of license or worker permit can be generated from the “My Licenses and Permits” tab on the left side of the webpage. If you mailed your application, OPS will email you a PDF of the proof of license.

As a reminder, manufacturer, service center and laboratory licensees must display a proof of licensure in a prominent place on the licensed premises. Facilitator licensees must be able to provide proof of licensure when performing preparation, administration, or integration sessions.

### **Facilitator Applicant Information**

#### **Holding Other Professional Licenses**

Oregon Psilocybin Services (OPS) is unable to provide advice about how becoming a licensed psilocybin services facilitator will impact your professional license. We encourage you to consult with your professional licensing board for guidance on any risks that may exist if licensed under ORS 475A.

Although licensed facilitators may also hold other professional licenses, they may not practice on any other professional license types while providing preparation, administration, or integration sessions to clients. Licensed facilitators may decline services to clients for any reason but may also refer clients to other licensed facilitators that may have more experience serving specific client needs.

#### **OPS Facilitator Regulations Exam**

The OPS Facilitator Regulations Exam is made up of questions based on rule requirements outlined in [Oregon Administrative Rules \(OAR\) Chapter 333, Division 333](#). This is an important distinction as the regulations exam is not a skills-based exam, which is administered by training programs as a requirement for training completion.

The following information may also be helpful to know regarding the OPS Facilitator Regulations Exam:

- A score of 75 percent is passing.
- An applicant who does not pass the exam may retake the exam.
- The exam may be retaken immediately.
- There is no limit on exam retakes.
- Applicants may access and refer to the statute and administrative rules found in [ORS 475A](#) and [Oregon Administrative Rules](#) when answering exam questions. It may be helpful to have these links open while completing the exam.

More information about the OPS Regulations Exam can be found on the OPS Facilitator License webpage in the online and mailed application guides. In addition, a copy of the full exam can be viewed and printed from within the [Facilitator License Printable Application](#).

## Site Location Information

### Local Opt-Out

Local governments may adopt ordinances that prohibit issuing service center and/or manufacturer licenses within their jurisdiction. After an ordinance is adopted by a local government, it must be referred to voters at the next statewide general election in accordance with [ORS 475A.718](#). When a local government adopts an ordinance, they must notify OPS by sending a copy of the adopted ordinance to our general email address:

[OHA.Psilocybin@odhsoha.oregon.gov](mailto:OHA.Psilocybin@odhsoha.oregon.gov)

Upon receiving notice of an adopted ordinance, OHA will not issue licenses to those premises to which the prohibition applies until the date of the next statewide general election. If the ordinance is not approved by voters in the next general election, OHA will begin licensing psilocybin businesses that meet the criteria established in statute and rule on the first business day of the January immediately following the date of the next statewide general election.

The [OPS Local Ordinance Spreadsheet](#) includes data regarding local psilocybin ordinances and is based on local government reporting per ORS 475A.718 (3) and information gathered from the Oregon Secretary of State. This spreadsheet is

updated regularly but may not be comprehensive. Please reach out to local governments directly to confirm ordinance information.

### **Zoning Requirements**

Land use and zoning determinations are made by local governments. If the proposed site is located within city limits, you would generally contact the city. If the proposed site is located in an unincorporated area, you would generally contact the county. OPS cannot verify whether a specific address is an appropriate zone for a service center or provide guidance on local government processes. To determine whether zoning is appropriate please complete a [Land Use Compatibility Statement \(LUCS\) form](#) and submit it to the local planning, land use, or development office (city or county) for their review.

We also encourage you to review the licensed premises location requirements outlined in [OAR 333-333-4300](#).

### **Co-Location of Licensed Premises**

OPS rules do not prohibit issuing a psilocybin license at a site that is adjacent to another business, but the licensed premises may not overlap with the other business. For example, a licensed manufacturer could be on the same tax lot as a licensed service center but must have a separate licensed premises that is clearly defined and separated by barriers. Both licensees would need to comply with their rules, operating separately and independently. Every license application will be evaluated individually to determine whether the proposed business complies with requirements for licensure. These requirements include a Land Use Compatibility Statement (LUCS) from the city or county and operational requirements related to access, security, and separation from adjacent businesses.

### **Co-Location with a Cannabis Business**

[Oregon Administrative Rules \(OAR\) 333-333](#) do not prohibit issuing a psilocybin license at a site that is adjacent to another business, but the licensed premises may not overlap with the other business. An Oregon Psilocybin Services licensed manufacturer could be on the same tax lot as an OLCC licensed cannabis grower but must have separate license premises that are clearly defined and separated with barriers. Both separate licenses would need to comply with their rules, operating separately and independently. Also, please note that every license

application will be evaluated individually to determine whether the proposed business complies with requirements for licensure. These requirements include a [Land Use Compatibility Statement \(LUCS\)](#) from the city or county and operational requirements related to access, security and separation from adjacent businesses.

### **Co-Location with a Residence**

A licensed premises itself cannot be located at a primary residence per Oregon Psilocybin Services (OPS) rules but could be on the same tax lot as a primary residence. There may be additional local zoning rules and regulations apart from OPS rules. The licensed premises needs to be separate from any residence and comply with all operational rules on access and security. We are unable to make a determination regarding specific premises until we receive a completed license application including a floorplan, as described in [OAR 333-333-4000\(3\)\(e\)](#).

### **Service Center School Proximity Requirements and Barrier Exceptions**

[ORS 475A.310](#) prohibits OPS from issuing a license to a service center located within 1,000 feet of a school. For purposes of measuring the 1,000 feet distance between a service center and a school “within 1,000 feet” means a straight-line measurement in a radius extending for 1,000 feet or less in any direction from the closest point anywhere on the boundary line of the real property comprising a school to the closest point of the licensed premises of a service center.” [See OAR 333-333-4130\(4\)\(b\)](#)

It is the applicant's responsibility to ensure the location of the service center is not within 1,000 feet of a school.

The [Psilocybin School Exclusion Map](#) was developed by Oregon Psilocybin Services to support applicants with the process of identifying if a proposed location is within 1,000 feet of a school to comply with ORS 475A.310. The mapping tool is being updated regularly but may contain inaccuracies. Please do not rely solely on this tool for making a determination for a proposed location.

While the exclusion map tool may be used as a reference to locate possible schools near the proposed location, private schools are not required to register with Oregon Department of Education (ODE), and the information captured by the tool may be incomplete. For more information, please see the [Oregon Department of Education \(ODE\) Public and Private School Directory](#).

OPS has a process for verifying whether a facility meets the definition of a school and whether the facility is still operating at the location identified on the map. The definition of elementary and secondary school can be found in our administrative rules. See [OAR 333-333-1010](#)(29) and (73). Facilities that offer only kindergarten and pre-k are not considered schools for the purpose of determining school exclusion zones for psilocybin service centers. The method for measuring distances between schools and service centers is described [in OAR 333-333-4130](#)(4)(b).

To summarize, the measurement goes from the footprint of the licensed premises to the property line of the school. When a building is partially located within a school exclusion zone, it may be possible to issue a service center license within areas of that building that are outside of the exclusion zone. This is a fact-specific determination, and it requires separation between the licensed and unlicensed areas of the building. All security and operational requirements for licenses need to be satisfied regardless of whether the address also contains unlicensed areas. Our section cannot approve any location until we receive a completed application, but we are happy to discuss this issue if you have any further questions.

ORS 475A.310 creates an exception to the prohibition of a service center being within 1,000 feet of a school. If a proposed service center premises is within 1,000 feet of a school but is located more than 500 feet from a school, *and* if OPS determines that there is a physical or geographic barrier capable of preventing children from traversing to the proposed service center premises, the service center is eligible for licensure. An example of a physical barrier is a prison or an interstate highway. An example of a geographic barrier is a river or a mountain. Private properties, small streams, or property fences do not meet the criteria for a school exclusion exception request. See [OAR 333-333-4130](#)(4)

To meet the criteria for a school exclusion exception, the applicant must demonstrate that a physical or geographic barrier exists and demonstrate that the barrier would prevent children from traversing to the proposed licensed premises. If OPS determines that the physical or geographic barrier meets the criteria, an applicant may be granted a school exclusion exception.



To apply for a school exclusion exception, an applicant must complete the [School Exclusion Exception Request Form and](#) submit all the information required to be submitted along with the form.

1. If applying for a service center license by paper application, the Psilocybin School Exclusion Exception Form and other required information must be submitted with the license application.
2. If applying for a service center license in TLC, upload the Psilocybin School Exclusion Form and required information as requested in TLC.

Applying for a school exclusion exception does not guarantee that an exception will be granted by OPS. OPS will review the request and communicate the approval or denial to the applicant.

### **Licensing Responsibilities of a Landlord**

In certain instances, a landlord may be considered an applicant if they receive revenue from the licensed business or exercise control over the business, but a landlord-tenant relationship does not create a licensable interest for the landlord unless other factors are present. You can find our definition of applicant at [OAR 333-333-1010\(7\)](#).

Under ORS 475A.290(3)(a), landlords must provide permission for a tenant to manufacture psilocybin at the proposed address if the applicant does not own the property. OPS has created a [form](#) for applicants of a manufacturer license to use to fulfill this requirement.

### **General Premises Information**

#### **Premises Plan Requirements**

Oregon Psilocybin Services (OPS ) has created a [Premises Plan Checklist](#), which outlines the required elements of a premises plan per [Oregon Administrative Rule \(OAR\) 333-333](#).

#### **ADA Requirements**

Title III of the of the American Disabilities Act (ADA) applies to all places of public accommodations and requires facilities to comply with ADA standards. The ADA applies to all business and is not addressed by OPS rules. ADA requirements will depend on the type of business and the building where the business is located. For information about the ADA, the [Northwest ADA Center](#) is a good resource.

Complaints regarding ADA compliance can be filed with the following agencies, on their website:

BOLI: [BOLI : File a Complaint : For Workers : State of Oregon](#)

US DOJ: [File a Complaint | ADA.gov](#)

### **Restroom Requirements**

[OAR 333-333](#) only addresses client restrooms at licensed service centers. Licensed service centers may use portable restrooms to satisfy our rule requirements for client restrooms. If they do so, these restrooms must be located in a licensed outdoor area on the premises and must be discussed during all client preparation sessions. For other restroom questions, such as employee restrooms, and for other license types you may want to consult the [Oregon Occupational Safety and Health Agency](#) (OSHA) or local building code for relevant requirements.

### **Security System Requirements**

Oregon Psilocybin Services (OPS) rules related to security systems are broken down into a few categories:

Alarm System - [333-333-4600](#)

Video Surveillance Equipment - [333-333-4620](#)

Required Camera Coverage and Camera Placement - [333-333-4630](#)

Video Recording Requirements for Licensed Facilities - [333-333-4650](#)

The camera system needs to meet all requirements in OPS administrative rules. Rule requirements include, but are not limited to, back-up power for the system, minimum retention periods, and the ability to produce copies of the video when needed. Cloud based storage of security camera footage is allowed under our rules.

Security camera systems will be reviewed with the premises plan and in pictures that are submitted before and during the in-person site inspection. Changes in camera angles and potentially additional cameras may be requested in these reviews.

Every premises will be inspected prior to a license being issued, and video and alarm systems required by administrative rules need to be in place at the time of inspection. As a practical matter, applicants are not required to have these

systems in place at the time of the application but will need to have a premises plan that documents the locations of cameras and other items. Because applications can be deactivated if too much time elapses between the initial application and the final inspection, we recommend that applicants have at least started installing these systems at the time of their application. We will not be able to conduct a site inspection if these are not in place.

### **Product Storage – General Requirements**

OPS administrative rules offer two options for storage of psilocybin products. Psilocybin products can be stored in an enclosed area secured with a steel door and steel frame. Alternatively, psilocybin products may be stored in either a safe or a locked refrigerator (See [OAR 333-333-4510](#)).

Any type of cabinet located in an enclosed area secured with a steel door and steel frame may be used to store psilocybin products. However, if the cabinet is not located in such an area, it must meet the definition of a safe. Under OPS rules a safe is defined as a fireproof metal cabinet with a mechanical or electronic combination lock that is capable of storing psilocybin products and weighs at least 375 pounds.

### **Product Storage - Locked Refrigerators**

OPS cannot provide recommendations for specific types of refrigerators for storage. Refrigerators with factory-installed locks or added locks would both be permissible if they provide adequate safeguards against theft and are able to prevent access to the stored product. OPS cannot determine if a refrigerator meets rules requirements without specific details.

## **Specific to Service Center Premises**

### **Non-Contiguous or Unlicensed Areas**

OPS rules do not allow for a premises to have areas that are unconnected.

In addition, moving psilocybin products through unlicensed areas is prohibited except when transferring between licensees in compliance with OPS rules. If there is unlicensed space between two licensed spaces, they would count as two separate licensed premises and we would therefore not be able to license them under a single application.

## **Client Administration Areas – Open Stairwells are Safety Hazards**

[OAR 333-333-4450\(2\)](#) requires that client administration areas must be free of conditions that could pose a risk to clients experiencing the effects of consuming psilocybin. Open stairwells in client administration areas present a safety hazard and must be excluded from client administration areas identified in the premises plans.

## **Overnight Guests**

Overnight guests are prohibited on the licensed premises of a service center and would be a violation of administrative rules related to hours of operation. [OAR 333-333-4480\(1\)](#). The security and operational requirements in administrative rules apply to all areas of a licensed premises. These requirements include use of cameras and alarms and limiting access to the premises to persons under the age of 21 years. Local governments may adopt Time, Place, and Manner (TPM) regulations that may be more restrictive than administrative rules.

It may be possible to host guests, including overnight guests, in an unlicensed area that is located on the same property as a licensed service center. Doing so would require physical separation between licensed and unlicensed areas, and the licensed area would need to satisfy all statutory and rule requirements. We are unable to offer pre-approval of business plans, and each premises will be evaluated on a case-by-case basis when a completed application is received.

## **Specific to Manufacturer Premises**

### **Licensed Premises – Roof of Structure**

Unfinished building materials, such as a clear plastic corrugated roof, may not meet the requirements of [OAR 333-333-2020](#). This rule requires manufacturers to maintain their 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. When the ceiling of a structure appears to be unfinished and the roof has openings and gaps in its construction that could allow rodents and other pests to enter the interior space, it does not satisfy the rule requirements. An unfinished roof also creates an environment that could be conducive to the development of microbials, molds, and unintended fungi. These unfinished structural features create an environment that may result in contamination of psilocybin products and is not suitable for safe and sanitary operations.

In addition, a clear plastic corrugated roof on a licensed premises does not meet the requirements of OAR [333-333-4550\(1\)](#). The rule states that a licensee “is responsible for the security of all psilocybin products on the licensed premises or in transit from the licensed premises, including providing adequate safeguards against theft or diversion of psilocybin products.” If the roof of the structure is constructed of thin corrugated clear plastic material, the structure does not adequately safeguard against theft. Unreinforced corrugated plastic material is insufficient in prevention of unauthorized entry without the use of tools or special equipment.

### **Manufacturing in a Greenhouse**

We will evaluate greenhouses on a case-by-case basis to determine whether they satisfy applicable security rules and premises requirements. They must meet the same standards of security stated in rules. Hoop houses are not allowed for cultivation because they cannot be adequately secured. For more information, please review [OPS administrative rules](#).

### **Manufacturing in a Culinary Facility**

The licensed premise cannot overlap with other culinary operations. [Oregon Administrative Rules \(OAR\) 333-333](#) do not prohibit issuing a psilocybin license at a site that is adjacent to another business, but the licensed premises may not overlap with the other business. An Oregon Psilocybin Services licensed premises could be on the same tax lot as another business but must have separate license premises that are clearly defined and separated with barriers. Both separate licenses would need to comply with their rules, operating separately and independently. Also, please note that every license application will be evaluated individually to determine whether the proposed business complies with requirements for licensure. These requirements include a [Land Use Compatibility Statement \(LUCS\)](#) from the city or county and operational requirements related to access, security and separation from adjacent businesses.

### **Equipment Requirements for Manufacturing Facilities**

Oregon Psilocybin Services does not have any specific advice on equipment or set up. We do not require specific equipment for manufacturing, but you will need to meet all the rules for a manufacture license. Depending on which endorsement

you are planning on requesting, you will have different rules that must be followed.

Any equipment set up should be with the intent to follow all OPS rules including not allowing high heat or pressure for extraction.

### **Handwashing**

Manufacturers are required to have a hand washing station on their licensed premises in order to keep a clean and sanitary work environment to meet the requirements of [OAR 333-333-2020\(1\)\(c\)](#).

### **Potable Water**

All manufacturers must use potable water when manufacturing psilocybin products.

### **Naming “Strains”**

There is nothing in rule that disallows or references naming of strains, as long as you don’t use names that are appealing to minors (OAR 333-333-6100(1)(b)) or advertise your product with specific attributes like “relaxing” or “energizing”, that is not supported by the totality of publicly available scientific evidence. (OAR 333-333-6100(1)(e)). Also, manufacturers are expected to adhere to OPS requirements related to adulterants in their cultivation practices. This means that adulterants may not be applied to fungi, substrates or growing medium during cultivation.

## **Licensee Operations**

### **General Operations**

#### **Developing Operational Best Practices**

In developing best practices and operational guidelines for your licensed business, please remember that OPS rules set minimum standards designed to protect public health and safety. The rules are a floor, not a ceiling, and offer flexibility for varied operational models. If licensees choose to adopt practices that exceed the minimum requirements established in rule, they are welcome to do so.

#### **Approval Status of Worker Permit Applications**

A worker permit application with the status *approved, pending fee payment and clearance* is not approved and the applicant cannot exercise privileges associated with the worker permit. Once the worker permit fee payment clears, there are several processes our team must complete in order to issue the worker permit. Once approved with all the applicable fees paid, the applicant will receive a notice indicating the worker permit has been issued.

#### **Sharing Applicant Information**

OPS cannot provide updates on the status of applications to persons not listed on the application due to privacy and confidentiality. If any applicant has questions about the status of their application, they should reach out to the OPS Licensing Program directly. OPS processes applications in the order they are received, and the application review process may take several weeks. We can only process applications that are complete and rely on responsiveness from applicants to keep the process moving.

#### **Verifying License Status**

Please visit the [Oregon Psilocybin Services \(OPS\) – Search for Licensee and Worker Permit Status webpage](#) to verify license or worker permit status. You must enter the license number and license type to verify.

In addition, OPS issues licensees a proof of license which includes a QR code which can be scanned to verify the status of the license or worker permit.

#### **OPS Licensee Directory**

The [Oregon Psilocybin Services \(OPS\) Licensee Directory](#) provides licensees the opportunity to connect with each other for business purposes and for the public to locate licensed service centers. The directory contains information provided by OPS licensees who have consented to have their information published. Please note that the directory is not a comprehensive list of all OPS licensees. During the license application process, applicants are asked if they consent to be listed in the OPS Licensee Directory. Being listed in the directory is optional and if the license applicant does not consent, they may still be licensed with OPS. As a reminder, although participation in the directory is optional, information provided in application materials, including applicant name, is subject to disclosure under Oregon's public records laws.

The OPS Licensee Directory is not used for license verification. Please visit the [OPS – Search for Licensee and Worker Permit Status webpage](#) to verify license or worker permit status.

### **Transferring a License**

Under [ORS 475A](#) licenses are not transferrable. If a licensee wishes to sell their business, the buyer will need to apply for a new license in their own name. Once the new license is granted, the prior license will be surrendered.

### **Charity Auctions**

Offering psilocybin services to charity auctions is not prohibited by ORS 475A or administrative rules. Charity auctioning of psilocybin services may not include psilocybin products. Psilocybin products cannot be discounted or donated to auctions per [OAR 333-333-6000\(9\)](#), which states that “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.”

### **Local Government Verification Hotline**

[ORS 475A.582](#) requires the Oregon Health Authority to maintain a telephone hotline for designated city or county employees to verify the address of a location of a premises for which a license has been issued under ORS 475A.210 to 475A.722 or the location of a premises for which an application for licensure has been submitted under ORS 475A.245. City and county employees must submit an [Authorized Personnel Form](#) before verification may begin.



Once authorization has been completed, the authorized city or county employee may contact the Local Government Verification Hotline at (971) 673-0225 with the full address of the location they request to verify is licensed by Oregon Psilocybin Services (OPS). OPS will only confirm or deny if the address is licensed under ORS 475A.

### **Use of the Term “Therapy”**

Although people may sometimes refer to Measure 109 as “psilocybin therapy”, neither statute nor OPS administrative rules refer to, or define, the provision of psilocybin services as therapy, and clients may receive services for any reason. OPS rules on scope of practices require that facilitators shall not engage in conduct that requires additional licensure while providing psilocybin services, including diagnosing and treating mental health conditions. Facilitators who hold licenses in other fields are prohibited from practicing under those licenses while providing psilocybin services. See [OAR 333-333-5130](#).

For licensees, all advertising must comply with [OAR 333-333-6100](#), which prohibits statements that are deceptive, false, or misleading in addition to claims of curative or therapeutic effects.

### **Advertising Requirements**

Oregon Psilocybin Services (OPS) hosts an online license directory. This directory is limited to licensees who choose to participate and lists only certain contact information. Any licensee may choose to advertise in other forums if subject to applicable rule requirements. These requirements include:

- [333-333-6100](#)
  - Deceptive, false or misleading advertising is prohibited.
  - May not target persons under 21 years of age.
  - May not encourage activity that is illegal under state law.
  - May not claim that psilocybin products are safe because they are tested and regulated.
  - May not claim a curative or therapeutic effect or make health claims that are not supported by the totality of publicly available scientific evidence. This doesn’t mean that 100% of the available evidence

must support the claim. It does mean that all available evidence must be considered.

- [333-333-6110](tel:333-333-6110)
  - No more than 30 percent of the audience for television, radio, billboard, print media or internet advertising may be persons under 21 years of age. Companies that sell advertising are usually able to provide demographic information on the target audience.
  - Licensees must use reasonable efforts to prevent persons under 21 years of age from visiting their website, for example by using “age gates.”

Advertising that does not conform to these requirements must be removed and may be the subject of an administrative violation.

### **Out-of-State Advertising**

Oregon Psilocybin Services cannot provide legal advice. Although OPS enforces administrative rules on advertising, other states may have laws that restrict psilocybin related advertising. OPS cannot advise you on such matters.

### **Unlicensed Sales**

Oregon Psilocybin Services has authority to regulate licenses issued under ORS 475A. Activity in the unregulated space may be subject to criminal penalties and is a matter for law enforcement. We encourage you to contact law enforcement regarding these concerns.

### **Filing a Complaint**

Licensees, clients, and the general public can submit concerns or complaints using the online [Oregon Psilocybin Services \(OPS\) complaint form](#) or by mailing in a complaint form. Once we receive a complaint, OPS will determine if there are potential violations of ORS 475A or OAR 333-333 and whether the Oregon Health Authority has the authority to take further action. OPS will only investigate violations of ORS 475A or OAR 333-333. If your complaint is related to criminal activity, please contact law enforcement.

Complaints are subject to public disclosure under Oregon's Public Records Law. If you are concerned about your privacy or safety, OPS will make effort to keep your identity confidential to the extent permitted by law.

## **General Client Safety and Confidentiality**

### **Client Safety – General Considerations**

OPS rules support client safety in many ways, including rules on facilitator conduct, client safety and support planning, transportation planning, informed consent, client bill of rights, duty to contact emergency services and other requirements. One of the most important factors in ensuring client safety is the licensed facilitator’s interaction with clients, as well as understanding their own limitations as a licensed facilitator. Trained and licensed facilitators work within their scope of practice and level of expertise to identify potential safety risks. Ensuring client safety begins with preparation sessions, before any products are consumed, and continues through administration sessions, through follow-up contact with clients within 72 hours of administration sessions, and through optional integration sessions. Although OPS rules provide an important framework for client safety, the facilitator-client relationship and service center operating guidelines will ultimately be the most important factor in ensuring safe and effective psilocybin experiences.

OPS rules create a container to support client safety, but it is the responsibility of all licensees to ensure practices that support the safe provision of psilocybin services in Oregon. OPS will investigate complaints, incidents, or concerns related to safety issues or statute and rule violations that occur on licensed premises and during the provision of psilocybin services.

### **Consumption Limits – General Considerations**

OPS rules on client consumption limits should be considered in the context of other administrative rules that support client safety. First, the required client informed consent document contains an acknowledgement that “the risks and benefits of consuming doses greater than 35 mg of psilocybin analyte are unknown.” One should also note that dose-dependent minimum durations for administration sessions are minimums. After the specified minimum period elapses, OPS rules require facilitators to consult with clients and “determine whether the administration session should be concluded.” Licensed facilitators will rely on their training and expertise, in addition to input from clients, in making this determination. As with other aspects of client safety, the licensed facilitator plays a key role in ensuring clients consume appropriate doses of

psilocybin. Facilitators are required to receive training on dosing strategies and considerations, in addition to other training designed to promote client safety. During preparation sessions, clients complete a client information form and safety and support plan designed to identify safety risks and measures to mitigate those risks. Under [ORS 475A.370](#) facilitators may refuse to provide services for any reason. Therefore, facilitators are not required to provide services to a client who requests higher doses, and service centers can create operational guidelines that prohibit higher doses as well.

### **Client Support Person**

A client support person is for necessary medical or physical assistance, examples include mobility, toileting, consuming psilocybin products, and using medical or communication devices during an administration session. Client support persons roles can be referenced in [OAR 333-333-5050](#) and [5070](#). Client support persons are not allowed for emotional support. A “sober coach,” sponsor or other person present to provide emotional support does not qualify as a client support person.

Facilitators and licensee representatives are prohibited from acting as a client support person while providing psilocybin services or acting on behalf of a licensed service center. Facilitators and service centers may provide referrals to client support persons but may not compensate client support persons who attend administration sessions, nor require clients to use specific client support persons.

### **Portability of Client Records**

The Authorization to Disclose Personal Identifiable Information form referenced in [OAR 333-333-4810](#) is required for any disclosure of personally identifiable information, including sharing the information with other licensees that have not provided psilocybin services to the client. If a client requests to have their information shared with another licensee, they need to complete an Authorization to Disclose Personal identifiable Information form. Facilitators can access client records through the service center where the client participated in an administration session. If the facilitator or client would like to move the records to another service center, the client needs to complete an Authorization to Disclose Personal identifiable Information form.

It is important that client records are kept confidential and only shared with client consent. Client records are not to be shared with others, including other licensees that have not provided psilocybin services to the client, without the client understanding who will receive the documents and for what reason before consenting to their records being shared.

### **Disclosure of Information by Clients**

OPS administrative rules and statute do not have specific restrictions on what clients can share or communicate about psilocybin services they have received. We encourage the clients to also uphold client confidentiality if they participate in group administration sessions. Service centers and facilitators do have requirements that protect client confidentiality, however.

A service center must review any content they put on their website that contains client reviews to ensure the comments meet OPS advertising requirements in [OAR 333-333-6100](#) and client confidentiality requirements found in [OAR 333-333-4810](#) and ORS 475A.450. A service center, facilitator, permitted worker, or other employee may not disclose any information that may be used to identify a client, or disclose any communication made by a client related to psilocybin services or selling psilocybin products to a client, except with client's consent or otherwise as allowed by ORS 475A.450.

## **Facilitator Operations**

### **Facilitator Scope of Practice and Adverse Reactions**

All three components of psilocybin services, including preparation, administration, and integration sessions, are provided by a licensed facilitator. Licensed facilitators must remain within their scope of practice, as described in OPS rules in [OAR 333-333-5130](#). This includes taking a non-directive approach to psilocybin services. OPS rules define non-directive facilitation as “a client-directed approach to facilitation in which the facilitator maintains a consistent disposition with a client, while avoiding giving the client direct advice or directly interpreting a client's statements, behaviors or needs unless appropriate for health and safety reasons.”

Facilitators are trained to respond to and assist clients during an administration session if their experience becomes uncomfortable or challenging. Facilitators and

service center licensee representatives are required to make reasonable efforts to resolve any activity or conditions on the licensed premises that endangers the safety of any person present on the premises. If the situation persists, they must contact emergency services and are required to notify OPS if emergency services are called.

One of the most important factors in ensuring client safety is the licensed facilitator's interaction with clients, as well as understanding their own limitations. Trained and licensed facilitators work within their scope of practice and level of expertise to identify potential safety risks and support the client through psilocybin services.

Because the role of a licensed facilitator includes many requirements, facilitators must fully understand and operate in compliance with OPS administrative rules.

For more information, please reference the rules sections highlighted below:

Facilitator conduct rules: [OAR 333-333-5120](#)

Preparation session rules: [OAR 333-333-5000](#)

Administration session rules: [OAR 333-333-5200](#)

Integration session rules: [OAR 333-333-5260](#)

### **Documenting Client Doses**

The secondary dose form is based on [OAR 333-333-5000](#)(7) which requires additional written consent for secondary doses. This additional written consent is required prior to beginning an administration session because clients are unable to consent to consuming secondary doses while experiencing the effects of a primary dose. Primary doses and total amount consumed are addressed by other rules. Specifically, [OAR 333-333-5100](#)(1) requires facilitators to create a detailed record of all products a client consumes, including dose amount and UID for primary and secondary doses, and to store those records at the service center. OPS has not published a form for this record keeping requirement and the client doesn't need to sign this record.

### **Virtual (Video) Preparation Sessions and Digital Signatures on Forms**

Preparation sessions can be conducted via a video conference call and do not have to be in-person. Client forms may be provided before or during the

preparation session and can be signed digitally. All required client forms must be signed prior to the start of the administration session.

### **Required Client Forms**

If a client answers yes to questions (3)(f), (3)(g), (3)(l), or (3)(m) on [the client information form](#), the client and facilitator must work together to complete a [Client Medication and Medical/Assistive Device Form](#) and an [Interpreter or Client Support Person Plan](#).

If a client answers yes to questions (3)(d) on the client information form, the client and facilitator must work together to complete a Client Medication and Medical/Assistive Device Form. If the client needs assistance to take medication, they must also complete an Interpreter or Client Support Person Plan.

Clients who take medication, or use medical, mobility, or assistive devices, without assistance from a client support person are required to complete a Client Medication and Medical/Assistive Device Form but are not required to complete an Interpreter or Client Support Person Plan.

Reference OAR [333-333-5050](#):

- (3)(d) Are you currently taking any medications that might need to be consumed during an administration session?
- (3)(f) Will you require assistance from a client support person for catheter, ostomy, or toileting assistance, ambulation or transfer mobility support, or medical device assistance during the administration session?
- (3)(g) Will you require assistance from a client support person for augmentative and alternative communication (AAC) device support or assistive listening device support during the administration session?
- (3)(l) Do you require any assistive mobility devices?
- (3)(m) Will you require assistance to consume psilocybin products?

### **Consumption of Supplements and Other Medications During an Administration Session**

OPS interprets the term medication to mean prescription medications as well as over-the-counter medications and supplements. OPS rules prohibit facilitators from providing medications to clients or assisting clients with taking medications.

In order to remain within their scope of practice, facilitators must refrain from recommending supplements or other medications to clients.

Clients are not prohibited from taking medication during an administration session in compliance with applicable rules. A facilitator should encourage clients to schedule administration sessions at a time when medication does not have to be taken. Facilitators should also encourage clients to consult with their providers about taking medication during an administration session. (See [OAR 333-333-5050](#)).

If a client will consume medication during an administration session, the client must complete a [Client Medication and Medical/Assistive Device Form](#) prior to participating in an administration session and must bring the medication they will consume to the service center at the time of the administration session. If the client needs assistance with taking medication, that assistance can only be provided by a client support person and the client must complete a [Client Support Person Plan](#) prior to participating in an administration session.

If a client wishes to consume food during their administration session they may do so, but they must follow applicable rules for consuming packaged food items (See [OAR 333-333-5170](#)). Regardless of whether the client consumes a supplement or a food item, they may not consume any items that has intoxicating effects.

### **Accompanying Clients in Restrooms**

A facilitator should never join a client in a restroom except when doing so is necessary to mitigate unforeseen risks to health and safety. Facilitators are only permitted to touch clients using the types of supportive touch described in [333-333-5170](#), and clients must consent to any use of touch in writing prior to beginning an administrative session by completing the [Client Consent for Use of Supportive Touch](#) form. If a client needs assistance in the restroom, they should plan for having a client support person present to assist them in these activities and must complete a [Client Support Person Plan](#) prior to participating in an administration session. Facilitators and licensee representatives may not act as client support person.

### **“Bad Trips”**



The term “bad trip” is not used in OPS administrative rules nor statute. Facilitators are trained to respond to and assist clients if their experience during an administration session becomes uncomfortable or challenging. Facilitators and service center licensee representatives are required to make reasonable efforts to resolve any activity or conditions on the licensed premises that endangers the safety of any person present on the premises. If the situation persists, they must contact emergency services and are required to notify OPS if emergency services are called.

### **Clients Refusing to Sign the Release Form**

There are many reasons why a client may refuse to sign the required release document, and we are unable to offer general guidance for every scenario that may arise. In case of an investigation, OPS would want to understand why the client refused to sign the release form, including but not limited to, whether the client was properly prepared for the administration session, whether the expectations around the release from the session were thoroughly covered in the preparation session, whether the client was truly ready to be released from the administration session, and so on.

We would recommend that the licensed facilitator document in detail the reasons why the client refused to sign in case a complaint is made. The client should not be forced to leave the licensed service center if they are not ready, so it is very important that details about the release are included if the client is unwilling to sign.

### **Early Discharge**

An administration session cannot be ended before the minimum time required for the dose that was consumed. See: [OAR 333-333-5250](#), Duration of Administration Session.

### **Integration Sessions**

Integration sessions are optional for clients, but facilitators are required to offer them to clients after administration sessions. In addition, facilitators are required to check on clients within 72 hours of the administration session. [OAR 333-333-5250\(7\)](#).

## Service Center Operations

### Sharing Data with Third Parties

Data collection and reporting required by SB 303 does not begin until 2025. OPS will conduct rulemaking in 2024 to specify data collection and reporting requirements for service centers. Under SB 303, service centers are required to report certain data related to adverse events, number of clients served, average dosage, and other data to OHA beginning in 2025. SB 303 requires data collection and reporting to OPS, not to third parties. Service centers should not be collecting or reporting SB 303 data at this time as the final administrative rules have not been finalized, and SB 303 collection and reporting does not begin until 2025. If a service center chooses to voluntarily report data to a third party, they must do so in compliance with applicable administrative rules. Specifically, [OAR 333-333-4810\(5\)](#) states that “A service center or facilitator must provide a client with a disclosure form **during or prior to** a preparation session if the facilitator or service center intends to share de-identified data related to the client’s receipt of psilocybin products or services.” The rule contains an exception for reporting data to the OHA, but there are no exceptions for reporting data to third parties. Because the form requests information that is related to a client’s receipt of psilocybin products or services, service centers may not provide data related to a client’s receipt of psilocybin products or service unless the clients whose de-identified data is submitted have completed the required disclosure form **during or prior to a preparation session**. Service centers who share data with third parties must use either the [Notice and Opt-Out of Disclosure of De-identified Data](#) and [Authorization to Disclose Personal Identifiable Information](#) forms in accordance with administrative rules.

A service center that shares de-identified data related to a client’s receipt of psilocybin products and services without first receiving a completed disclosure form violates OPS administrative rules. Client confidentiality protections were part of administrative rules adopted in 2022 and include the requirement for client consent to disclose both de-identified data and personal identifiable information. SB 303 contains separate reporting requirements and all data required by SB 303 will be reported directly to Oregon Health Authority. OPS will communicate directly with licensees regarding the form and manner of reporting SB 303 data after rules are adopted in 2024.

### **Communication with Potential Clients at Service Centers**

Licensee representatives of a service center may communicate with prospective clients regarding service center business operations and services offered. However, licensee representatives may not perform duties of a facilitator license, including completion of forms that are required to be discussed during a preparation session or activities within the facilitator scope of practice related to facilitation of preparation, administration, and integration sessions. Prospective client information should be treated as client information, kept confidential, and stored securely.

### **Presence of Potential Clients at Service Centers**

Any potential clients who are over 21 years of age may visit a licensed service center but must be accompanied by a licensee representative for the duration of their visit. Potential clients may not visit limited access areas and may not visit nor observe client administration areas while an administration session is taking place. Service centers must comply with all applicable rules when allowing potential clients to visit their premises, including but not limited to rules on security and client confidentiality.

### **Authorized Visitors of Limited Access Areas and Client Administration Areas**

Visitors are not permitted in limited access areas of a licensed premises. A limited access area can only be entered by licensee representatives, laboratory personnel from a laboratory licensed by OHA, contractors, vendors or service providers, including authorized media representatives. All visitors in the limited access area must be supervised by a licensee representative and must be logged as directed by [OAR 333-333-4400\(3\)](#). If the licensee authorizes media to be present at a licensed service center, they can access a limited access area but must follow all requirements in rule.

### **Musician, Breath Worker, Other Performer or Service Provider Present During Administration Sessions**

OPS administrative rules describe who may be present during an administration session. Specifically, [333-333-5200\(8\)](#) requires that only clients, facilitators and licensee representatives of a service center, and interpreters or client support persons may be present during an administration session. Additionally, [333-333-5200\(9\)](#) states licensee representatives of a service center “may only be present

to assist with operations and shall not interfere or otherwise participate in the administration session.” OPS administrative rules do not allow for other people, including performers, entertainers, or those performing additional healing practices outside of ORS 475A, to be present during an administration session. It is important to note that ORS 475A created non-directive facilitation of psilocybin services.

### **Client Consent for Others to be Present During Administration Sessions**

The Client Consent for Other Individuals to be Present During and Administration Session is intended to be used when the client plans to see different facilitators for their preparation and administration sessions. It is not required for clients to consent to the presence of back up facilitators who assist due to unforeseen circumstances.

### **Requirements for Video Recording Client Administration Sessions**

Service centers may make video and audio recordings of client administration sessions using portable recording equipment with the prior written consent of every client and facilitator who will be recorded. ([See OAR 333-333-4640.](#)) Every client and facilitator who will be recorded must provide prior written consent to be recorded. The form required depends on the type of client administration session. Clients and facilitators will complete either a [Consent to Record Individual Administration Session](#) or a [Consent to Record Group Administration Session](#). For group sessions, every client and facilitator must complete a consent form prior to the session. Recordings must be made using portable recording equipment provided by the service center.

After a client administration session has been recorded, OPS rules require that the recordings must be stored and maintained at the service center in a manner that protects the confidentiality of the individuals recorded. Service centers are required to make recordings available to clients and facilitators who have been recorded and may not charge a fee for this service. OPS rules require that no client information may be shared without prior written consent. For the purpose of video recordings, this requirement extends to facilitators as well. Unless the persons recorded have signed a [Consent to Disclose Personal Identifiable Information](#) , the recordings may only be accessed in order to share them with the persons recorded. If the service center wants to share the recordings with any other persons or use them for any other purpose, they must receive prior written

consent from every person who was recorded. Service centers may only share recordings with licensee representatives or facilitators if they have received prior written consent. If licensees and license representatives of a service center intend to review recordings of administration sessions for any purpose, the service center must receive prior written consent from every person who was recorded. Recordings must be destroyed upon the request of any person who has been recorded.

### **Media at Service Centers**

During administration sessions, media cannot be present in client administration areas. Only clients, licensed facilitators, licensee representatives of the service center, and interpreters or clients support persons can be present in client administration areas during administration sessions as directed by [OAR 333-333-5200\(8\)](#). Clients may not be recorded or filmed in an administration area without consent and completion of all the required operational forms. Filming equipment in an administration area must be portable, and service centers must follow all rules for recording an administration session, including [OAR 333-333-4640](#). If portable filming equipment is brought into a client administration area during an administration session, only those allowed to be in the room may record the session with the equipment.

### **Ketamine (and other intoxicants) on a licensed premises**

No licensed psilocybin business, including service centers, may occupy the same space as a location where ketamine is administered. Ketamine and other intoxicants may not be consumed on a licensed premises by clients or any other individuals. OAR 333-333-4400 requires that: “A licensee or permittee may not permit the on-site consumption of any intoxicants by any individual, except for clients consuming psilocybin products during an administration session.” Intoxicants are defined to mean “any substance that has intoxicating effects, and includes alcohol, prescription drugs, non-prescription drugs and any other controlled substances. Intoxicant does not include caffeine or nicotine.” (See OAR 333-333-4400.)

### **Food and Beverages at Service Centers**

A service center cannot prepare food or beverages onsite for clients.

Food and beverages that will be consumed in conjunction with psilocybin products are limited by [OAR 333-333-5170](#). Under this rule, clients may mix psilocybin with packaged food, packaged beverages, or potable water prior to consuming. No other foods or beverages may be mixed with psilocybin products. Service centers may not offer food or beverages that were prepared onsite, including coffee and tea. Packaged food and beverages may be provided by the service center or brought by the client.

Clients may provide their own food that is not being consumed with psilocybin products as long as it is a food or non-alcoholic beverage item as described in [OAR 333-333-4480\(7\)](#). These foods and beverages may not be mixed with psilocybin products and cannot contain intoxicants. Although these food items may not be mixed with psilocybin products, they may be consumed before, during or after and administration session.

A service center's licensed premises may not overlap with restaurant or similar location licensed under ORS Chapter 624. [OAR 333-333-4300](#). Although a service center may not operate a restaurant, it is permitted to have catered food or takeout for client consumption. These food items may not be mixed with psilocybin products, but they may be consumed before, during or after an administration session. When bringing food into a licensed service center, client safety is a priority. Licensees and permitted workers are responsible for ensuring client safety at licensed service centers at all times, including when having food delivered or catered.

### **Secondary Doses**

Service centers may provide multiple secondary doses to clients as long as the total amount consumed is less than 50 mg of psilocybin analyte, and they are compliant with all other rule provisions.

All psilocybin products must be transferred to the client prior to beginning their administration session and consuming any psilocybin product. Clients cannot make purchases nor be transferred a secondary dose while under the influence of psilocybin.

## Secondary Doses - Storage and Retrieval

OPS administrative rules create minimum standards to promote client safety and allow licensed service centers flexibility to meet those standards in a manner that fits their premises and operations. The rules do not function as operational best practices for service centers. The operations and premises of each licensed service center are unique, and every licensee must determine how to best meet the requirements established in rule. OPS has provided notes on [OAR 333-333-5240](#) below to assist service centers in developing practices for storage and access to secondary doses that are consistent with rule requirements.

Service centers can meet the requirements for storage and retrieval of secondary doses in a number of different ways. For example, the secondary dose could be stored in a locked drawer that is unlocked by the service center to allow the client to retrieve and consume the dose. The secondary dose could also be stored in a folder or other container within a locked file cabinet. The service center would then grant access to the folder or container when a client is ready to retrieve and consume their dose. There are many options, and OPS staff are available to meet with service center licensees to discuss the specifics of their premises and operations. If you would like to request a meeting, please e-mail [OHACompliance.Psilocybin@odhsoha.oregon.gov](mailto:OHACompliance.Psilocybin@odhsoha.oregon.gov).

333-333-5240

*(1) A service center licensee or licensee representative may not allow a client to consume more than a total of 50 mg of psilocybin analyte during an administration session. Both initial doses and secondary doses described in this rule may be transferred and consumed in multiple packages. For example, a dose consisting of 20 mg of psilocybin analyte could be transferred to a client in the form of two packages containing 10 mg of psilocybin of analyte.*

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

**Notes for (1) and (2):** Maximum consumption limits include the total of all doses a client consumes, including the primary dose and any secondary doses. An individual dose may be delivered in multiple packages.

*(3) If a client wants the option to consume secondary doses during their administration session, up to a total of 50 mg of psilocybin analyte, a service center must:*

*(a) Receive written consent from the client prior to the beginning of their administration session.*

**Notes:** Facilitators will use [this form](#) to obtain prior written consent.

*(b) Require the client to purchase and take possession of secondary doses prior to beginning their administration session.*

**Notes:** 475A.504 states: “(1) A person may not sell, give or otherwise make available a psilocybin product to a person who is visibly intoxicated. (2) Violation of this section is a Class A misdemeanor.” In order to align with the statute, this subsection requires client to purchase secondary doses prior to consuming their primary dose.

*(c) Require the client to store secondary doses at a designated secured location outside of a limited access area and within the service center’s licensed premises.*

**Notes:** Under [OAR 333-333-4400](#), clients and other members of the public are not permitted to be present in the limited access area of a licensed premises.

*(d) Require the client, or a client support person, to retrieve secondary doses from the designated location and consume without assistance from a licensee representative or facilitator if the client chooses to consume the secondary dose.*

**Notes:** In addition to prohibiting sales, 475A.504 also prohibits making psilocybin product available to a person who is visibly intoxicated. Therefore, this subsection requires clients to retrieve their dose without assistance. This section does not prohibit a service center from removing



security measures in order to allow a client to retrieve their dose. For example, a licensee representative could unlock a cabinet to allow a client to retrieve their dose.

*(e) Ensure that secondary doses remain in sealed client packaging until consumed.*

**Notes:** This subsection allows for accurate product tracking and hygienic returns.

*(f) Require the client to return the secondary dose to the service center at the conclusion of their administration if they do not consume it during their administration session.*

**Notes:** Psilocybin products may only be consumed on the premises of a licensed service center.

*(4) A service center licensee or licensee representative may decline to make secondary doses available for purchase for any reason.*

**Notes:** A service center may decline to offer secondary doses if doing so is inconsistent with its operational model.

*(5) During an administration session, a service center licensee representative, in consultation with the client's facilitator, may decline to make a secondary dose available to a client who has purchased the secondary dose pursuant to section (3) of this rule. A service center must provide clients a refund for the purchase price of any secondary dose that is not made available to clients.*

**Notes:** A service center may decline to allow an individual client to retrieve and consume a secondary dose that the client has purchased.

*(6) A service center must provide clients a refund for the purchase price of any secondary dose that is not consumed and remains in its original sealed client packaging. After providing a refund, a service center may make the product in its original sealed client packaging available for sale to other clients.*

**Notes:** This return must be tracked and recorded in PTS according to applicable rules.

### **Duration of Administration Session**

[OAR 333-333-5250](#) states that the minimum duration of administration session is dependent on the total amount of psilocybin a client consumes, including any secondary doses. When clients consume secondary doses, the minimum duration for the entire amount consumed begins when the client consumes their final secondary dose.

### **Service Center Liability for Dosing Decisions**

OPS rules describe the duties and obligations of service centers and facilitators. Generally, the responsibility for determining dosage and transferring the appropriate dose of psilocybin to a client is a shared responsibility. Facilitators work with clients during their preparation session to determine appropriate dosage, licensee representatives of service center transfer products to clients, and service centers store psilocybin products, provide the administration areas for consumption of psilocybin products, and create operational guidelines for the service center.

### **Service Center Worker Serving as a Translator**

An interpreter would be considered a client support person.

If a client requires assistance from a client support person, they should fill out an Interpreter or Client Support Plan. This includes assistance with interpretation, assistance administering medication to a client, assistance with a medical device, assistance with catheter, ostomy, or toileting assistance, ambulation, or transfer mobility support, assistance with alternate communication device support or assistive listening device support, or assistance consuming psilocybin products. For more information about Interpreter or Client Support Persons, please see the [Interpreter or Client Support Person Plan](#) operational form.

### **Service Center Worker Serving as a Support Person**

A licensee representative of a service center may not assist a client with any of the activities required to be performed by a client support person. A client support person would be responsible for supporting clients with toileting,

mobility, medication, assistive medical devices, or interpretation needs. For more information about Interpreter or Client Support Persons, please see the [Interpreter or Client Support Person Plan](#) operational form.

### **Medical Professionals at Service Centers**

Any individual that holds an independent professional license cannot exercise the privileges of that license while serving as a facilitator at a psilocybin service center. Any questions about regulations or compliance related to that professional license should be referred to the appropriate professional licensing board or regulatory body. Service centers are not medical facilities. Licensee representatives and facilitators may provide first aid and CPR in the case of emergency, but doing so does not relieve them of their obligation to contact emergency services if required to do so by [OAR 333-333-4700](#)(4).

### **Service Center Forms - Supplementary Forms used Pre-preparation**

Service centers and facilitators may not use their own forms in place of the client information form. Every client must complete the [client information form](#) published on the OPS website prior to participating in an administration session. [OAR 333-333-5050](#). The client information form is completed in coordination with a facilitator rather than a service center representative.

In addition to the client information form, facilitators and service centers may use their own supplementary forms to assess if psilocybin services are appropriate for a client as long as doing so is otherwise compliant with OPS rules, including rules on scope of practice. For example, supplementary forms cannot be used to diagnose health conditions or perform any other function that would require independent professional licensure.

All client records, including the client information form and any supplementary forms, must be stored at the licensed service center where the client participated or intends to participate in an administration session. Forms may be converted into electronic versions but must maintain all of the same aspects as the original form. Client records must be stored and maintained in a manner that protects client confidentiality and prevents unauthorized access. Facilitators may access client records for the purpose of providing services to clients and service center representatives may access client records to support operations of the service

center where the client receives or has received psilocybin services. If client records will be shared with any other parties or used for any other purpose, the client must first complete an [Authorization to Disclose Personal Identifiable Information](#).

### **Requirements for Notice When Administration Session Goes Beyond 11:59 pm**

OPS administrative rules require service centers to provide notice in a “form and manner” specified by the Oregon Health Authority when administration sessions extend beyond 11:59 p.m. [OAR 333-333-5250\(4\)](#). This guidance specifies the form and manner for that notice.

If an administration session extends beyond 11:59 p.m. to ensure client safety, the service center should email the compliance team at [compliance.psilocybin@odhsoha.oregon.gov](mailto:compliance.psilocybin@odhsoha.oregon.gov) by 11:00 a.m. the following day with the following information as required by [OAR 333-333-5250\(4\)](#):

- Start time of the administration session.
- Amount each client consumed during the administration session, including any secondary doses.
- Minimum duration of the administration session required by [OAR 333-333-5250](#).
- Whether the administration session was a group session or an individual session.
- For group sessions, the number of clients participating in the administration session.
- The names and worker permit numbers, if applicable, of all facilitators, licensee representatives and other authorized individuals who were present at the licensed service center after 11:59 PM.

### **Receiving Transfers of Psilocybin Product at a Service Center**

Service center licensees or licensee representatives of a service center may receive transfers of psilocybin product from a licensed manufacturer or another service center. [OAR 333-333-4400](#). A facilitator may not receive product for the service center unless they are also an owner, director, officer, manager, employee, agent, or other representative of the service center and are not providing psilocybin services under the facilitator license at the time of receipt.

See [OAR 333-333-1010\(43\)](#), [333-333-4480\(1\)\(b\)](#), [333-333-8100\(1\)\(a\)](#), and [333-333-8100\(4\)](#).

### **Point-of-Sale Systems**

OPS rules do not require point-of-sale (POS) systems. If service centers choose to use a POS system, it is up to the service center to decide where the system should be placed. Service centers should consider security of the premises and client confidentiality when thinking about where to place their POS system. Electronic devices that could capture client information should be kept out of a client administration room that has clients actively participating in an administration session.

### **Restrooms**

A service center premises is required to have a restroom on the licensed premises ([OAR 333-333-4465\(1\)](#)). A licensed premises is not open to the general public for use, so a restroom on the premises would not be available for those not working or participating in psilocybin services; this would include any prospective clients. A service center may have an alternative restroom that can be located in an unlicensed area and could be accessible to the general public ([OAR 333-333-4465\(2\)](#)). An alternative restroom may be used by clients if the restroom on the licensed premises is occupied.

### **Minors on the Licensed Premises**

A licensee and/or licensee representative must check IDs as people enter a licensed premises to confirm they are 21 years old or older. ORS 475A.495. Anyone under 21 years of age must immediately leave the licensed premises after their identification check. ORS 475A contains an exception for a person temporarily at the premises to make a service, maintenance, or repair call, or for other purposes independent of the premises operations.

### **Requirements for Temporary Use of Licensed Premises**

Under [OAR 333-333-4300\(6\)](#), a service center may authorize the temporary use of the licensed premises for activities that are unrelated to the exercise of license privileges. During the authorized temporary use, all rules remain in effect and a licensee representative must be present for the duration of the temporary use. A service center must provide advance written notice of the authorized temporary

use to Oregon Psilocybin Services. Service centers may use a single written notice to provide advance notice of multiple and reoccurring events occurring within 90 days following the date of the notice. Psilocybin products may not be sold or transferred, and psilocybin services are prohibited during an authorized temporary use. During an authorized temporary use, service centers must observe the following requirements:

- a. Only persons 21 years or older are allowed on the licensed premises at all times, even during temporary use events.
- b. No intoxicants of any kind allowed at any time during temporary use events.
- c. Attendees of temporary use events should not have access to limited access areas for any reason. Limited access areas must be locked and inaccessible.
- d. Cameras cannot be turned off at any time during a temporary use event.
- e. Licensees and licensee representatives are responsible for protecting confidentiality of client and business records, client information, and administration session recordings during temporary use events.
- f. Licensees and licensee representatives are responsible for maintaining confidentiality of all records, including storage of devices that contain this information.
- g. Psilocybin products and waste that is not rendered unfit for consumption may not be accessed and must be locked away and inaccessible.
- h. Licensees and licensee representatives are responsible for staying within occupancy requirements and comply with local ordinances, including time, place, and manner regulations, noise ordinances, etc.
- i. Licensees and licensee representatives are responsible for complying with OPS requirements around operating hour restrictions.
- j. OPS has regulatory oversight over the licensed premises during the temporary use event and will investigate complaints.
- k. Licensee or licensee representatives are responsible for any unlawful activity that may occur on the licensed premises during temporary use events.
- l. Licensee and licensee representatives are responsible for ensuring that participants in temporary use events understand that all requirements apply during temporary use and that the licensed premises may not be used as a service center during temporary use.

## **Local ‘Time, Place and Manner’ (TPM) Regulations**

OPS will not be tracking local time, place, and manner (TPM) regulations, so local governments do not need to send these to us.

Our section will not evaluate local business licenses or compliance with local time place and manner regulations as part of the licensure process. We’ll only be reviewing the Land Use Compatibility Statement (LUCS). We’ll also inspect every premises for compliance with our operational rules before issuing a license. As a practical matter, this means that construction must be complete before OPS will issue a license. So, any required building permits would need to precede the Oregon Health Authority licensure process.

Additional information is available on our [Local Government Information](#) webpage.

## **Manufacturer Operations**

### **Detectable Psilocybin - Culture and Spore Requirements**

Licensed psilocybin manufacturers may only receive psilocybin products from other licensed manufacturers, licensed service centers, and licensed laboratories. [OAR 333-333-4400\(7\)](#). [ORS 475A.220](#) defines psilocybin products to mean “(A) Psilocybin-producing fungi; and (B) Mixtures or substances containing a detectable amount of psilocybin.” Psilocybin products are produced by licensed manufacturers, packaged, and transferred to service centers and are required to undergo potency testing that measure the amount of psilocybin analyte contained in the product ([OAR 333-333-7040](#)).

Items that are used in cultivation, such as mycelium cultures, are not subject to required testing. If such items are received from unlicensed sources, manufacturers should make reasonable efforts and use good judgement to determine whether the items contain a detectable amount of psilocybin. Items that contain a detectable amount of psilocybin cannot be legally received from unlicensed sources.

ORS 475A requires OHA to regulate the production of psilocybin products and provision of psilocybin services. “Psilocybin products” means psilocybin-producing fungi and mixtures or substances containing a detectable amount of psilocybin. Spores do not contain detectable psilocybin until they begin producing mycelium,

so the sale or transfer of spores is outside of ORS 475A. While OHA cannot speak to the sale or transfer of spores, there may be applicable laws in other states to consider.

### **Cultivation Batches**

Fruiting bodies become a cultivation batch and must be entered in the OPS Product Tracking System in TLC-PTS:

1. When the spawn (mycelial tissue) is transferred to the production growth medium.
2. If it has or is going to have fruiting bodies.

OPS rules define cultivation batch to mean “a quantity of unharvested fruiting body or mycelium that is grown together under the same conditions that may contain fungi that originates from diverse spores or mycelial tissue of *psilocybe cubensis*.” [OAR 333-333.1010](#). A cultivation batch may contain fungi that is grown from different sources of spores or mycelium if it is grown at the same time and location. While using diverse fungi genetics in a cultivation batch is permitted, licenses should be aware that all fungi tested together as a cultivation batch will be assigned the same test results. Also, OPS administrative rules do not define “strains” of *psilocybe cubensis*. Licensees may choose to use descriptive language for strains on product labels and marketing material as long as they comply with applicable [advertising restrictions](#).

[OAR 333-333-1010](#)(59) states “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. Mycelium that is in the pre-production process is not considered a cultivation batch.

Cultivation batches cannot be combined or "added to."

### **Harvest Lots and Process Lots**

[OAR 333-333-1010](#)(36) states: “Harvest lot” means a specifically identified quantity of fungi that is cultivated and dried under the same conditions and harvested within a seven-day period at the same location within the licensed premises, that may be partially harvested and may use the substrate material for



multiple harvests. Harvest lots of whole fungi cannot be combined and must be tested separately. Manufactures may combine harvest lots to make a process lot and the combined harvest lots will be tested as a process lot.

[OAR 333-333-1010](#)(60) states: “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.

### **Drying Fungi**

Product must be dried to the point that it inhibits unwanted growth and contamination. [OAR 333-333-2110](#)(1) states ‘A manufacturer with a fungi cultivation endorsement must completely dry all fungi before transferring to another licensee.’

It is important to package the product so that it prevents contamination and excessive moisture ([OAR 333-333-2300](#): Packaging for Sale to Client).

### **Capsules**

Ground and homogenized fungi may be encapsulated. OPS does not consider encapsulated fungi to be an edible product for purposes of endorsement, and the Oregon Department of Agriculture (ODA) does not recognize encapsulated fungi as an edible product for purposes of food safety licensure or additional ODA oversight.

### **Whole and Homogenized Fungi Testing Requirements**

Bulk whole fungi and/or homogenized fungi does not need to be potency tested before being transferred to another manufacturer for further processing because it is not a "finished product" at this stage.

### **Potency Testing and Product Degradation**

Potency tests are performed by licensed laboratories and are recorded as a concentration of milligrams of psilocybin analyte per gram of raw material. After the lab provides the concentration, licensed manufactures will be able to calculate and record the psilocybin analyte in milligrams in the Product Tracking System as required by [OAR 333-333-8210\(1\)\(c\)](#). For example, if a harvest lot of dried whole fungi has a psilocybin concentration of 5 mg/g, a five-gram package

created from that lot will contain 25 mg of psilocybin analyte. Once the potency test has been performed the value for the test does not change, regardless of any potency degradation that may occur over time.

Degradation is not addressed directly in OPS administrative rules, but licensees should be aware of two requirements. First, potency test results expire after one year. [See OAR 333-333-7020\(6\)](#). Second, manufacturers are required to identify a “best by” date on psilocybin product labels. [See OAR 333-333-2400\(3\)\(f\)](#). Facilitators and service centers must rely on the psilocybin analyte results listed in the Product Tracking System and printed on the product label to comply with rule requirements including but not limited to rules on maximum doses and duration of administrative sessions. The listed analyte values cannot be adjusted to account for degradation that may have occurred since testing. Service centers that are concerned with potency degradation are encouraged to work with their suppliers to ensure clients have access to fresh products.

### **Re-Testing Psilocybin Products**

Requirements for compliance testing of psilocybin products are described in OPS administrative rules and include mandatory potency testing to measure psilocybin analyte. [OAR 333-333-7040](#). Under these rules, a manufacturer is required to include certain compliance test results on their product labels and may only perform compliance testing one time.

Manufacturers are permitted to perform additional testing for the purpose of quality control or product development. [OAR 333-333-7150](#). These additional tests could be helpful to evaluate manufacturing processes or determine accurate “best by” dates for products. However, these additional quality control and product development tests do not replace the required compliance tests. Only the results from the required compliance test for potency may be listed on the product label. And, facilitators must use the compliance test results for potency to calculate minimum duration of administration sessions, client to facilitator ratios and client consumption limits.

### **Rounding Product Weight**

For rounding of psilocybin analyte, weight of psilocybin product, and bulk product use standard rounding by rounding up a value of 5 or more.

- Psilocybin analyte is always measured in milligrams. Milligrams of psilocybin analyte should be rounded to 2 decimal points.
- Total weight of tested and packaged products is always measured in grams. Grams of packaged product weight should be rounded to 2 decimal points.
- Total weight of bulk products that have not been packaged for final sale is always measured in grams. Grams of bulk product weight should be rounded to 2 decimal points after the whole number.

For example:

- A packaged product weight of 3.456 g would round to 3.5 g.
- Psilocybin analyte of 2.52 mg would round to 2.5 mg.
- Bulk product weight of 304.576 g would round to 304.58 g.

### **Product Information Document**

Product labels may include information that is also required to be included on the product information document; however, the product information document still must be created and sent with the product.

The product information document is required by rule. Manufacturers must provide a product information document with all psilocybin products transferred to a service center. A facilitator is required to share the document with clients prior to the administration session. Without the product information document, a facilitator cannot follow this rule.

Each psilocybin product, including the products that are the same but for the quantity of psilocybin analyte (dose), must have their own product information sheet.

## **Laboratory Operations**

### **Wasting Test Samples**

Once a laboratory has recorded test results for a passing test, the remaining sample should be wasted out as soon as practical. Laboratories may not use the remainder of the psilocybin product for the lab's internal shelf-stability studies and internal quality control tests.

## **Sampling for Required Tests**

Whole dried fungi must be sampled by a licensed laboratory prior to being packaged. OAR 333-333-7100 states that, “(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 laboratory’s sampling policies and procedures.” Pre-packaged products do not meet the sampling requirements because the lab would not be able to ensure that the batch was homogenous, nor freely choose their sample.

## **Product Testing, Packaging, and Labeling**

### **Individual Serving Size**

OPS rules specify a maximum analyte content per serving, but not a minimum. [333-333-2310](#) states: A serving of psilocybin product may not contain more than 25 mg of psilocybin analyte.

### **Listing Dosage on Product Labels**

OPS administrative rules require total content of psilocybin analyte, measured in milligrams, to be listed on product labels. Packaged psilocybin products may contain one serving and a serving may not exceed 25 mg.

### **Psilocybin Analyte - Weight**

OPS rules define “psilocybin analyte” to mean only content of psilocybin measured by required potency tests. [OAR 333-333-1010](#). All rules regarding dosage, duration, client to facilitator ratio, and labeling use milligrams of psilocybin analyte as a unit of measurement. These rules reflect recommendations from the Oregon Psilocybin Advisory Board and were adopted after a thorough rule making process in 2022.

Psilocybin analyte refers to the content of psilocybin as measured by a potency test. A potency test gives a ratio of milligram (mg) of analyte per gram (g) of weight. This is displayed as mg/g. In a packaged product, the total analyte present is determined by the weight of the product and the potency test results. For example, a packaged product that weighs 2g and a potency test of 5mg/g will have a total psilocybin analyte content of 10 mg. Client dosing must be based off of the psilocybin analyte content listed on the packaged product.

## **Psilocybin Analyte - Labeling**

Every psilocybin product must be tested for potency before it can be transferred to licensed service centers and made available to clients. [OAR 333-333-7040](#). The Oregon Environmental Laboratory Accreditation Program (ORELAP), which is also part of OHA, is responsible for the accreditation of laboratories that intend to apply to OPS for licensure and sets standards for testing methodology.

Although ORELAP rules require results to be reported for psilocybin analyte, psilocin analyte, and total potential psilocin, OPS rules only require use of psilocybin analyte measured in milligrams. OPS has offered guidance to laboratories and manufacturers that labeling requirements in OPS rules are minimum standards. Manufacturers may choose to include the full series of potency test results on their product labels, but they are not required to do so.

Please note that in addition to labels, OPS rules on dosage, duration, serving size and licensee possession limits are all dependent on psilocybin analyte and this is the only value that will be tracked in the psilocybin tracking system.

## **Including Psilocin Analyte on Label**

Although licensed laboratories test for psilocin content, it is not required to be listed on product labels.

OPS label rules specify minimum content for labels. OPS rules use psilocybin analyte to ensure accurate dosage. Manufacturers may choose to include “total potential psilocin” on their labels, but it is not required.

## **Products that Require Refrigeration**

Licensed service centers should consult manufacturer recommendations to determine whether a psilocybin product needs to be stored in a refrigerator. As stated in 333-333-2410(1)(m), if the psilocybin product is perishable, manufacturers are required to add a statement noting that the product must be refrigerated or kept frozen. Some psilocybin products may require additional labeling requirements from Oregon Department of Agriculture (ODA). ODA is the authority on which products require refrigeration and which do not, and that information would be passed on from the manufacturer to you (333-333-2080).

## **Best By Dates – Product Degradation and Label Information**

All client packaging must be labeled with a best by date as required by [OAR 333-333-2400](#). In addition to the required best by date, manufacturers may choose to include more detailed information on product degradation. If additional information on product degradation is included, a best practice would be to reference the study/evidence that the estimate was based on. Information listed on labels cannot contain statements that are deceptive, false, or misleading. A label may not display any untruthful 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.

### **Best By Dates – Expired Products**

OAR 333-333-2400 requires manufacturers to include “best by” dates on client packaging for all psilocybin products. These dates are determined by the manufacturer and describe the time that the product will retain its original quality. There is no requirement that psilocybin products must be sold before reaching their best by date and manufacturers are free to set their own policies regarding product returns. If psilocybin products are returned to a service center the products may not be repackaged. They must be either destroyed as waste or transferred to another licensee in their original client packaging. OPS requirements for product safety are separate from the requirement to include a best by date on product labels. The requirements of OAR 333-333-2050 include ensuring that psilocybin products are free from any unsanitary, decomposed or putrid substance and are fit for human consumption. In order to comply with this, and other requirements, service centers must store products under appropriate sanitary conditions, including temperature-controlled storage if necessary. Service centers should also monitor aging psilocybin products to ensure they remain fit for human consumption.

### **Product Packaging Requirements**

The packaging requirements are found in [OAR 333-333-2300](#): (1) Client packaging must protect the packaged psilocybin product from contamination and excessive moisture and must not impart any toxic or harmful substance to the packaged item. (2) All psilocybin products must be transferred to a service center in sealed client packaging for ultimate sale to a client. (3) Psilocybin products for ultimate

sale to a client must: (a) Not be packaged or labeled in a manner that is attractive to minors. (b) Comply with serving size requirements identified in [OAR 333-333-2310](#). (c) Be labeled in accordance with [OAR 333-333-2400](#). (4) Client packaging may not display any untruthful or misleading content.

### **Sealed Client Packaging**

Products must be sold and transferred in sealed client packaging ([OAR 333-333-2300](#)). Sealed client packaging is intended to be opened by the client themselves. Client packaging is required to be sealed using a tamper evident seal that indicates whether the package was opened before the client has received the product. This preserves product integrity by preventing the package from being split and ensures that clients are receiving safe and untampered product.

Any packaging that is being reused for further packaging must be sterilized and relabeled before use. Please see guidance on 're-using Product Packaging' for more details.

Additional ODA packaging and labeling requirements may apply if the product is an edible or extract. Please work with ODA to understand their requirements. Additional resources and references to ODA requirements can be found on the [OPS Manufacturer License](#) webpage.

### **Re-using Product Packaging**

OPS administrative rules establish requirements for packaging and labeling psilocybin products that are sold to clients. All psilocybin products must be transferred from manufacturers to service centers in sealed client packaging that is appropriately labeled and packaged in a manner that is sanitary and prevents contamination. [OAR 333-333-2300](#).

While OPS rules allow re-using packaging, any re-used packaging must comply with requirements described above. [OAR 333-333-2300\(5\)](#). This means that packaging that is intended to be re-used must be routed to a licensed manufacturer. That manufacturer is responsible for ensuring that the packaging is properly sanitized and re-labeled to accurately reflect its contents. Some types of packaging, paper for example, may not be able to be sanitized and therefore may not be re-used.

## **Handwritten Labels**

Handwritten labels are allowed in rule, but the text must be legible and equivalent to 8 point large font in printed text ([333-333-2400\(1\)\(b\)](#)).

## **Product Tracking, Transfer, Storage, and Waste**

### **Recording Product Price in TLC-PTS**

Sales should be recorded as product price before taxes. This data may be shared with the Department of Revenue as it is the basis for calculating the taxes that are due for sale of psilocybin product ([333-333-5180](#) Collection of Taxes).

### **Trade Samples**

OPS rules do not address “trade samples.” Manufacturers may set any price they choose for their products and may choose to transfer psilocybin products to service centers at no cost. If the receiving service center would like to allow licensee representatives or facilitators to consume products for product education or to inform purchasing decisions, the individuals consuming the products are considered clients and must be treated identically to all other clients under ORS 475A and OAR 333-333, including but not limited to completing a preparation session with a licensed facilitator and all required client forms. Additionally, ORS 475A.662(6)(a) prohibits service centers from offering free products to clients, regardless of whether the service center received the product at no cost. When products are transferred to a service center at no cost, the service center must charge clients receiving the product at least a nominal fee.

### **Product and Product Waste Storage**

Licensees may store product in a safe (as defined in rule) and store product waste in separate locked receptacles in a limited access area of a licensed premises. This will meet the requirement for storage outlined in [OAR 333-333-4510](#) and [OAR 333-333-8000](#).

[OAR 333-333-4510\(2\)](#) states that all psilocybin product on a licensed premises is to be stored in a limited access area in a locked safe located within a limited access area of the licensed premises, in a locked refrigerator or freezer located within a limited access area of the licensed premises or a locked, enclosed area within a limited access area of the licensed premises that is secured with at a



minimum, a properly installed steel door with a steel frame, and a commercial grade, non-residential lock.

It is acceptable to store product in a safe (as defined in rule) and product waste in separate locked receptacles in a limited access area of a licensed premises. This will meet the requirement for storage outlined in OPS rules.

[OAR 333-333-8000\(1\)\(b\)](#) states that psilocybin waste is to be stored in a locked waste receptacle or limited access area in the possession of and under the control of the licensee.

[OAR 333-333-1010\(71\)](#) states a safe is defined in rule as a fireproof metal cabinet with a mechanical or electronic combination lock that can store psilocybin products and weighs at least 375 pounds.

### **Psilocybin Product Quantity Limits**

The limits in rule are expressed in terms of psilocybin analyte rather than product weight. Psilocybin analyte is the actual amount of psilocybin contained in fungi (or other product type) as determined by required laboratory tests. You will not know this number until your product has been tested; however, the limits were designed to allow for flexibility in operations.

Manufacturers are limited to having 200 grams of psilocybin analyte on the premises of a manufacturing property. Considering that psilocybin products must be packaged in a serving dose of no more than 25 milligrams of psilocybin analyte, this means a manufacturing premises could have up to 8,000 individual servings of psilocybin.