

# Oregon Psilocybin Services Section

## July 2022 Public Listening Sessions

### Summary of Questions and Answers

The Oregon Health Authority (OHA) held a series of three virtual public listening sessions in July of 2022. The listening sessions were two hours in length and open to the public. OHA staff compiled questions across the three listening sessions and summarized questions and answers in this document. The listening sessions were recorded and can be found on our [Public Listening Sessions](#) webpage in English, Spanish and American Sign Language (ASL).

Input from the public listening sessions will continue to inform draft rules, program development, educational materials and future community engagement.

#### Definitions

**OHA** = Oregon Health Authority, the state agency that regulates psilocybin services in Oregon

**OPS** = Oregon Psilocybin Services, the section within OHA that implements the Oregon Psilocybin Services Act

**M109** = Ballot Measure 109 passed by Oregonians in 2020, also known as the Oregon Psilocybin Services Act

**ORS 475A** = M109 codified as law in the Oregon Revised Statute, Chapter 475A — Psilocybin Regulation

**RAC** = Rules Advisory Committee, made up of members of the public who participate in discussions about draft rules during the rulemaking process (RACs will meet in September 2022 to discuss the remaining rules required to implement M109)

**May Rules** = The first subset of rules adopted in May 2022, related to psilocybin products, testing and facilitator training programs

**December Rules** = The remaining rules required to implement M109, which will be adopted by the end of December 2022

**OPAB** = The Oregon Psilocybin Advisory Board

**ORELAP** = Oregon Environmental Lab Accreditation Program

\* For more definitions of terms used in this document, please refer to Section 220 of the [Oregon Psilocybin Regulation \(ORS 475A\)](#)

## General Programmatic Questions

### **How is the cost of psilocybin services being determined?**

Under ORS 475A, OPS does not have the authority to control or regulate the cost of psilocybin products or services. Licensed psilocybin manufacturers, testing labs and service centers and/or facilitators will determine the cost of their services. Similarly, OHA-approved and HECC licensed psilocybin training programs will determine the costs of admission for students.

### **When can I access services? Is there a way to get on a wait list to receive services?**

Each licensed service center, and the licensed facilitators that work with them, will manage their own operations and communications with clients.

OPS will begin accepting applications for licensure on January 2, 2023. Psilocybin products must be cultivated and/or processed by licensed manufacturers and tested by ORELAP accredited, licensed testing labs. Psilocybin service centers and facilitators must also be licensed before offering psilocybin services to clients 21 years or older. It will take some time for all four license types (manufacturing, testing, service centers and facilitators) to become licensed and set up operations. For more information, please see the Oregon Psilocybin Services [website](#).

### **How will the consumer/client base be educated on psilocybin?**

In partnership with the Oregon Psilocybin Advisory Board (OPAB), OPS published a scientific literature review (in [English](#) and [Spanish](#)), which will be updated in the future. In addition, OPS published a 2-page fact sheet in [English](#) and [Spanish](#). OPS will continue to develop resources, offer presentations and facilitate public events. New resources and learning opportunities will be posted to the [OPS website](#), sent out through the [OPS mailing list](#) and shared through direct engagement with community partners. We welcome ideas and invitations to educate the public on Oregon Psilocybin Services.

### **Are there resources for people with brain injuries?**

At this time, OPS does not have resources available regarding the effect of psilocybin for people with brain injuries. While psilocybin and brain injury are still emerging research areas, it is possible that psilocybin may play a future role in treatment. OPS will work with the Oregon Psilocybin Advisory Board on updating the Scientific Literature Review as more information becomes available.

### **How will safety and equity of services be evaluated? Will there be a monitoring system? Will facilitators collect data? Will it be public access so that everyone can learn more?**

In ORS 475A.450 regarding confidentiality of client communications and information, the law states that a psilocybin service center operator, a psilocybin service facilitator, or any employee

of a psilocybin service center may not disclose any information that may be used to identify a client, or any communication made by a client during the course of providing psilocybin services or selling psilocybin products to the client. It also lists exceptions to this rule which include the ability of a client to voluntarily give consent to disclose information. OPS will be going through the final round of rulemaking for 2022 in the fall and anticipates hearing from RAC members and members of the public on issues related to data collection.

### **Can OHA hire indigenous program consultants?**

OHA works closely with the Oregon Legislative Assembly for approval on budget authority, which includes expenditures and hiring. Any positions for the Oregon Psilocybin Services Section go through an approval process within the state agency structure. We encourage anyone interested in working on the OPS team to apply for open positions.

## **General Licensing Questions**

### **Will the number of licenses be limited?**

No. OPS does not have the authority to limit the number of licenses issued for any of the four license types.

### **When can license applications be submitted?**

OPS will begin accepting applications for licensure on January 2, 2023. The OPS team is developing an online Training Program, Licensing, and Compliance System that we refer to as "TLC." This system will allow for a streamlined online application process, although paper applications will also be made available. The OPS team will also develop an application guide and training materials to assist applicants through the process.

### **How will applications be reviewed for approval? Are they reviewed in the order they are received?**

The OPS Section is divided into three program areas: the Policy and Engagement Program, the Licensing Program, and the Compliance Program. The OPS Licensing team will be reviewing applications and is currently developing processes and procedures including those for application review. When OPS begins accepting applications for licensure, the TLC application portal and resources to support applicants will be made available on our website.

### **Will the application process include site visits? From submitting application, how long will it be until the process completes (with inspection, etc.)?**

Licensed manufacturers, service centers and testing lab applicants will require a site visit before they can be issued a license. The application process will vary in length, depending on number of applications received and number already being reviewed.

**What will the license fees be?**

License fees will be determined through the state agency budget process and adopted in final rules by December 30, 2022. The sum of annual license fees collected must cover the cost of operating the Oregon Psilocybin Services Section.

**What is the current and future budget for the OPS Section?**

OPS has a fee-based funding model, which means the license fees must cover the costs of the section's work. OPS received General Funds for start-up costs and staff positions for the 21-23 biennium to begin implementation of M109. OPS is currently working on the 23-25 budget through the state agency budget process.

**Where does the psilocybin tax on products go?**

Under ORS 475A, there will be a 15% sales tax on the sale of psilocybin products payable to the Oregon Department of Revenue. Oregon Department of Revenue will deduct administrative costs, and any remaining revenue will go back to support the Oregon Psilocybin Services Section. While OPS is a fee-based structure, information is not yet available regarding whether tax revenue will be significant enough to impact license fees.

**If we are a property owner renting our place to a licensee, do we as the owner need a license?**

Property owners must provide written consent for use of property for manufacturer licenses. Rules regarding licensed premises will be adopted later this year.

**Can service centers be on the same property as a manufacturer license? What if you have a property that has one manufacturer and multiple service centers (that could help create cost efficiencies)?**

Rules regarding licensed premises will be adopted later this year. These rules will focus on allowing flexibility while ensuring public safety. The rules will address access, boundaries and security for licensed premises. We cannot provide specific information on co-location requirements at this time. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

**For manufacturers and service centers, do the same security measures apply to rural properties that are protected by land mass and security gates?**

Rules on licensed premises security will be adopted later this year. These rules will focus on allowing flexibility while ensuring public safety. The rules will address access, storage and security systems for licensed premises. We cannot provide specific information on security requirements at this time. We anticipate further discussion of this issue during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

**Could you clarify the different rules and dates, relevant to local government decisions?**

Local governments (cities and counties) may adopt ordinances that prohibit issuing service center and/or manufacturer licenses within their jurisdiction. Ordinances must be approved by voters at the next general statewide election (in 2022, the statewide general election will take place on November 8, 2022). For more information, please visit the [Oregon Secretary of State's webpage on Voting and Elections](#).

When Oregon Psilocybin Services Section receives notice that a local ordinance has been passed, we will not be able to issue licenses within that jurisdiction. If the ordinance does not pass in the general election, OPS will continue to issue licenses. For more information, please go to the OPS [Local Government Considerations webpage](#) and see the [Local Government FAQ](#).

**Do we have any recourse if our County opts out?**

If a local government passes an ordinance and it is approved by voters, the recourse would be to change the local law. For more information go to the Oregon Secretary of State's webpage on [How to Make or Change Local Law](#).

**How do we contact our local jurisdictions for land use approval? What does that look like?**

OPS will create a Land Use Compatibility Statement (LUCS) form available for applicant use by early fall. The LUCS form can be used to determine whether the proposed facility use is consistent with local government land use and zoning regulations. An applicant will complete sections of the form and submit it to their appropriate city or county planning office (where the proposed facility will be located). The city or county planning office will complete the LUCS form and indicate whether the proposed activity is compatible with local plans and regulations. Once completed the applicant will submit the LUCS form as part of their license application package.

**What can the property (for a manufacturer or service center) be zoned as?**

ORS 475A states that service centers cannot be located on property zoned for exclusive residential use within city limits. ORS 475A also states that a county may allow the manufacture of psilocybin products on property zoned for exclusive farm or forest use. Other zoning requirements are determined by the local jurisdiction (city or county) and will need to be documented in the LUCS form (see question directly above).

### **Are licensees required to obtain ‘continuing education’ credits?**

Continuing education credits were not required in ORS 475A and was not considered in OPAB recommendations. When final rules for training programs were adopted on May 20, 2022, a requirement for continuing education credits was not included.

### **Will there be a tiered licensing system for small business vs. larger businesses?**

A tiered licensure system is not required by ORS 475A. The Oregon Psilocybin Advisory Board (OPAB) recommended reduced license fees. Because ORS 475A created a fee-based structure, license fees must cover the cost of administering the section’s work, and OPS must create sustainability without reliance on state funds to operate. We anticipate further discussion of this issue during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

## **Manufacturing License**

### **What are the pre-requisites for a manufacturer license?**

Manufacturer license applicants will be required to produce a Land Use Compatibility Statement (LUCS) which demonstrates that the proposed use of the property is consistent with local zoning code. Applicants will also need to provide proof that the property owner consents to the production of psilocybin. Applicants for a license to manufacture psilocybin must be 21 years of age or older and pass a criminal background check. A manufacturer must meet residency requirements as outlined in statute (ORS 475A.290). OPS recommends reviewing [ORS 475A](#), as well as the subset of [rules related to manufacturing products that were adopted in May](#) (see final rules 333-333-1010 through 333-333-2110 [here](#)). These are some of the pre-requisites, however more details are yet to be determined will be addressed in the December Rules. The first draft of these remaining rules will be available September 1, 2022, and OHA will have a public comment period in November before finalizing rules in December.

### **Can real property be leased, or must it be owned?**

Rules on licensed premises locations will be adopted later this year. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

### **Can a manufacturer be co-located with a cannabis manufacturer (and use the same security camera system, etc.)?**

Rules on licensed premises locations will be adopted later this year. These rules will focus on allowing flexibility while ensuring public safety. The rules will address access, boundaries and security for licensed premises. We cannot provide specific requirements for co-location at this

time. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

**How much product can a manufacturer have at any given time? Will there be production limits?**

Yes. ORS 475A requires possession limits for manufacturers and those limits will be included in the December rules, with draft rules available by Sept 1, 2022.

**Is there an expectation that both psilocybin and psilocin will be administered?**

ORS 475A defines “psilocybin” to include both psilocybin and psilocin. The [rules adopted in May 2022](#) prohibit the manufacturing of psilocybin by chemical synthesis. The rules also limit the species to *psilocybe cubensis*.

**Has a maximum of material been established for any one dose?**

This is not specified in ORS 475A but will be determined in rule. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

**In terms of packaging, does everyone get the maximum dose in a package or are products to be packaged in increments smaller than the maximum dose? Can we sell the product in bulk to service centers and then they can weigh out a custom dose?**

This is also not specified in ORS 475A but will be determined in rule. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

**Is the product to be dried on site, or are we transporting fresh mushrooms?**

Fungi are dried on site. In the May rules, “harvest lot” is defined as a quantity of fungi that is cultivated and dried under the same conditions and harvested within a 24-hour period at the same location within the licensed premises. A manufacturer with a fungi cultivation endorsement must completely dry all fungi before transferring to a testing laboratory or to another manufacturer for processing.

**Will we have to have an example of our methods and final product so inspectors can see our process and controls in place? Or do we just walk through what we propose to do? Will we be required to show where spores, liquid cultures, and agar dishes come from? Will the sourcing of materials be tracked?**

This is not specified in ORS 475A. Some of these topics may be addressed in the December rules. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

**Will manufacturers be connecting directly with producers (of oils/extracts for example) and directly with service centers (in terms of an outlet for product), or will OHA facilitate that?**

OPS will not facilitate the movement of product between manufacturers and service centers. ORS 475A does, however, require products and the movement of products to be tracked in the product tracking system.

**Will it be feasible to ship products to psilocybin service centers?**

No. Products may only be transported by a licensee or licensee representative. More details regarding product transportation will be determined in the December rules.

**Does a greenhouse/shed structure count as indoors?**

The production rules adopted in May do not define indoor cultivation. We may consider this issue in the remaining rules.

**Can we use heat to make mushroom tea and other similar products?**

A manufacturer with a psilocybin extraction endorsement may apply heat, as long as it does not exceed 140 degrees Fahrenheit. However, this rule was not intended to prohibit the boiling of water.

**Will there be reassurances of a market to sell the product?**

OPS is not able to offer this reassurance. OPS cannot predict the exact supply, demand and other market dynamics. Manufacturers will be assuming risk in entering this emerging sector.

**What are the pathways for excess product, other than destruction? Can supply go to non-profits, research, etc.?**

Management of excess product, as well as other solid and liquid wastes generated during production and processing of products will be covered in the December rules. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.



## Service Centers

### **What can service centers do now to get prepared for licensure?**

Service centers may not be located within 1,000 feet of a school, must have defined boundaries, and cannot be located on public lands. In addition to rules adopted by OHA, other requirements may be established by local governments. Applicants will be required to produce a Land Use Compatibility Statement (LUCS) which demonstrates that the proposed use of the property is consistent with local zoning code.

Currently, local governments are considering adopting ordinances to prohibit service centers and manufacturers from operating in their local jurisdictions. These ordinances must be referred to voters at the next statewide general election. We encourage you to pay attention to what ordinances are passed by voters before making business decisions. If you live in a city or county that has not adopted an ordinance, you will still be required to provide a LUCS form as mentioned above.

Please review requirements in [ORS 475A](#) and stay tuned to our rulemaking process that will determine final rules by December 2022.

### **What structures will be allowed for service centers? Do they have to be a separate physical structure from other businesses/uses? For instance, can they be in an office building and share a single occupancy restroom or waiting room?**

Rules on licensed premises facilities will be adopted later this year. These rules will focus on allowing flexibility while ensuring public safety. The rules will address access, boundaries and security for licensed premises. We cannot provide specific requirements at this time. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

### **Can churches be licensed premises? What if a church includes a school? Will there be an opportunity to apply for an exemption?**

Churches can be licensed as long as they meet all of the license application requirements. However, there is no exception in ORS 475A for schools. ORS 475A requires that services centers may not be located within 1,000 feet of “a private or parochial elementary or secondary school, teaching children as described in ORS 339.030.”

### **What are the types of outdoor areas permitted for service centers?**

OPAB has recommended that outdoor areas be allowed. The details of any requirements for both indoor and outdoor portions of a licensed premises will be addressed in the December rules. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

**Will there be an exemption process for existing hospice centers that are within 1000 feet of school?**

There is no exemption under the law for a hospice service center. The only exemption to the prohibition in ORS 475A that a service center cannot be within 1000 feet of a school has to do with physical barriers like bodies of water or highways. If OHA determines that there is a physical or geographic barrier capable of preventing children from traversing to the premises, the service center may be located as close as 500 feet to a school.

**Are there regulations on the size of a service center?**

This was not specified in ORS 475A and was not considered in OPAB recommendations.

**Can a service center be located within incorporated cities and/or unincorporated areas, subject to the jurisdiction of a county?**

Yes, as long as the service center is not in an exclusively residential zone within city limits, it does not conflict with local ordinances or local land use code, and the local jurisdiction has not opted out of allowing licensed service centers to operate within their respective jurisdiction.

**Will people be able to have administration occur in their own private overnight accommodation?**

The only place that administration sessions can take place is within a licensed service center within the defined boundaries of the premises, in the presence of a licensed facilitator. Applicants will need to work with their local government to determine if defined premises meets local land use code and regulations.

**Will I be able to use a rural hotel for a psilocybin service center?**

All service center locations must meet requirements in ORS 475A and those set in rule. In addition, a service center location must meet local land use and zoning requirements. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

**What are the options for leftover psilocybin product at service centers?**

Management of excess product will be covered in the December rules. We anticipate further discussion during our Rules Advisory Committee (RAC) meetings in September and public comment period in November.

**Can there be mobile service centers?**

No. ORS 475A.265 states that OHA may not license a mobile premises.

## Facilitators, Training Programs, and Clients

### **What are the general requirements for facilitators?**

A high school diploma, or its equivalent, is required to become a licensed facilitator. Individuals must be 21 years of age or older and complete an OHA approved psilocybin facilitator training program, which includes a comprehensive exam administered by the training program. Information about training program curriculum requirements can be found in [administrative rules adopted May 20, 2022](#) (333-333-3005 through 333-333-3090), and a list of training programs with approved curriculum can be found [here](#). Applicants for a psilocybin facilitator license must provide proof of Oregon residency for two or more years (this requirement will no longer apply beginning January 1, 2025) and must pass a criminal background check. Before receiving a license, facilitators must also pass an exam administered by OHA to demonstrate an understanding of statutory and administrative rule requirements.

### **Do you need to complete a training program before you can apply for licensure? Have approved training programs been announced yet?**

Yes. As a requirement of licensure, facilitators must complete a training program with curriculum that has been approved by OPS. The [list of training programs with approved curriculum](#) is on the OPS website and is automatically updated as additional training program curriculums are approved.

### **If I have already received training elsewhere, can I get an exemption on the Oregon training for facilitation?**

A full exemption of training requirements is not possible. An individual seeking facilitator licensure in Oregon may work directly with an OHA-approved training program to determine whether past training/experience qualifies them for accelerated training. A training program may choose to award a student up to 48 hours (out of the 120 hours of core training hours required). To do this, a training program must establish and document criteria for granting accelerated hours to qualifying students. This may include transcripts and other records that document the number and type of accelerated training hours that will be granted. Regardless of past training, students are required to complete the following modules with an OHA-approved training program: (a) Cultural Equity in relation to Psilocybin Services;(b) Safety, Ethics and Responsibilities;(c) Preparation and Orientation;(d) Administration; (e) Integration; and all required practicum hours (at least 40 hours of practicum).

### **How is OHA working with the Higher Education Coordinating Commission (HECC) to get the training programs up and running?**

OPS has been partnering with HECC to provide information about ORS 475A and the OPS training program curriculum approval process. More information can be found [here](#).

**How will the training programs continue to be evaluated for appropriateness and standards?**

This is not addressed in ORS 475A. OPS curriculum approval is valid for 5 years, upon which a training program must renew their application with OPS. Training Programs are required by rule to submit to OPS any changes made to their programs including changes in program staff, instructors, and curriculum content. OPS will continue to ensure that these changes meet training program curriculum requirements set in rule.

HECC will oversee licensure and compliance of training programs. Under ORS 345, HECC responds to any written complaints with an investigation that could result in requiring training programs to take corrective action, suspend or revoke a training program's license. We expect future discussions on the evaluation of training program standards.

**Can people with disabilities and end-of-life communities access treatment at home or in hospice? How will in-home patients/ end-of-life patients access services?**

ORS 475A states that psilocybin services can only be administered in licensed service centers. Psilocybin products cannot be taken offsite and can only be consumed within the defined boundaries of a licensed premises. ORS 475A also states that licensed service centers cannot be located on property zoned exclusively for residential use if within city limits. Although there are challenges, OPS will continue to work with the Oregon Psilocybin Advisory Board, community partners and members of the public to ensure access for clients within ORS 475A.

**Will group retreats be permissible? How many clients can one facilitator oversee at one time?**

OPAB has recommended that group administration sessions be allowed. The training program curriculum requirements adopted in the May rules include a module on facilitating group administration sessions. The specific rules related to group administration have not yet been adopted and will be addressed in the December rules. These will likely include requirements related to preparation before a group session, informed consent, client to facilitator ratio, and maximum number of clients. We anticipate hearing from RACs and members of the public on rules related to group administration.

**Will there be minimum and maximum dosages?**

This has not yet been set and will be determined in the December rules. OPS is interested in hearing from RACs and members of the public on rules related to dosage.

**Is there a limit to the number of administration sessions a client can have?**

This was not specified in ORS 475A. It could be determined in rule, however it was not considered in OPAB recommendations.

**How do we determine how long a session lasts – what deems it complete?**

This has not yet been set and will be determined in the December rules. OPS is interested in hearing from RACs and members of the public on rules related to duration of administration sessions.

**Are licensees mandatory reporters?**

ORS 475A does not require all licensees to be mandatory reporters, although there may be opportunities for requirements that address reporting abuse in rule. Some licensees may be mandatory reporters if they meet the definition of those who are subject to requirements of [ORS 419B.010](#).

**Can preparation and integration occur virtually online?**

Facilitation of administration sessions must be provided in-person at a licensed service center. The preparation and integration sessions could occur virtually using video conferencing technology, however this is not yet set in rule. OPS is interested in hearing from RACs and members of the public on this topic.

**How will we screen for people who may be at risk of psychosis?**

ORS 475A requires that clients complete a preparation session, which includes a client intake. OPAB has made recommendations about determining client suitability, as well as an informed consent form and client bill of rights. OPS is working on drafting rules related to this requirement and anticipates hearing from RACs and members of the public on this topic.

**Can breathwork or yoga professionals be a part of the services provided?**

Although specific rules on provision of services have not been adopted, it is possible that breathwork and yoga will be permitted. The rules will focus on protecting public safety and will allow activities that do not create a risk to public safety.

In the training program rules adopted in May, the practicum requirements section (333-333-3070) mentions the use of altered states of consciousness that could be induced through breath work, meditation, or spiritual journeys. A yoga or breathwork professional could also choose to pursue a facilitator license.

**Will there be CPT code such as 90865 narco-synthesis available to bill insurance for dosing, or are all psilocybin services needing to be an out-of-pocket expense?**

At this time, there are no known health insurance plans that cover the cost of psilocybin services.

**Will the OPAB/OPS be educating medical professionals that if they facilitate psilocybin services, they will be violating Federal law and thus invalidating their medical malpractice insurance policies?**

Psilocybin is still a Schedule I substance under the Federal Controlled Substances Act.

Individuals and entities should review their policies and understand the risks of participating in this work.