Oregon Psilocybin Services

July 2023 Public Listening Sessions

Summary of Questions and Answers

Oregon Psilocybin Services (OPS) held a series of three virtual public listening sessions in July of 2023. The listening sessions were two hours in length and open to the public. Spanish and American Sign Language (ASL) interpretation were provided, as well as CART captioning.

The OPS team did not answer questions during the listening session. Instead, the purpose of the listening sessions was to provide an opportunity for members of the public to provide feedback on the ongoing administration of the Oregon Psilocybin Services Act (ORS 475A).

The OPS team 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 <u>Public Listening Sessions</u> 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

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

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

ORS 475A = The Oregon Psilocybin Services Act, codified in Oregon Revised Statutes, 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

* For more definitions of terms used in this document, please refer to Section 220 of the <u>Oregon Psilocybin Regulation (ORS 475A)</u>

Accessing Psilocybin Services

Is psilocybin still illegal?

The Oregon Psilocybin Services Act, passed by Oregon voters in 2020, directs the Oregon Health Authority to license and regulate the production of psilocybin products and the provision of psilocybin services. It is now codified in Oregon law in <u>ORS 475A</u>, meaning that psilocybin services within this statutory framework are legal in Oregon. Under ORS 475A, psilocybin products may only be provided to a client at a licensed psilocybin service center during an administration session. Oregon law does not allow people to purchase or consume psilocybin outside of a licensed service center, and the requirements in statute and administrative rules must be followed by all licensees.

Although psilocybin services are a new health and wellness option in Oregon, psilocybin is still federally illegal and a Schedule I substance under the Controlled Substances Act.

For more information, please see the OPS Fact sheet available in <u>English</u>, <u>Spanish</u> and <u>American Sign Language (ASL)</u>. You can also <u>Watch a Video</u> or <u>Read a Comic</u> to learn more.

When will services be available to clients?

The Oregon Psilocybin Services section began accepting applications for four license types on January 2, 2023. These include facilitators, service centers, manufacturers, and laboratories.

Some licensed service centers are beginning to open their doors to clients. It takes time to become licensed and set up operations. Each licensed service center will manage their own operations including communications, waiting lists and scheduling with clients.

To learn more about accessing psilocybin services, please visit our page on <u>How to</u> <u>Access Psilocybin Services</u>. To view a list of licensees who have consented to have their contact information publicly listed, please go to the: <u>OPS Licensee Directory</u>.

Will psilocybin therapy be offered as an option?

Although people may sometimes refer to Psilocybin Services as "psilocybin therapy", it is important to clarify that the Oregon Psilocybin Services Act did not create a medical or clinical model. The term "therapy" is not defined in statute. Under <u>ORS 475A</u>, a licensed facilitator must take a non-directive approach to facilitating psilocybin services, which is supporting a safe, client-centered experience.

OPS rules on scope of practice require that facilitators shall not engage in conduct that requires additional licensure while providing psilocybin services, including diagnosing and treating mental health conditions. This means that facilitators may hold other professional licenses in Oregon but are not allowed to practice on those licenses while providing preparation, administration, or integration sessions to clients.

Clients may choose to work with a therapist or other professional outside of the OPS framework. This could include therapy, or other supports or services, before or after accessing psilocybin services.

What is specifically required with preparation and integration sessions?

Although a prescription or referral from a medical or clinical provider is not necessary, a client must participate in a preparation session with a licensed facilitator before they can consume psilocybin.

A preparation session includes a client information form, informed consent, a review of a client bill of rights, safety and support planning, transportation planning, and additional discussion with a licensed facilitator. Preparation sessions may be completed in person or virtually using video conferencing technology. If you are interested in learning more about the required preparation session, please visit our page on <u>How to Access Psilocybin Services</u>. You will find important operational documents used during a preparation session, which are currently available in English and Spanish.

After a client has participated in a preparation session, they may participate in an administration session at a licensed service center with the support of a licensed

facilitator. The administration session is the only time a client may purchase and consume psilocybin products.

After the administration session, clients may also participate in optional integration sessions with a licensed facilitator. Clients may discuss additional safety and support needs or be referred to peer-support networks and other community resources.

Is there a billing code for psychedelic therapy? If/when that is true, does that mean insurance will be an option for covering psilocybin services?

It is important to understand that OPS is not a medical or clinical model. Currently, there are no known health insurance plans that will cover the cost of psilocybin services.

Although psilocybin services are now a new health and wellness option in Oregon, psilocybin is still federally illegal as a Schedule 1 substance under the Controlled Substances Act.

Has OPS considered including bios and other information in the 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 connect with licensed service centers. The directory contains information provided by OPS licensees who have consented to have their information published.

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.

General Questions about the Regulatory Framework

Does microdosing fit within the OPS framework?

The term "microdose" is not defined in statute. If a service center offers lower dose administration sessions, clients may request to consume a lower, subperceptual dose of psilocybin in the preparation session with a licensed facilitator. There is no minimum dose set in OPS rules. Clients who choose a lower dose administration session are still required to complete a preparation session with a licensed facilitator and follow all other rules related to psilocybin services.

How will indigenous practices be integrated into psilocybin services?

The Oregon Psilocybin Services Act created the legal boundaries for psilocybin services in Oregon. While we must work within the statutory container of the act, our mission is to ensure safe, effective, and equitable psilocybin services in Oregon while aligning with the OHA strategic plan goal to eliminate health inequities and addressing the goals of Oregon's State Health Improvement Plan, Healthier Together Oregon. Oregon's State Health Improvement Plan advances equity for priority populations, which include Black, Indigenous, people of color, tribal communities, people with low incomes, people who identify as LGBTQIA2S+, people with disabilities, and people living in rural areas. The five priorities address: institutional bias; adversity, toxic stress, and trauma; behavioral health; economic drivers of health; and access to equitable preventative health care. Whether our section is working to address institutional bias and economic drivers of health or clients are accessing psilocybin services to address trauma or behavioral health issues, psilocybin services have a role in the creation of healthy communities.

We understand that many people belong to intersecting communities that experience discrimination and disadvantage, specifically when working within systems and institutions. It is our priority to reduce harm to communities though trauma-informed communications that make accessibility a standard of practice instead of an exception. Part of our work is prioritizing the State of Oregon's government-to-government relationship with Oregon's Nine Federally Recognized Tribes. It is our responsibility as a state agency to honor, respect, and uphold that relationship. The Nine Federally Recognized Tribes in Oregon will determine if, and when, they would like to engage with OPS on psilocybin services in Oregon.

In addition, OPS offers culturally responsive community circles to individuals who prefer to engage with us in ways that better meet their cultural needs. OPS is interested in continuing to learn from, and engage with, members of indigenous communities and respects that not all indigenous practices may fit within the Oregon Psilocybin Services Act.

We will continue to work with communities to better understand how to ensure flexibility for varying practices within the legal boundaries of the Oregon Psilocybin Services Act.

Is it against the rules to call it "therapy"?

Again, it is important to clarify that the Oregon Psilocybin Services Act did not create a medical or clinical model. The term "therapy" is not defined in statute. Under ORS 475A, a licensed facilitator must take a non-directive approach to facilitating psilocybin services, which is supporting a safe, client-led experience. The term "therapy" is not defined in statute and may be defined differently from person to person. OPS does not have authority to address the use of this term by individuals and organizations that are not licensed by OPS.

For licensees, administrative rules cover scope of practice requirements for facilitators as well as advertising. OPS rules on scope of practice require that facilitators shall not engage in conduct that requires additional licensure while providing psilocybin services, including diagnosing, and treating mental health conditions. This means that facilitators may hold other professional licenses in Oregon but are not allowed to practice on those licenses while providing preparation, administration, or integration sessions to clients. Advertising must comply with <u>OAR 333-333-6100</u> which prohibits statements that are deceptive, false, or misleading.

What are the requirements/norms around using the word "sacred"?

OPS does not have requirements related to the use of the word "sacred".

Will OPS be able to fund itself through license fees?

Oregon Psilocybin Services (OPS) is a fee-based section, which means that licensing fees must cover the costs of administering the work associated with the Oregon Psilocybin Services Act (M109), ORS 475A. This fee-based structure was created by the Oregon Psilocybin Services Act.

OPS is expected to transition to Other Funds (OF) revenue funded by licensing fees during the 2023-25 biennium. As part of a large center of regulatory sections that are fee-based, OPS will continue to establish budget sustainability with a commitment to working toward more equitable licensing fees.

Under ORS 475A, the Oregon Health Authority does not have the authority to set or regulate costs of products or services. Licensees will determine these costs as independent businesses.

The Oregon Psilocybin Services section does require in rule, however, that licensees submit social equity plans with license applications and license renewals. The purpose of the social equity plan requirement is to ensure that every psilocybin licensee in Oregon considers how certain communities have been disproportionately harmed by systemic inequities, and how they propose to address these inequities in their business practices with the intention of working toward equity, access, and affordability. More information can be found <u>here</u>.

Providing Input on Rules

How do people change the rules?

Under ORS 475A, OPS has the authority to adopt administrative rules to administer ORS 475A, the Oregon Psilocybin Services Act. The rulemaking process is informed by recommendations from the Oregon Psilocybin Advisory Board (OPAB), input from members of the public during public listening sessions, input from Rules Advisory Committees (RACs), and feedback received during public comment periods, including public hearings on rules. The first full set of administrative rules were adopted in December 2022 (<u>OAR 333-333</u>).

If you have suggestions on draft rules, please provide feedback during the public comment period that will be held later this year. During a public comment period on draft rules, we host virtual public hearings for members of the public to register official comments on draft rules in a virtual setting, which includes options for non-verbal communicators to participate. Real-time captioning (CART) and simultaneous Spanish and American Sign Language (ASL) interpretation are also provided, in addition to accommodation requests we receive. During the public comment period, we accept written comments submitted through email. After the conclusion of a public comment period, OPS publishes a letter to the public explaining some of the substantial changes made in response to public input.

All scheduled public meetings and hearings will be posted on our website. If you would like to receive updates and information, we hope you will <u>sign up to our</u> <u>distribution list</u>.

It is important to know that any proposed changes to the statutory language of the Oregon Psilocybin Services Act (<u>ORS 475A</u>), which is already set in law, will require legislative action to amend.

Will there be input from psychologists, neurologists, and other clinicians?

OPS has received input from psychologists, neurologists, and other clinicians throughout the rulemaking process.

In addition, the Oregon Psilocybin Advisory Board (OPAB), which is comprised of governor appointed members that serve four-year terms, includes memberships that include a psychologist, physician, psychopharmacologist, mycologist, and others. The advisory board has made recommendations on the requirements, specifications, and guidelines for providing psilocybin services in Oregon. You can find a current list of board members on the <u>OPAB webpage</u>.

Psilocybin products

How do clients get the product?

After a client has completed a preparation session with a licensed facilitator, they can schedule an administration session at a licensed service center, which is the only premises where a client can purchase and consume psilocybin products. At the beginning of an administration session, the client will purchase the product from the licensed service center. The product cannot be taken off-site, and the client must remain in the licensed service center in client administration area for the duration of their administration session with a licensed facilitator.

Psilocybin products are cultivated and processed by a licensed manufacturer. Products may be consumed as dried whole mushrooms, extracts, powdered mushroom that can be put into capsules or stirred into tea or edibles such as chocolate, and other edible food products. Only natural psilocybin products are allowed. As part of the preparation session, the client will work with their facilitator to understand and decide on product type and dosage.

Psilocybin products are tested by licensed laboratories. After testing requirements are met, licensed manufacturers can transfer packaged products to a licensed service center. Throughout this process, the psilocybin products are tracked in a state psilocybin product tracking system.

What happens to unconsumed product?

If the product remains in its original sealed packaging, the service center may return the product to inventory and sell the item to another client after providing a refund to the purchaser. If the packaging has been opened, then the product must be destroyed and recorded as waste.

Facilitator practice, training

Will students taking substances during practicum be treated like clients?

Yes, students in practicum may only consume psilocybin if they are treated as clients under ORS 475A and OAR 333-333. Psilocybin can only be consumed by students of training programs in a legal manner. In Oregon, the only option is

through an administration session at a licensed service center under the legalized regulatory framework of ORS 475A after completion of a preparation session.

Do indigenous practitioners have to pay training programs to learn what they already know?

OPS rules allow for OHA approved training programs to offer qualified students accelerated training hours not to exceed 40 percent of the total number of core training hours required. Accelerated training hours may be awarded based on students professional credentialing, prior training and education, or relevant experiences such as practicing in established plant or fungi-based healing traditions. (See: <u>333-333-3080 - Accelerated Training Hours</u>)

Training programs determine their application process, cost, duration, and overall structure of their program while meeting the training program rule requirements and may not offer accelerated training hours for practicum. Training programs that offer accelerated training hours must ensure they are meeting all requirements.

Licensing, Worker Permits, and Employment

What are the timelines for licensing? What items are commonly missing in applications?

<u>ORS 475A</u> and <u>Oregon Administrative Rules (OAR) Chapter 333, Division 333</u> outline all rules and requirements regarding licensing. License applicants must meet requirements before applying for a license.

To better understand license requirements, please visit the following webpages that cover more details about each of the four different license types:

Facilitator License Manufacturer License Service Center License Laboratory License The webpages for each license type include a fact sheet that summarizes each license requirement. The webpages also include a comprehensive application guide that explains the entire application process.

Applications are reviewed in the order received. The application process may be impacted by many factors. For example, if an application is incomplete or additional documentation needs to be submitted, this could delay the processing time. We suggest that applicants have all documents prepared before submitting their applications.

In addition, the background check process may take time, specifically if additional or supporting documentation will be provided before a decision is made. For any questions about the background check process, applicants can review our <u>Background Check Process Overview document</u>.

Finally, for manufacturer, service center, and testing laboratory licenses, the OPS team will conduct site inspections to ensure that the proposed premises is compliant with requirements. If applicants meet all requirements of the site inspection, they will be issued a license much faster than those that will need to make corrections following the site inspection. Again, being prepared for the application process and site inspections will help ensure a more efficient application process.

You can direct more specific questions about the license application process to the OPS Licensing Team at: <u>Licensing.Psilocybin@odhsoha.oregon.gov</u>.

Why are worker permits required for facilitators? Does it entail additional duties?

The Oregon Psilocybin Services Act (<u>ORS 475A</u>) requires that certain individuals who perform work for, or on behalf of, a licensee must have a valid permit issued by the Oregon Health Authority (OHA). This includes any individual/employee who participates in:

• The provision of psilocybin services at the premises for which the license has been issued;

- The possession, manufacturing, securing, or selling of psilocybin products at the premises for which the license has been issued;
- The recording of the possession, manufacturing, securing, or selling of psilocybin products at the premises for which the license has been issued; or
- The verification of any document described in ORS 475A.445.

You can learn more about how to apply for a worker permit on the <u>OPS Worker</u> <u>Permit</u> webpage.

For more information about how to prepare for the application process, please read the information on the <u>OPS Worker Permit</u> webpage and refer to the application <u>Worker Permit Application Guide</u>.

How can people interested in working in this area get involved? Is there a community of practice?

The Oregon Psilocybin Services (OPS) Licensee Directory provides licensees the opportunity to connect with each other for business purposes. To find psilocybin businesses licensed with Oregon Psilocybin Services (OPS) please review the <u>OPS</u> <u>Licensee Directory</u>. The directory contains information provided by OPS licensees who have consented to have their information published. We will continue to update the Licensee Directory as licenses are issued and licensees consent to be added to this list.

If you have identified a service center, manufacturer, laboratory and/or facilitator that you are exploring employment with, you can ask them for their license number and use the <u>license verification tool</u> provided on the OPS website to confirm that their license is valid and active.

Each licensed service center, manufacturer, laboratory, and facilitator will manage their own operations and communications with potential employees. The role of OPS is to license and regulate licensees to ensure that psilocybin manufacturers, laboratories, service centers, facilitators, and permitted workers comply with Oregon law.

Client safety

How do we hold licensees accountable when clients are harmed?

If a client, licensee, or any member of the public has a complaint or a concern about a psilocybin licensee, they can go to the OPS webpage and <u>File a Complaint</u>.

The information provided will be carefully reviewed by the Oregon Psilocybin Services Compliance Program. OPS will determine if there are potential violations of ORS 475A or OAR 333-333 and whether the Oregon Health Authority is the agency with jurisdiction to take further action. OPS is authorized to conduct inspections and investigations. Depending on the number and severity of violations, a licensee may face civil penalties, revocation, or other administrative actions. If the complaint is related to criminal activity, law enforcement is the appropriate authority to contact.

How will academic research and primary data collection be included?

In accordance with <u>ORS 475A</u>, the Oregon Psilocybin Advisory Board reviews available medical, psychological, and scientific studies, research, and other information related to the safety and efficacy of psilocybin in treating mental health conditions. The first version of the Scientific Literature Review was published in 2021. In addition, the Oregon Psilocybin Advisory Board acknowledged cultural and anthropological information regarding centuries of psilocybin use that was not included in the scientific literature review, and a subsequent Cultural and Anthropological Review was published in2022 which amplified some of the cultural and anthropological information presented in subcommittee meetings throughout the development period.

These publications can be found in both English and Spanish on the <u>Scientific</u> <u>Literature Review and Cultural and Anthropological Information webpage</u> and will be updated periodically by the Oregon Psilocybin Services section, in partnership with the Oregon Psilocybin Advisory Board.

During Legislative Session 2023, SB 303 was passed by the Oregon Legislative Assembly. SB 303 directs service centers to collect, aggregate, and report client

data related to psilocybin services to OHA, and directs OHA to share data with OHSU in addition to licensing and compliance data. In September of 2023, OPS will convene a Rules Advisory Committee (RAC) to begin rulemaking required for the implementation of Senate Bill 303. For more information, please visit the <u>Administrative Rules and Rulemaking Process</u> page on the OPS website.