Oregon Psilocybin Services

2024 Public Listening Sessions Summary with Questions and Answers

Oregon Psilocybin Services (OPS) held a series of three virtual public listening sessions in June of 2024. The listening sessions were 90 minutes in length and open to the public. Spanish and American Sign Language (ASL) interpretation were provided, as well as CART captioning. The sessions were recorded and can be found on our 2024 Public Listening Sessions webpage in English, Spanish, and American Sign Language (ASL).

The OPS team did not answer questions during the listening sessions. Instead, the purpose of the listening sessions were 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 themes and questions asked across the three listening sessions. This document summarizes themes heard and provides answers to the questions asked.

Input from the public listening sessions will continue to inform 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 Oregon Psilocybin Regulation (ORS 475A)

Themes to be considered in 2024 rulemaking

OPS received multiple comments during the 2024 Public Listening Sessions on a few key themes listed below. These issues may be considered during the upcoming rulemaking process. The 2024 Rules Advisory Committees (RACs) are scheduled to meet between August 5 and August 16.

- Administration session minimum duration requirements
 We received several comments regarding minimum duration requirements
 for administration sessions.
- Transportation plan requirements for low dose administration sessions
 We received several comments regarding transportation plan requirements
 for low dose administration sessions.
- Back-up facilitator requirements

We received several comments regarding requirements for back-up facilitators to be available during client administration sessions.

• Emotional support people

We received several comments regarding the presence of family and other individuals who support clients during an administration session.

Restroom requirement in Informed Consent Form

We received comments regarding the requirement to discuss restroom locations during preparation sessions.

Draft rules may be updated based on RAC input provided during August meetings. The next version of proposed rules will be made available for public comment in October. The public comment period will be from October 1 to October 21, 2024. For more information, please go to the OPS Administrative Rules webpage.

Other Issues Highlighted in Public Listening Sessions

Analog products and public education

OPS received a few comments regarding the need for more public education on psilocybin, safety, and education on risks of analog products and psilocybin use in the unregulated space.

OPS currently has limited capacity to provide public education on issues outside of our regulatory authority. Although OPS only covers product issues within the regulated framework of ORS 475A, the Oregon Health Alert Network (HAN) and the Centers for Disease Control (CDC) Health Alert Network (HAN) both provide alerts about investigations related to health risks associated with products marketed as containing mushrooms. You can sign-up to receive HAN alerts to learn about analog products that may cause adverse health effects.

If you have ideas for how the Oregon Psilocybin Services section can continue to expand outreach and education about the OPS regulatory framework, please email: OHA.Psilocybin@oha.oregon.gov.

Advertising rules

OPS received a few comments regarding the need for more clarity or flexibility with advertising rules.

OPS has previously published guidance on advertising psilocybin products and services which may be found in the OPS Guidance on Administrative Rules document. Based on comments, OPS will evaluate previously published guidance for opportunities to clarify advertising requirements and may publish updated guidance in the near future.

Minors on licensed premises

OPS received comments requesting that rules be changed to allow for minors, persons under 21 years of age, to be allowed on licensed premises. ORS 475A.495 prohibits persons under 21 years of age from entering licensed premises. Changing this requirement would require legislative action.

 Providing psilocybin services to homebound clients who are not able to travel to a service center location

OPS received comments requesting that clients with mobility limitations or who are in hospice have the option to receive psilocybin services at home. This issue cannot be handled in administrative rule and is currently prohibited by law. ORS 475A.498 states that psilocybin products may only be consumed at licensed service centers. Changing this provision would require legislative action.

Summary of Questions and Answers

What needs to happen to change the statute or change things that are outside of OPS rulemaking authority?

The Oregon Psilocybin Services (OPS) section administers the statute <u>ORS chapter</u> <u>475A</u>, the Oregon Psilocybin Services Act, which was passed in November 2020 as Ballot Measure 109. OPS is required to adopt administrative rules to administer ORS 475A. OPS may also amend administrative rules but does not have the authority to amend law (statute).

Making any changes to a statute requires that a legislator sponsor and propose an amendment to ORS 475A. The amendment must then be passed by both houses through a step-by-step process. We recommend reviewing the Oregon State Legislature resource: How Ideas Become Law. You can use the tool provided on the Oregon State Legislature webpage to Find Your Legislator and you can work with other individuals or organizations who share your interests.

How do we know if something is going to be considered as a rule change in the 2024 rulemaking process?

The first version of 2024 draft rules will be shared with the Rules Advisory Committees (RACs) and discussed in the RAC meetings in August. RAC meeting information, such as Zoom links and meeting materials including copies of the draft rules, will be posted on the OPS Administrative Rules page. Recordings of the meetings will also be posted in the days following each meeting.

The next version of proposed rules will be published in October. The public may comment on any rule during the public comment period scheduled for October 1 through October 21, 2024. The final rules will be adopted by the end of the year and will be effective January 1, 2025.

We expect to open administrative rules each year and there are several ways to engage throughout the year. You can attend <u>OPAB and/or subcommittee meetings</u> and share your ideas in the public comment periods during these meetings. You can attend and provide comments in our annual <u>public listening sessions</u>. You can apply to serve on a Rules Advisory Committee (RAC). You can provide written testimony or verbal testimony during the rulemaking public comment periods.

We recommend that you <u>subscribe to the OPS Distribution List</u> to receive updates and opportunities and you can always email us at: OHA.Psilocybin@oha.oregon.gov.

Can you share an update about SB303 implementation? What data will be made public?

Senate Bill 303 (SB 303) was passed by the Oregon Legislature in 2023 and is now codified in ORS 475A.372 and ORS 475A.374. SB 303 requires service centers to collect and report certain client and service center data. It also requires OPS to compile and publish specific service center, licensing, and compliance data.

OPS will address specific requirements related to SB 303 data collection and reporting in 2024 rulemaking. RAC #1 will discuss rules related to the implementation of SB 303. You can find the dates of RAC meetings, along with meeting materials which include draft rules, on the OPS Administrative Rules page.

In July 2024, OPS sent licensed services centers a <u>letter about preparing for SB 303 implementation</u>. This letter was also posted online and can be found on the <u>Senate Bill 303 and Data Collection Information</u> webpage. This webpage will be updated as more information about SB 303 implementation becomes available.

OPS is currently working to develop the SB 303 Data Reporting Portal to ensure a consistent process for service centers to report the required client and service

center data. We continue to prioritize data privacy and security. OPS will follow data standards set by the Oregon Health Authority, including de-identification standards, before publishing SB 303 data on the OPS Data Dashboard. OPS plans to begin publishing SB 303 data on the OPS Data Dashboard beginning after the first quarter of 2025.

Why is the total potential psilocin content not included in labeling requirements?

Although licensed laboratories test for psilocin content, it is not required to be listed on product labels. OPS rules on product labeling specify minimum requirements for content on product 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.

Can a church be a licensed premises?

A church can be licensed by OPS as long as the premises meets all requirements set in statute and rule. As a first step, we recommend reviewing the Service
Center License fact sheet which summarizes the steps to licensing a new psilocybin service center. There are several important considerations, including verifying that the proposed location is at least 1,000 feet from a school and meeting all requirements outlined in the General Premises Plan Checklist, the Service Center Premises Plan checklist, and the Inspection Orientation for Service Center License Applicants which are resources to help ensure that your premises is compliant with statute and rule requirements.

Can a backyard that abuts a driveway be part of the licensed premises?

Each premises must have a scaled floorplan, which can include outdoor areas. Outdoor areas must have clearly marked boundaries to mitigate any hazards, or access to minors. For specific questions related to a licensed premises, please visit the resources on our <u>Service Center License webpage</u> and <u>Manufacturer License webpage</u>.

Can a residence be connected to a service center?

The floorplan of a licensed premises cannot overlap with a primary residence. However, a licensed premises could be on the same tax lot as a residence. The boundaries of the proposed licensed premises need to be separate from any residence and comply with all requirements set in statute and rule. 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).

It's important to understand that there may be additional local zoning rules and regulations apart from OPS rules. Before submitting an application, you will need to work with your local city or county jurisdiction to complete an OPS Land Use Compatibility Statement (LUCS) form, which demonstrates that the proposed property is in compliance with local land use and zoning requirements. Your local jurisdiction will need to review and approve the LUCS. Once you make the request, your local jurisdiction is required to respond within 21 days.

We want to thank everyone who participated in the 2024 OPS Public Listening Sessions. Thank you for sharing your feedback and asking important questions. We are always interested in learning from you. If you have any additional comments or questions, please contact the Oregon Psilocybin Services section at: OHA.psilocybin@oha.oregon.gov