

DATE: November 14, 2024

TO: Hearing Attendees and Commenters –  
Oregon Administrative Rules chapter 333, division 333  
Oregon Psilocybin Services

FROM: Brittany Hall, Hearing Officer

SUBJECT: Presiding Hearing Officer’s Report on Rulemaking Hearings and Public  
Comment Period

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### Hearing Officer Report

**Date of hearings:** October 15, 2024, October 16, 2024, and October 17, 2024,  
via Zoom

**Purpose of hearings and public comment period:** To receive testimony and comments regarding the Oregon Health Authority (OHA), Public Health Division's proposed permanent amendment of Oregon Administrative Rules in chapter 333, division 333 related to Oregon Psilocybin Services. The proposed rules implement ORS chapter 475A, the Oregon Psilocybin Services Act (“the Act”).

The proposed rules are needed to implement data collection and reporting requirements of Senate Bill 303, passed in 2023 and now codified as ORS 475A.372 and ORS 475A.374. The statute requires licensed psilocybin service centers to collect certain data and report aggregated data to OHA on a quarterly basis and contains provisions that allow clients to request their data is not submitted to OHA. The 2024 proposed rules supplement previously adopted rules by clarifying existing requirements for collection and reporting client data and describing required reporting of licensee and applicant data.

The proposed rules are needed to refine curriculum requirements for psilocybin training programs and supplement the existing framework for psilocybin services to provide culturally responsive services and promote client safety. OHA previously adopted rules addressing curriculum requirements and approval process for psilocybin training programs. The current proposed rules amend existing rules to require practicum at a licensed service center, modify curriculum requirements for training programs and require continuing education for licensed facilitators. The proposed rules also create new requirements for facilitators and service centers to describe culturally and linguistically responsive services offered to clients and amend other requirements for providing psilocybin services to increase access and mitigate risks to client and public safety.

The proposed rules make additional changes related to licensed premises and provision of psilocybin services. These changes address all aspects of implementation and support ORS chapter 475A's goals of promoting access and equity while protecting health and safety. The proposed rules are necessary to effectively implement ORS chapter 475A because they make important changes to the previously adopted rules that will provide greater clarity and efficiency of operations for both licensees and the Oregon Psilocybin Services section. The proposed rules also strengthen existing provisions for protecting client safety and confidentiality.

**Hearing Officer:** Brittany Hall

**Comments and testimony received:** In OHA's Notice of Proposed Rulemaking, OHA announced that individuals could submit written comments by sending them to OHA's designated email address for receiving such comments, or by fax or mail. In addition, OHA took public testimony at the public hearings that were held on October 15, 2024, October 16, 2024, and October 17, 2024. OHA received oral testimony from 25 individuals at the public hearings (some individuals testified at more than one hearing) and received many written comments. OHA staff have considered the written comments and public testimony received prior to the deadline on October 21, 2024, at 5:00 p.m. Pacific Time. OHA thanks all Oregonians who provided public comment and appreciates the varied input they have provided to the rulemaking process.

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Themes of the testimony and written comments relevant to the current proposed rules, in no particular order, are summarized below. Copies of audio recordings of the hearings and hearing transcripts are available online at [www.oregon.gov/phrules](http://www.oregon.gov/phrules).

- OHA received comments voicing concern about the potential economic barriers that the proposed rules might create. While necessary for safety, the increased costs of licensure, training, and service compliance could result in higher prices for psilocybin services, disproportionately affecting low-income individuals. Comments requested that the agency support policies that both maintain the integrity and safety of psilocybin services and prioritize equitable access for all Oregonians.

**Agency response:**

Oregon Psilocybin Services Section (OPS) strives to balance the cost of regulation with the need to protect public health and safety. As discussed in the fiscal impact statement, there will be costs to comply with the rules. This cost of compliance is offset to some degree by rule changes that reduce costs, such as the removal of the back-up facilitator requirement, or create new opportunities for revenue, for example by allowing out-of-state training programs to conduct practicum at Oregon service centers. More importantly, the rule changes are necessary to mitigate risks to client and public safety and ensure a sustainable program going forward.

- OHA received comments voicing concern about proposed changes to OAR 333-333-5120 that prohibit facilitators from supervising, observing, or supporting individuals consuming psilocybin outside of a licensed service center. It was questioned what “observe” and “support” mean. While there is support for regulation of commercial psilocybin facilitation, safe use of psilocybin between consenting adults and in settings outside of a service center, such as a private setting like one’s home, should not be subject to oversight by the OHA. Concern was also expressed that OAR 333-333-5120(13) is overly restrictive and prevents facilitators from providing harm reduction services at events like concerts and festivals, which may not fall under the definition of “urgent or emergent events” in section (14).

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Also related to OAR 333-333-5120(16), OHA heard concerns about the prohibition of a facilitator conducting preparation and integration sessions at a location outside of the United States or U.S. Territories. If a facilitator is doing their work on vacation in another country, there should be no restrictions on conducting online preparation and integration work with a client who is in Oregon. Likewise, if a client is overseas and traveling to Oregon specifically for the administration session, online sessions are imperative. Otherwise, the client would have to be present in Oregon for the preparation, administration and integration sessions, which would increase the financial burden on clients.

**Agency response:**

ORS 475A requires licensed facilitators conduct psilocybin administration sessions at licensed psilocybin service centers without exception. The 2024 rules clarify this statutory requirement while also describing certain activities that do not apply, such as harm reduction activities, work at locations outside of Oregon, or participation in research if they hold the necessary license or authorization or it is otherwise lawful to do so.

In response to comments, OPS revised the draft rules to remove the words “observe” and “support” from OAR 333-333-5120(13) and revised OAR 333-333-5120(14) to provide more detail on allowable harm reduction activities.

OAR 333-333-5120(16) has been deleted.

- OHA received comments voicing concern about proposed changes to OAR 333-333-5140 that imposes an overly broad duty on facilitators to report misconduct, including private, consensual psilocybin use outside of licensed settings. The requirement forces facilitators into an uncomfortable role that undermines trust, requiring them to police their peers. It was suggested that the rule could be amended to say that report of misconduct should be limited to violations that create risk of harm, or in instances of serious crimes such as abuse or exploitation.



**Agency response:**

Conducting administration sessions at unlicensed locations creates a risk to client and public safety and is prohibited by ORS 475A. OPS has an interest in requiring licensed facilitators to report this activity when they become aware of it. Separate rules create a duty for facilitators to place clients' interest above their own. The reporting requirement is consistent with this duty. It also helps to support a client centered experience and mitigates risks to client and public safety.

OPS revised OAR 333-333-5140 in response to comments to narrow the required reporting to violations involving clients, products, and facilitators.

- OHA received comments regarding OAR 333-333-5200 and the requirement that audio and visual materials used during an administration session be non-directive. The rule is vague and difficult to enforce, and it is not clear how “non-directive” music is defined. Clients should have to consent to any music being played during their administration session and should be able to request that it be changed or turned off if it becomes disruptive to them.

**Agency response:**

Separate provisions of OPS rules define “nondirective facilitation” and require facilitators to use nondirective facilitation when providing services to clients. OAR 333-333-5200(6) is consistent with these requirements. In response to comments, the rule has been revised slightly to focus on client consent to use of materials rather than client request.

- OHA received comments on OAR 333-333-5250 regarding the proposal to restart the minimum session duration hours when a booster dose is given. The concern is that some clients on SSRIs, opioids, or other blunting medications need the maximum dose as an initial dose and then as a booster, but still experience very short and mild effects. Requiring that they stay at the service center for the minimum session duration based on booster dosage when they are not under the influence of the medicine is not cost effective and is an additional strain on service centers and facilitators. The booster is not additive,

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so the session duration should not be either. Facilitators should have the ability to use their skills and capabilities to determine when a client can leave safely.

Also related to OAR 333-333-5250, OHA received comments concerning the need for facilitators to contact an emergency contact person if a client leaves their administration session prior to the minimum duration window. Contacting an emergency contact person in a non-emergent situation is a potential stress for the client and their emergency contact, and adds an unnecessary burden of paperwork for facilitators, clients, and for the state.

**Agency response:**

The referenced amendments to OAR 333-333-5250(1) and (6) have been removed.

- OHA received comments stating that mandatory reporting of sexual orientation and gender identity for psilocybin licensees and applicants is invasive and inappropriate, and this highly sensitive and personal information should not be required as a condition of receiving a professional license. It was suggested that the rule should be amended to allow for an answer such as “decline to answer” or be eliminated.

**Agency response:**

ORS 475A.374 requires collection of sexual orientation and gender identity information from licensees and applicants. OPS will address the concerns raised in comments through implementation by providing an option to decline to answer individual questions. The questions themselves are not included in rule. This information will be collected through OPS Training program, Licensing and Compliance (TLC) system.

- OHA received comments regarding OAR 333-333-5100 and changes to recordkeeping and storage of client records. The requirement to transfer client files conflicts with professional licensure standards for facilitators who are dual licensed and required to keep records for a certain period of time. When a client doesn't know which service center they are going to work with and doesn't decide within the 48-hour requirement for records to be transferred

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after they are created, the requirement to transfer client records to a service center that the client may not even work with is an undue time and financial burden to service centers to support paperwork for clients who never materialize. There is also an increased risk of potential Health Insurance Portability and Accountability Act (HIPAA) violations each time a file is transferred, and there is no way to promise clients that their confidential information would be secure. It was also questioned how the client records will be transferred from one service center to another once the client chooses a service center and who is responsible for that transfer.

**Agency response:**

Previously adopted rules already require all client records to be stored at a licensed service center. The 2024 amendments clarify this requirement and are designed to preserve confidentiality of client records by ensuring that those records are only stored at licensed locations. Because HIPAA does not apply, OPS must create its own standards for client confidentiality. Existing rules address client consent for transfer of records from one service center to another.

In response to comments, OPS revised the rules to ensure that clients are notified of the locations where their records are stored and increased the time frame for transferring records to service centers from 48 hours to 15 calendar days.

- OHA received comments requesting that OAR 333-333-3070 be expanded to allow out of state training programs to do practicum at Oregon licensed service centers. It was requested that the rule be amended to allow students enrolled in out-of-state approved training programs to observe administration sessions at a service center functioning as a practicum site.

OHA also received comments questioning the delay of implementation in OAR 333-333-3070, requiring that after January 1, 2027, all practicum must take place at a practicum site and alternative practicum will no longer be allowed. It was questioned why changes are delayed until 2027 and not effective July 1, 2025, or January 1, 2026. The delay in implementation allows for training to occur outside of the regulated framework with no guardrails to follow the

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Oregon process that should be experienced by the student facilitators and takes away business from Oregon licensed service centers.

**Agency response:**

OAR 333-333-3070 has been revised to allow out of state training programs to conduct practicum at Oregon service centers. The operational date for OAR 333-333-3070 has been changed to January 1, 2026.

- OHA received comments regarding OAR 333-333-4470 stating that the requirement for a service center that functions as a practicum site to notify OHA at least 10 business days prior to practicum taking place at their location is burdensome, particularly if they need to do it for each practicum. It was requested that a blanket notification be allowed.

**Agency response:**

OAR 333-333-4470 has been revised to clarify that a blanket notification may satisfy the rule requirement.

- OHA received comments regarding OAR 333-333-5070 and suggested that the language allowing for a facilitator to request that a client support person acting as an observer leave the administration area at any time be stronger. As written, “Facilitators *may request...*” allows for the client support person to say “no” and not leave. The language needs to be written in a way that gives authority to the facilitator to direct the client support person to leave an administration session.

**Agency response:**

The quoted rule language should be read in conjunction with preceding sentence which reads “...client support persons must comply with the facilitator’s reasonable directions during an administration session.” Observers are subject to the same rules as all other client support persons and must comply with facilitator’s directions, including directions to leave the administration session.

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- OHA received comments regarding the minimum session duration and transportation plan requirement for subperceptual, microdose (consumption of less than 2.5 mg of psilocybin analyte) administration sessions. It was suggested that the first subperceptual psilocybin administration session have a minimum stay of no more than 30 minutes, and subsequent sessions should not have a time requirement as long as the client signs a waiver affirming they are not impaired by the psilocybin dose. Facilitators should retain the ability to extend the required stay time if they have reason to believe a client is unfit to leave.

It was also requested that the transportation plan requirement for all subperceptual sessions (consumption of less than 2.5 mg of psilocybin analyte) be removed. Given the very low doses involved, clients should be allowed to drive themselves after signing a waiver stating they are not impaired. This would make services more accessible.

**Agency response:**

Adopted rules have been revised to shorten the duration of low dose administration sessions to 30 minutes for the first session and 15 minutes for subsequent sessions. Rules requiring transportation plans have not been amended because a transportation plan is necessary to protect public health and safety regardless of the dose consumed. This decision is supported by HB 2316, which was adopted in 2023 and adds psilocybin to the list of intoxicants identified in Oregon law prohibiting driving under the influence of intoxicants.

- OHA received comments requesting a change to the definition of “post-session reaction” to include that a visit to the emergency room or care from a medical provider that occurred within 72 hours of a client’s release from an administration session should only be reported to the OHA if emergency services or the medical care provider indicated the subject reaction was likely related to psilocybin consumption.

**Agency response:**

The definition of “post-session reaction” has been revised to include only those reactions that are likely related to psilocybin consumption.

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- OHA received comments that OAR 333-333-4810 regarding non-identifiable data conflicts with SB 303 implementation. As written, section (5) would require that licensees use the prescribed OHA disclosure form during or prior to a preparation session in order for the facilitator or service center to utilize a representative, designee, or vendor to perform the task of compiling, aggregating, and computing SB 303 data. Without the ability to utilize a designee or vendor, licensees run the risk of falling out of compliance, and/or passing the administrative burden of SB 303 data aggregation onto clients in the form of increased services fees, which would impact equitable access to services. It was recommended that section (5) be deleted along with the associated de-identified data disclosure form.

**Agency response:**

OAR 333-333-4900 has been revised to clarify that service centers may enter into agreements with individuals and organizations to act as licensee representatives for the purpose of collecting, reporting, storing, maintaining, and destroying 303 client data.

- OHA received comments concerning the amendment to OAR 333-333-4200 that would require a licensee to submit a new application including all required forms, documents, and license fee if the licensee no longer qualifies for a reduced fee. The revision effectively penalizes licensees who qualified for reduced license fees for improving their economic conditions and would require them to pay 1.5x the fee that a non-reduced fee licensee pays for a single annual license.

**Agency response:**

These proposed revisions to OAR 333-333-4200 have been removed.

- OHA received comments about the proposed amendment to OAR 333-333-4810 that exempts a facilitator from the requirement to obtain a completed and signed client consent form to disclose identifiable information about a client. It was questioned “how can a facilitator obtain consent to disclose a client’s personally identifiable information without a consent form?” A facilitator may

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need to share information identifying a client for many reasons. A facilitator must be free to share identifying client information with client consent, without first having a service center collect a client consent form.

**Agency response:**

The comment is referring to a correction of a drafting error rather than an exemption. The reference to facilitators in OAR 333-333-4810(2) was removed because client records are required to be stored at a service center. Service centers, rather than facilitators, are custodians of client records and are therefore the appropriate party to obtain client consent to release records.

- OHA received comments regarding proposed changes to OAR 333-333-5040 that would require service centers to notify clients of the status of their records when a service center closes. “Closes” is not defined, so it is not possible for a service center to know when it must notify a client of the status of their record. A service center may serve thousands of clients over the life of the business, and notifying every client whose records the service center stores would be onerous. It was requested that line 32 of the Informed Consent document described in OAR 333-333-5040 be amended to remove the requirement that clients will receive notice of the status of their records if a service center closes.

**Agency response:**

The proposed revision to OAR 333-333-5040 has been removed.

- OHA received comments regarding the addition of “culturally and linguistically responsive services” throughout the proposed rule text. Codifying the accommodation of diverse cultural and linguistic preferences of clients as a specific obligation to offer a non-specific, vague, and highly subjective set of services increases confusion and adds another layer of regulatory obligations that would be difficult to meet for every client. Without any specific guardrails for what constitutes sufficient “culturally and linguistically responsive services,” a licensee cannot reliably comply with any of the rules that have added that language.

**Agency response:**

These comments misunderstand rule requirements related to culturally and linguistically responsive services. 2024 rules define “culturally and linguistically responsive services” and require facilitators to inquire whether clients request such services. The rules also require documentation of requests if applicable. The rules do not require service centers and facilitators to offer any culturally or linguistically responsive services. Instead, the rules require information to be shared with clients and client requests to be documented. Although no such services are required to be offered, the rule is intended to encourage discussion and aid clients in selecting facilitators and service centers that are appropriate and safe for each client’s individual needs.

- OHA received comments regarding OAR 333-333-5200 and the requirement that service centers must provide notice to clients participating in an administration session the names of the licensee representatives who may be present at the service center while their administration session takes place. Requiring notification of the names of individuals who the client is unlikely to encounter during an administration session seems unnecessary.

**Agency response:**

The proposed revision to OAR 333-333-5200 has been removed.

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