

DATE: December 13, 2023

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:** November 15, 2023, November 16, 2023, and November 17, 2023, 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 adoption and 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”) and are related to technical fixes, training, and data collection and reporting.

Oregon Psilocybin Services (OPS) identified technical fixes to clarify and amend rules adopted in 2022 that address a variety of subject matter including requirements for licensure such as storage and security, standards for manufacturing psilocybin products, packaging and labeling, safety standards and guidelines for provision of psilocybin services, client rights and informed consent processes, facilitator duties, compliance, product tracking, and transportation. The technical fix rules address all aspects of implementation and support the Act’s goals of promoting access and equity while protecting health and safety. These technical fixes will provide increased clarity and efficiency of operations for both licensees and OPS.

The training rules are needed to clarify curriculum approval requirements for psilocybin training programs. Under ORS 475A, licensed facilitators must complete training at a program whose curriculum has been approved by OHA. The Higher Education Coordinating Commission (HECC) independently requires all training programs in Oregon to hold a license or qualify for

an exemption regardless of the type of training the program provides. The training rules amend existing psilocybin rules to align with state law by clarifying that psilocybin training programs must hold a license from the HECC to maintain curriculum approval by OHA.

The data collection and reporting rules are needed to implement Senate Bill 303, which requires licensed psilocybin service centers to collect certain data and report aggregated data to OHA on a quarterly basis, and allows clients to request that their data is not submitted to OHA. The data collection and reporting rules amend existing definitions and other rule sections and adopt standards for collection and maintenance of data and reporting of data. Further rules to implement SB 303 may be considered in 2024.

**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 November 15, 2023, November 16, 2023, and November 17, 2023. OHA received oral testimony from 22 individuals at the public hearings (some individuals testified at both hearings) and received many written public comments. OHA staff have considered the written comments and public testimony received prior to the deadline on November 21, 2023, 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.

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

<https://www.oregon.gov/oha/PH/RULESREGULATIONS/Pages/index.aspx>.

- OHA received 167 emails containing the same letter, which urged the Oregon Health Authority "to require the reporting of service center averages and information on adverse events for all Oregon Psilocybin Services clients." Additional written comments also addressed the need for the rules to align with the legislative intent and plain language of SB 303 (2023) to allow client opt outs to be limited to information provided by the client, and the need to amend the rules such that "all Service Centers are required to report the total number of psilocybin administration sessions held and clients served" and "the total number of safety events." Additional written comments state that "mandatory aggregate reporting on service averages and adverse events for all clients is critical to the understanding and improving program safety and should be required as part of SB 303."

OHA also received comments requesting that the ability for clients to completely/fully opt-out of any data aggregation and reporting be retained in rule and that "the legislative

history of SB 303 requires a full opt-out option.” Comments also requested that “clients’ ability to opt out of 303 data aggregation and reporting is extremely clear to clients and understood by them” and that “clients know they can decline to answer any 303-related question,” explicitly stated in consent forms related to 303. Comments also call for “service centers to promptly dispose of 303 data collected from clients who opt out.”

**Agency response:**

The adopted rules have been revised to differentiate between information collected directly from clients and information compiled by service centers. By doing so, OPS maintains our commitment to confidentiality while implementing the legislation in a manner that addresses the concerns raised during the public comment period. The adopted rules continue to protect client confidentiality by ensuring that data is properly stored and aggregated. The data collection and reporting requirements are not operational until 2025. These preliminary rules are needed to allow OPS to begin work on building program infrastructure for data collection and reporting. Further rules to implement SB 303 will be considered in 2024. OPS will also develop forms and systems used to collect and report data in 2024.

- OHA received comments regarding the requirement for psilocybin training programs to hold a license from the Higher Education Coordinating Commission (HECC). Comments request that “the ability for programs to have an exemption from HECC licensing” be retained, stating that “programs that are spiritually oriented, creative or secular need the autonomy to create curricula that meets minimum state guidelines but still aligns with their philosophy.”

**Agency response:**

These comments are not directly related to the proposed rule amendments. The amended curriculum approval rules for psilocybin training programs do not create new requirements for psilocybin training programs. Instead, they clarify that existing requirements for HECC licensure apply to psilocybin training programs and are necessary to maintain OPS curriculum approval. OPS does not have authority to grant exceptions to HECC licensure and is unable to address these comments via rulemaking.

- OHA received comments regarding the expansion of a non-directive facilitation approach to the preparation and integration sessions, and concern that the non-directive approach requirement should be limited to the administration session only. Recommendations were made to “change the definition of non-directive to better fit with commonly understood definitions and avoid unnecessarily restricting facilitators’ practice.”

**Agency response:**

OPS has revised the definition of non-directive facilitation to provide more clarity to facilitators. Extending non-directive facilitation to preparation and integration sessions is consistent with language in ORS 475A and Oregon Psilocybin Advisory Board recommendations, which both address psilocybin services. Psilocybin services are defined to include preparation, administration and integration sessions.

- OHA received comments requesting that the rules on dosage be amended “to require that both psilocybin and psilocin potency be calculated together as ‘total psilocybin equivalent.’” Request to also amend the rules “to require manufacturers to label all psilocybin products with psilocybin weight, psilocin weight, and ‘approximate total psilocybin equivalent’ weight, and require that service centers only sell psilocybin products so labeled.”

**Agency response:**

OPS rules on psilocybin content and labeling are based on recommendations from the Oregon Psilocybin Advisory Board and public input received during 2022 rulemaking. After careful consideration and review of differing perspectives, OPS adopted rules that use psilocybin rather than psilocin because OPS believes that this value provides the most accurate predictor of client experience. Under the adopted rules, manufacturers may choose to list values for psilocin and total available psilocin on product labels, as well as other compounds, but they are not required to do so. OPS may consider this issue again in 2024 as more information becomes available.

- OHA received comments requesting that clients have the right to record preparation and integration sessions if they wish to do so, in addition to administration sessions currently allowed in rule. Comments also recommended that “rules governing electronic records made by service centers from psilocybin therapy sessions must explicitly state that clients are to be given these records from their own sessions upon request.”

**Agency response:**

The rules allow recording of preparation and integration sessions but prohibit a client from using their own equipment and require the recordings to remain at the service center unless every party recorded consents to their release. This rule is designed to protect the privacy of all parties, including facilitators and other clients who may be present during a group administration session. Allowing individual clients to record administration sessions using their own equipment and retain those recording without the consent of all parties is inconsistent with this objective. The adopted rules are necessary to protect confidentiality of all individuals who have been recorded while receiving, providing or assisting with psilocybin services.

- OHA received comments requesting that clients be able to “bring family or friends with them for personal and emotional support during preparation and integration sessions” and that prohibiting this “robs clients of self-determination and may reduce a client’s ability to integrate healing into family support systems later on.”

**Agency response:**

Under ORS 475A, integration sessions are an optional component of psilocybin services and are conducted by a licensed facilitator. In addition to regulated integration sessions, individuals have a number of options to integrate their psilocybin experience that are not subject to the amended rules, including community circles and consultation with therapists and other professionals who are not acting as licensed facilitators. Clients who would like to have a broader integration experience can access these opportunities. The rules limiting preparation and integration sessions to clients, facilitators and client support persons are appropriate to support requirements related to facilitator scope of practice and client confidentiality.

- OHA received comments requesting that testing labs be allowed “to continue to test products as stated in the initial rules, instead of restricting what they can test,” prohibiting them from testing psilocybin products outside of this program. This would “support the broader harm-reduction movement.”

**Agency response:**

The quoted text is not an accurate representation of the requirements found in initial rules and ORS 475A. Licensed psilocybin laboratories have never been able to test psilocybin products from unlicensed sources. Specifically, OAR 333-333-4400(7) states that “A licensed premises may receive psilocybin products only from other licensed premises as allowed by these rules.” ORS 475A.410 states that “... the authority may immediately restrict, suspend or refuse to renew a license issued under ORS 475A.210 to 475A.722 if circumstances create probable cause for the authority to conclude that a licensee has purchased or received a psilocybin product from an unlicensed source ...” OPS has not adopted rules that allow licensed laboratories to receive and test products from unlicensed sources because doing so is not be consistent with provisions cited above.

- OHA received comments requesting that the requirement for service centers to notify clients every time they update their records be removed, as it is “burdensome and unnecessary as clients can request their updated records at any time.”

**Agency response:**

This requirement has been removed in the adopted rules.

- OHA received comments that the new reporting requirements for service centers to advise OHA of any temporary uses of licensed premises are “burdensome.” Comments recommend that the requirements be simplified for repeated or recurring temporary uses.

**Agency response:**

OPS has revised the adopted rules to clarify that service centers may include multiple temporary uses on a single written notice.

- OHA received comments requesting that “vegetable glycerin” be removed from the list of solvents used in extraction processes in OAR 333-333-2060, Psilocybin Extract Manufacturing Requirements, as “this was included based on erroneous information and is not an industry standard.”

**Agency response:**

While this solvent may not be an industry standard, OPS has not received any information that would indicate that the use of vegetable glycerin presents a safety risk or is otherwise inappropriate for psilocybin extraction. OPS may revisit the issue of allowable solvents for psilocybin extraction as more information becomes available.

- OHA received comments regarding OAR 333-333-7030, Speciation Testing, requesting “to decrease speciation testing frequency to initial phases during the establishment of novel genetics among manufacturers to balance accessibility and affordability with consumer safety.” It was also suggested to add “randomized audits of harvest lots for speciation tests to pair accountability with decreased testing frequency.”

**Agency response:**

The rules on speciation testing are designed to ensure compliance with the requirement that manufacturers only cultivate the fungi species *psilocybe cubensis*. OPS rules on allowable fungi species were adopted based on recommendations from the Oregon Psilocybin Advisory Board after robust discussions in the Products Subcommittee throughout the development phase. OPS may revisit frequency of speciation testing as more information becomes available.

- OHA received comments regarding 303 data, requesting that the rules “prohibit anyone from monetizing client records and 303 data.” It was further recommended that “OHA should utilize the rulemaking authority provided to it under SB 303 Section 2(7) to adopt rules that include a clarification that OHSU, its research and commercial partners, and anyone else who receives client or 303 data, are also prohibited from ‘otherwise monetizing’ client or 303 data.”

Also related to 303 data, comments request to “democratize access to 303 data” and suggest that “OHA could post the same aggregated, de-identified, 303 data that it shares with OHSU on the OHA website so that researchers, journalists, and other public interest groups may participate in the evaluation of the psilocybin services program.”

**Agency response:**

OPS does not have authority to regulate conduct outside of OPS licensed premises and those individuals we license. Therefore, the section cannot adopt rules related to OHSU or other parties’ monetization of data. The comments regarding posting data on an OHA website are related to operations rather than rulemaking. SB 303 reporting requirements are not effective until 2025 and OPS will be developing operational aspects of our implementation throughout 2024.

- OHA received comments about buffers in relation to service centers, stating that “there should be clear direction on whether a buffer should be included between public use areas such as parks, campgrounds, malls and a PSC. A similar buffer area as that from schools should apply to family friendly facilities.”

**Agency response:**

The required buffers for schools are found in ORS 475A. It is unclear whether OPS has authority to require buffers for other facilities. In any case, the comment does not articulate a safety risk that would support requiring a buffer between psilocybin service centers and facilities such as parks, campgrounds and malls.

- OHA received comments requesting that the definition of adverse medical events and adverse behavioral events be narrowed “to require that it apply only to cases where medical treatment is provided.” “Narrowing the definitions of medical and behavior adverse events will allow facilitators to seek medical opinions knowing that contact alone will not require reporting.”

**Agency response:**

OPS amended these definitions to include only those events that required care from a medical care provider or transport to a hospital.

- OHA received comments requesting rules “to enforce the existing prohibition on licensee advertising of Oregon psilocybin services as health or medical treatments.” Current rules prohibit licensees from making false medical claims, but there is “little or no intent to enforce this prohibition.”

**Agency response:**

This comment speaks to operations rather than rulemaking. Existing rules on advertising prohibit the use of unsubstantiated health claims and existing rules on administrative violations provide a mechanism for enforcing advertising restrictions.

- OHA received comments regarding the requirement for client forms to be stored at a service center. For a facilitation services company where facilitators use a local service center for their client administration sessions, facilitators “must maintain access to our client records on our HIPAA compliant, secure server in order to properly work with our clients for intake, preparation, and integration sessions” at offices that are not located at a service center. Under the proposed rules, when meeting with clients at their office they would not be able to have client records in front of them. “Facilitation services companies should be considered an appropriate entity to maintain and store the records of clients who come directly to them for services and only incidentally use a service center for administration sessions.”

**Agency response:**

OPS understands that this requirement could create additional administrative burden for facilitators, but requiring records to be stored at a licensed premises rather than an unlicensed location is appropriate to protect and maintain client confidentiality. Facilitator licenses are held by individuals and are not associated with a licensed premises. OPS lacks authority to adopt rules that apply to unlicensed locations and, therefore, does not have the ability to adequately safeguard client confidentiality for records that are stored at unlicensed locations.