

November 22, 2024

To Members of the Public,

Oregon Psilocybin Services (OPS) is pleased to present a final copy of the 2024 amended and adopted rules necessary to implement the Oregon Psilocybin Services Act: [Oregon Administrative Rules \(OAR\) Chapter 333, Division 333: Psilocybin](#).

OPS considered diverse perspectives throughout the rulemaking process while prioritizing equity, public health and safety, and working within statutory authority under the Oregon Psilocybin Services Act. In this letter, we share some of the frequent themes identified during rule making and how they have been addressed in the final 2024 rules.

OPS received sixty-eight written comments and held several public hearings during the October 2024 public comment period. These comments helped to further refine and revise the proposed rules, which have now been adopted as final and will become effective on January 1, 2025.

### **Rulemaking Process**

OPS conducts rulemaking transparently and with ample opportunities for public input. OPS met, and exceeded, administrative requirements for public noticing and public comment on proposed rules.

- In addition to receiving recommendations from the Oregon Psilocybin Advisory Board (OPAB) in accordance with ORS 475A, OPS holds annual public listening sessions to offer opportunities for members of

the public to share feedback. Three public listening sessions were scheduled this year, offering opportunities to participate at various times of the day, including morning, afternoon, and evening hours. Spanish and American Sign Language (ASL) interpretation and CART captioning are provided during these three listening sessions.

- After receiving OPAB recommendations and feedback from public listening sessions, OPS published the first draft of proposed rules on the [Administrative Rules and Rulemaking Process page](#) on the OPS website and sent a message to the OPS Distribution List, which includes over 13,100 subscribers.
- OPS began the Rules Advisory Committee (RAC) process by inviting members of the public to apply for RACs by sending messages through the OPS Distribution List, publishing information on the OPS website, and sharing information during OPAB meetings, Monthly Licensee Lunch Forum meetings, and in OPS Quarterly Newsletters.
- OPS scheduled multiple RACs to discuss different sections of proposed rules, the fiscal impact statement, and the equity impact statement. Multiple RACs offered additional opportunities for OPS to receive diverse perspectives. OPS posted all proposed rule drafts on the Administrative Rules and Rulemaking Process page on the OPS website. The 2024 RAC included over thirty volunteers representing a broad range of professional and lived experiences. RAC members joined OPS for twenty hours of in-depth discussion on the 2024 proposed rules.
- After RACS concluded, OPS revised draft proposed rules and published on the OPS website in preparation for the 21-day public comment period. During the 21-day public comment period, which is advertised through the OPS Distribution List and published on the OPS website, OPS hosted a series of three public hearings on rules. By offering multiple public hearings on proposed rules, OPS creates more opportunities for members of the public to participate at various

times of the day, including morning, afternoon, and evening hours. Spanish and American Sign Language (ASL) interpretation and CART captioning are provided during these three listening sessions.

- After the public comment period concluded, OPS considered all feedback and finalized administrative rules, submitting them to the Oregon Secretary of State for adoption.

### **Final Rule Changes**

OPS rules set minimum standards designed to protect public health and safety. The rules are a floor, not a ceiling, and offer flexibility for varied operational models. While recommendations made by the RAC members during the rulemaking process are important, Oregon Health Authority has authority to adopt rules that may differ from recommendations. Some rule changes occurred due to changes in statute. For example, the current licensing requirement for proof of Oregon residency will expire on January 1, 2025. The 2024 rules have been amended to make this change, which opens access to individual licensees and organizations from outside the state.

Preliminary rule drafts shared with the RACs contained a proposal to remove the transportation plan requirement for low dose administration sessions. However, that proposed language was not included in the adopted rules. OPS removed the proposed changes 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. Low dose administration sessions are not described in ORS 475A; however, OPS has made efforts to accommodate these sessions in administrative rules that are consistent with statute. The adopted 2024 rules shorten the minimum duration of these sessions to 30 minutes for the first session and 15 minutes for subsequent sessions to create access.

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.

The proposed rules contained provisions that expanded the requirement for licensees to report rule violations to OPS. During the public comment period, OPS received negative feedback in response to this provision with many commentors expressing that it was unrealistic and unfair to require the reporting of minor administrative violations. The adopted rule has been narrowed to focus on violations involving clients, products, and licensee conduct. A separate rule creates a duty for facilitators to place clients' interest above their own. The reporting requirement is consistent with this provision and supports a client centered experience that mitigates risks to client and public safety.

OPS adopted rules clarify requirements related to cooperation with investigations and retaliation against individuals who file complaints. Like other state agencies, OPS investigations and compliance actions are subject to the Administrative Procedures Act (APA), and licensees receive due process in accordance with these requirements. The 2024 rules clarify responsibility to cooperate with investigations, which is consistent with both the APA and practices employed by other state agencies. The provisions on retaliation supplement existing provisions in employment law and include facilitators and other individuals who may not be employees of a licensee.

Changes affecting facilitators include removal of the backup facilitator requirement, requirements for continuing education, and allowing observers to serve as Client Support Persons during administration sessions at the client's request. In response to issues raised by rural small businesses, the 2024 rules eliminate the requirement for an on-call backup facilitator. In

addition, the rules now allow clients an option to request a client support person over 21 years of age to attend their administration session as an observer. Service centers and facilitators may choose to decline this request. Finally, the rules now require facilitators to complete four hours of continuing facilitator education each year to maintain licensure. Continuing facilitator education must consist of skills and knowledge that are relevant to the core curriculum and may be provided by approved training programs or other organizations that have been approved to offer continuing education for other types of professional licenses or certifications.

The 2024 rules made several changes affecting training programs. The term for training program approvals has been changed from five years to one year. Training programs will now need to apply for annual curriculum approval. This requirement aligns with requirements for training programs subject to regulation by the Higher Education Coordinating Commission. Licensed facilitators must begin reporting continuing education hours on January 1, 2026, and training programs may begin to offer continuing facilitator education in 2025. Also beginning January 1, 2026, all practicums must take place at a licensed service center in Oregon. In addition, rules expand the minimum training hours in the core curriculum requirements to include an increase of 8 additional hours devoted to pharmacology, neuroscience, and clinical research. Based on input received, OPS has expanded practicum rules to allow licensed service centers in Oregon to function as practicum sites not only for training programs approved in Oregon, but for any training program authorized to provide psilocybin training in the United States.

Beginning January 1, 2025, every client who will participate in an administration session is required to complete a 303 Client Data Form as required by Senate Bill 303, adopted in 2023 and now codified as ORS 475A.372 and ORS 475A.374. While the 303 Client Data Form was not a part of the official rule making, RAC members provided helpful feedback on a draft prior to it being finalized. The form was not included in rule to allow

for necessary updates, such as any updates made to the standardized race, ethnicity, language, or disability (REALD) and sexual orientation or gender identity (SOGI) questions developed through a separate process led by the Oregon Health Authority Equity and Inclusion Division. The rules also address requirements for collecting applicant and licensee data as required by statute. OPS will implement these rules by requiring applicants and licensees to submit data via TLC. Every applicant and licensee are required to complete a submission in accordance with statutory requirements.

Licensed service centers will submit required 303 data in the TLC system. In July 2024, OPS sent a [Letter to Service Centers about Preparing for SB 303 Implementation](#), and OPS recently provided a 303 Data Reporting Guide for Service Centers. In response to feedback, OPS adjusted rules on required reporting of adverse events. Adopted rules include an amended definition of adverse events and create a new definition for post-session reactions related to a client's consumption of psilocybin that occur within 72 hours of an administration session.

OPS made clarifications to rules specifying requirements for storage and transfer of client records. Existing rules already required all client records to be stored at a licensed service center. Amended 2024 rules specify time frames for transferring client records to service centers. In response to comments, the adopted rules were revised to allow for records to be transferred within 15 calendar days and require notice to clients of where the records are transferred. OPS understands that requiring client records to be stored at a service center may create additional administrative burden, but this requirement is appropriate to protect and maintain client confidentiality. During the public comment period OPS also received comments expressing frustration that service centers are not able to share the total number of clients they have served. Similar comments had been made during RAC meetings, and the drafts for public comment had already addressed this issue by amending OAR 333-333-4810 to allow for

disclosure of aggregate number of clients served. OPS realizes that the larger issue of records and client confidentiality may benefit from further refinement and looks forward to engaging with community on this issue in 2025.

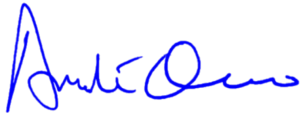
Some commentors expressed concern that cost of regulation has led licensed service centers to go out of business. The cost of compliance is required by law and only one factor that contributes to the overall cost of operating a business. OPS strives to balance administrative flexibility with the statutory requirement in ORS 475A to protect public health and safety and has no control over business decisions that may affect viability of licensed businesses.

OPS made several technical changes and deletions to the rule drafts in response to public comment. These changes included clarifying the notice requirement for practicum and reconciling supportive touch requirements with sections on client support persons. Based on public input, the adopted rules also remove proposed revisions to rules on minimum duration for secondary doses, notice to emergency contacts, and notice of licensee representatives who may be present at a service center and other sections.

More information about the rulemaking process, including recordings of public hearings, can be found on the [OPS Administrative Rules webpage](#). OPS expects to hold public listening sessions each summer and open administrative rules for public comment during the fall of each year. To receive updates about rulemaking in 2024, please sign up for the [OPS distribution list](#).

We would like to thank all the community members who participated in our 2024 public hearings and public listening sessions, and the members of the Rules Advisory Committees and the Oregon Psilocybin Advisory Board and subcommittees for volunteering their time.

Sincerely,



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