



PUBLIC HEALTH DIVISION
Center for Health Protection

Kate Brown, Governor

Oregon
Health
Authority

800 NE Oregon Street, Suite 640
Portland, OR 97232
Voice 971-673-0490
FAX 971-673-0553

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To Members of the Public,

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

These rules would not be as thoughtful or complete without the engagement of so many people, communities, and organizations that care about this work. We want to thank members of the Oregon Psilocybin Advisory Board and its five subcommittees who worked tirelessly during the development period to make recommendations that would set the foundation for draft rules. We also want to thank the Rules Advisory Committee members for your important discussions on draft rules that highlighted additional issues for consideration and further refinement. We want to thank everyone who shared written comments during the Public Comment Period or shared feedback during the Public Hearings, as well as those who shared their thoughts and ideas during public listening sessions, in meetings, and in community circles. We are deeply grateful for your collaboration in this process.

OPS received over 200 written comments and six hours of comments shared in the public hearings during the November 2022 public comment period. These comments helped to further refine and improve the rules, which have now been adopted as final. The final rules are a starting place for the nation's first regulatory framework for psilocybin services, and we will continue to evaluate and evolve this work as we move into the future.

OPS weighed competing priorities and viewpoints received throughout the rulemaking process while considering equity, public health and safety, and statutory authority under the Oregon Psilocybin Services Act. In this letter, we share some of the frequent themes identified during the public comment period and how they have been addressed in the final rules. Please keep in mind that this letter does not include all revisions.

Equity and Access

Many members of the public expressed support for a subperceptual or a “micro-dose” option that would allow clients the opportunity to consume small doses of psilocybin. The final rules on duration of administrative sessions have been revised to create a new tier for subperceptual doses. These doses are defined as products containing less than 2.5 mg of psilocybin analyte. After a client’s initial session, the minimum duration for a subperceptual dose of 2.5 mg of psilocybin analyte or less is 30 minutes. Other rules and requirements designed to support client safety remain unchanged for clients consuming subperceptual doses. OPS has made this change in the hope that subperceptual doses will increase access, equity, and affordability while ensuring public safety.

Some people expressed concern about the feasibility of service centers providing materials in languages other than English. The final rules state that service centers must provide translated materials upon client request. OPS will make forms that have been required in rules available in both English and Spanish. Because of our commitment to equity, we have provided interpretation services in Spanish and American Sign Language (ASL), as well as CART captioning for accessibility, for public listening sessions, public hearings for rules, and other public events such as the 2022 Fall Business Forum. Because equity and access are foundational to this work and to client safety, licensees should be responsible for ensuring that clients are able to access documents and services in their preferred language. This requirement both increases access, centers equity, and promotes client safety.

All license applicants are required to submit a social equity plan as part of their application. The final rules allow facilitators who are employees of a service center to use the service center’s social equity plan for ease of alignment across the organization. OPS added “religion” to the definition of “cultural equity” and expanded the Client Bill of Rights to emphasize the importance of a client’s right to receive competent and equitable care. The client’s right to choose their facilitator was also emphasized in the Informed Consent document language.

Public Health and Safety

OPS heard many concerns about client confidentiality and client data. OPS appreciates privacy concerns raised during the public comment period and has continued to uphold our commitment to client confidentiality. Several rule changes have been made to address the issue. The Agency has amended the definition of “de-identified” data to clarify that it means aggregate data. The Agency also made

technical changes to broaden protections for client confidentiality and clarify requirements for disclosure when facilitators and service centers intend to share de-identified data. Specifically, the revised disclosure form provides clients the ability to opt-out of sharing de-identified data.

We received recommendations for how to improve the Client Information Form to help facilitators identify and prevent health and safety risks. OPS included two additional questions that could result in a denial of services due to risks to clients health and safety. The rules proposed in November stated that a client may not receive psilocybin services if they have taken the prescription drug Lithium in the last 30 days. In addition to this condition, clients may not receive psilocybin services if they are having thoughts of causing harm, or wanting to cause harm to self or others, or if they have ever been diagnosed with active psychosis or treated for active psychosis. Clients may now inform facilitators whether they are pregnant or feeding with breastmilk and whether they would like to share anything about specific behaviors or internal or external stimuli (“triggers”) that could cause them to be uncomfortable during an administration session. OPS declined to make changes to the Client Information Form that are not yet supported by available data or would require licensed facilitators to act outside of their scope of practice.

OPS received various comments related to emergency planning and response. Based on these comments, OPS made changes in OAR 333-333-4700 (Duty to Contact Emergency Services) and OAR 333-333-5150 (Transportation Plans) to clarify that facilitators and services centers first take reasonable steps to mitigate safety issues before contacting emergency services. OPS also added to 333-333-5080 (Safety and Support Plans) that clients will be required to identify an emergency contact person that a facilitator or service center may contact in the event of a medical or other emergency. These changes support client safety while avoiding unnecessary encounters with emergency services.

Operational Flexibilities

In response to comments and to streamline processes, OPS removed section 333-333-5090 (Client Acknowledgement), which included an additional Client Acknowledgement document that was duplicative of other required documentation.

We received comments that requested additional flexibilities for how a licensed premises can be used. The final rules provide flexibility for the temporary use of facilities for activities that are unrelated to the licensed privileges.

The final rules include technical changes to clarify that required security video recordings can be stored using cloud storage and alarms are not required in outdoor areas.

Affordability

OPS received many comments regarding license fees. OPS is a fee-based structure which means that licensing fees must cover the costs of the section's work. OPS must work through the state agency process to establish fees that demonstrate budget sustainability and is expected to be entirely funded through fees.

The final rules include reduced license fees for applicants who are veterans, receiving social security income, receiving food stamp benefits, or are enrolled in the Oregon Health Plan. Creating a more complicated tiered license fee structure is not feasible due to the work required to identify appropriate tiers and evaluate license applications and supporting documentation. This work would require more staff capacity, which would result in higher license fees overall. As OPS receives fee revenue over the next biennium, OPS will share the budget balance of expenditures and revenues with the Oregon Psilocybin Advisory Board and continue to work with the board and community members to explore approaches to further balance licensure affordability and program sustainability.

Additional comments and responses can be found in the Hearing Officer Report. Many other technical changes were made to clarify the intent of the rules in response to feedback received during the public comment period.

As described in statute, we will begin accepting license applications on January 2, 2023. OPS will strive to support applicants in navigating license application requirements and will continue to provide technical assistance as we launch the nation's first regulatory and licensing framework for psilocybin services.

Thank you again for the time and energy you have dedicated to successful implementation of the Oregon Psilocybin Services Act. We appreciate you!

Sincerely,

André Ourso, Administrator, Center for Health Protection
Angie Allbee, Section Manager, Oregon Psilocybin Services