



June 16, 2023

Dear OPS Licensees,

Congratulations on recently receiving a psilocybin license!

This is an exciting time as we embark on the rollout of the nation's first regulated psilocybin services in Oregon. We understand that new licensees are focused on operational priorities, such as developing a thorough understanding of Oregon Psilocybin Services (OPS) rules and developing operational guidelines that align with these requirements. OPS has recently received concerns regarding client and product safety from some licensees, and we would like to take this opportunity to issue additional guidance to our regulated community.

Product Labeling

Every psilocybin product must be tested for potency before it can be transferred to licensed service centers and made available to clients. The Oregon Environmental Laboratory Accreditation Program (ORELAP), which is also part of OHA, is responsible for the accreditation of laboratories that intend to apply to OPS for licensure and sets standards for testing methodology. OPS is responsible for the overall licensing and regulation of manufacturer, laboratory, service center, and facilitator licensees pursuant to ORS 475A and OAR 333-333. OPS rules specify requirements for product labels, consumption limits, duration of administration session and client to facilitator ratios using potency test results. Although ORELAP rules require results to be reported for psilocybin analyte, psilocin analyte, and total potential psilocin, OPS rules only require use of psilocybin analyte measured in milligrams. OPS has offered guidance to laboratories and manufacturers that labeling requirements in OPS rules are minimum standards. Manufacturers may choose to include the full series of potency test results on their product labels, but they are not required to do so.

OPS rules reflect recommendations from the Oregon Psilocybin Advisory Board and were adopted after a thorough rule making process in 2022. The process for board recommendations for draft rules included 19 board meetings and 110 subcommittee meetings. The rulemaking process in 2022 included 12 hours of public listening sessions offered in English, Spanish, American Sign Language (ASL), and CART captioning; 6 Rules Advisory Committees (RACs) that consisted of 62 members, 13 meetings, and over 39 hours of discussion on draft rules; 2 public comment periods for rulemaking that totaled 44 days and hundreds of written comments; 5 public hearings on rules offered in English,

Spanish, American Sign Language (ASL), and CART Captioning for 10 hours of public testimony. After careful consideration and reviewing many differing perspectives throughout the rulemaking process, OHA adopted final administrative rules that use psilocybin analyte because this value provides the most accurate predictor of the effects clients may experience after consuming psilocybin products.

Consumption Limits

OPS rules on client consumption limits should be considered in the context of other administrative rules that support client safety. First, the required client informed consent document contains an acknowledgement that “the risks and benefits of consuming doses greater than 35 mg of psilocybin analyte are unknown.” One should also note that dose-dependent minimum durations for administration sessions are, in fact, minimums. After the specified minimum period elapses, OPS rules require facilitators to consult with clients and “determine whether the administration session should be concluded.” Licensed facilitators will rely on their training and expertise, in addition to input from clients, in making this determination. As with other aspects of client safety, the licensed facilitator plays a key role in ensuring clients consume appropriate doses of psilocybin. Facilitators are required to receive training on dosing strategies and considerations, in addition to other training designed to promote client safety. During preparation sessions, clients complete a client information form and safety and support plan designed to identify safety risks and measures to mitigate those risks. Under ORS 475A.370 facilitators may refuse to provide services for any reason. Therefore, facilitators are not required to provide services to a client who requests higher doses, and service centers can create operational guidelines that prohibit higher doses as well.

Safe Psilocybin Services

OPS rules support client safety in many ways, including rules on facilitator conduct, client safety and support planning, transportation planning, informed consent, client bill of rights, duty to contact emergency services and other requirements. One of the most important factors in ensuring client safety is the licensed facilitator’s interaction with clients, as well as understanding their own limitations as a licensed facilitator. Ensuring client safety begins with preparation sessions, before any products are consumed, and continues through administration sessions, through follow-up contact with clients within 72 hours of administration sessions, and through optional integration sessions. Trained and licensed facilitators work within their scope of practice and level of expertise to identify potential safety risks and support the client in determining appropriate dosage. OPS rules create a container to support client safety, but it is the responsibility of all licensees to ensure practices that support the safe provision of psilocybin services in Oregon.

OPS will investigate complaints, incidents, or concerns related to safety issues or statute and rule violations that occur on licensed premises and during the provision of psilocybin services. OPS hopes that licensees enter this new space with the intention of centering client safety, and service centers and facilitators roll out services cautiously. While OPS rules provide an important framework for client safety, the facilitator-client relationship and

service center operating guidelines will ultimately be the most important factor in ensuring safe and effective psilocybin experiences.

Best Practices

In developing best practices and operational guidelines for your practice, please remember that 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. If licensees choose to adopt practices that exceed the minimum requirements established in rule, they are welcome to do so.

We continue to learn as we move forward with implementation of the Oregon Psilocybin Services Act. We are challenged by being the nation's first regulated framework for psilocybin services and having limited access to research on natural psilocybin products. Receiving feedback from the regulated community and sharing this feedback with the Oregon Psilocybin Advisory Board is an important part of this process. Beginning in July, OPS will host a monthly series of forums for licensees to convene in a casual dialogue about what is working, what is challenging, and what improvements can be made as we move forward together. Your input is essential and may be reflected in technical revisions to rules in 2023 or more substantive rule revisions that will be considered in 2024.

Again, we thank you for your continued questions, feedback, and communication.

Sincerely,

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