



December 22, 2023

To Members of the Public,

Oregon Psilocybin Services (OPS) is pleased to present a final copy of the amended and adopted rules necessary to implement the Oregon Psilocybin Services Act: [Oregon Administrative Rules \(OAR\) Chapter 333, Division 333: Psilocybin](#). These rules address implementation of data collection and reporting required by Senate Bill 303, requirements for training program curriculum approval, and technical fixes to previously adopted rules.

OPS weighed many diverse 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 rule amendments.

OPS received over 200 written comments and over four hours of comments provided in public hearings during the November 2023 public comment period. These comments helped to further refine and improve the proposed revised rules, which have now been adopted as final.

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 share our gratitude for the Rules Advisory Committee (RAC) members, who convened for a total of nine hours of public meetings to discuss draft rules that highlighted opportunities for improvement and additional considerations. We share our gratitude for members of the public who provided written comments during the public comment period or feedback during the public hearings. Finally, we share our gratitude for those who provided suggestions during public listening sessions, in meetings, and in community circles. We are deeply grateful for your collaboration in this process.

## Data Collection and Reporting

OPS adopted data collection and reporting rules needed to implement [Senate Bill 303](#), Oregon Laws 2023, chapter 150. (SB 303). The rules amend existing definitions and adopt standards for collection, maintenance and reporting of data. The requirements of SB 303 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.

During the public comment period and rules advisory committee, OPS received extensive feedback on the nature of the client opt out provision contained in the legislation and the proposed rules to implement that provision. Some comments expressed support for the concept that all data related to clients' receipt of psilocybin services is subject to the client opt out provision found in SB 303. Other comments, including the majority of written comments, contended that the opt out provision only applies to demographic information collected directly from clients rather than aggregate data compiled by psilocybin service centers. These comments argued that aggregate data on receipt of psilocybin services, including number of administration sessions and number of adverse events, is essential to evaluating safety risks.

From its inception, OPS has been committed to maintaining client confidentiality. This commitment is demonstrated through existing rules that require clients to consent to the disclosure of personal information, regardless of whether it has been de-identified. This commitment does not override our duty to implement legislation. 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. OPS will develop forms and systems used to collect and report data in 2024. OPS recognizes that treating data collected pursuant to SB 303 differently from other data held by service centers may create an administrative burden for service centers. OPS will work to create forms and systems to help support service centers in effectively collecting SB 303 data and reduce administrative burden to the extent possible.

OPS also received comments regarding monetization of aggregated data shared with third parties. Specifically comments requested adoption of rules that would prohibit Oregon Health Sciences University from monetizing data. OPS does not have authority to regulate conduct outside of OPS licensed premises and those individuals we license.

### **Training Program Curriculum Approval**

OPS amended rules to clarify curriculum approval requirements for psilocybin facilitator training programs. Licensed psilocybin facilitators are required to complete training at a program whose curriculum has been approved by the Oregon Health Authority. Under Oregon law, the Higher Education Coordinating Commission (HECC) requires training programs that meet definitions of career training schools and degree granting programs to be licensed. OPS amended existing rules to align with Oregon law and HECC requirements by clarifying that psilocybin training programs must hold a license issued by HECC or qualify for an exemption from HECC to maintain OPS curriculum approval. During the public comment period, OPS received comments regarding the HECC exemption process and license requirements. However, these comments were 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.

### **Technical Fixes to Previously Adopted Rules**

OPS adopted rules in 2022 that established a first of its kind regulatory framework for production and sale of psilocybin products and provision of psilocybin services. In 2023, OPS identified the need for technical fixes based on the agency's guidance to licensees regarding interpretation of previously adopted rules. The amendments provide increased clarity and efficiency of operations for both licensees and OPS. They address all aspects of implementation and support the Oregon Psilocybin Services Act's goals of promoting access and equity while protecting health and safety.

OPS received a number of comments regarding these amendments. Some comments were supportive of the proposed amendment and others expressed concern. OPS did not consider comments that were outside of OPS' authority or that would require a change to statute. OPS may amend administrative rules but does not have the authority to amend law. The rules advisory committees and public comment process were instrumental in identifying ambiguous language in the proposed amendments and other opportunities to improve the drafting. This letter does not address all the changes made as a result of this input, but rather identifies several key issues. Examples include a revised definition of "nondirective facilitation" that provides additional clarity for psilocybin facilitators. The adopted rules were also revised based on comments regarding the timing for completing required client consent forms and were clarified to specify requirements for notice of temporary use of a licensed premises.

OPS did not revise proposed rule amendments based on comments that were contrary to statute or inconsistent with the section's policy objectives of promoting equity and protecting public safety. OPS also did not revise the rules for issues that require further research and discussion.

Some comments focused on product potency, testing and labeling of psilocybin products. Specifically, comments requested that psilocin content should be required on product labels and that rules for dosage and duration of client administration sessions be based on "total available psilocin," a value that is intended to represent both the psilocin and psilocybin content of a product. OPS rules on psilocybin content and labeling are based on recommendations from the Oregon Psilocybin Advisory Board and public input during 2022 rulemaking. After careful consideration and review of differing perspectives, OPS adopted rules that use psilocybin rather than psilocin because this value provides what OHS believes is 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. Similarly, OPS declined to modify rules on product adulterants to allow stabilizers because sufficient information is not available to indicate how these additives would affect the safety of psilocybin products. Finally, OPS declined to revise rules to allow for licensed laboratories to test psilocybin products from unlicensed sources because doing so would be inconsistent with provisions of the Oregon Psilocybin Services Act.

Other comments focused on operational requirements for licensed businesses. For example, some comments expressed concern that the rule amendments required client records created by facilitators to be stored at a licensed service center. OPS understands that this amendment 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. OPS also received comments regarding amendments that limit integration sessions to only clients, facilitators and other authorized persons. Under the Oregon Psilocybin Services Act, 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. For clients who chose to participate in integration sessions with a licensed facilitator subject to OPS regulation, the amendments are appropriate to support requirements related to facilitator scope of practice.

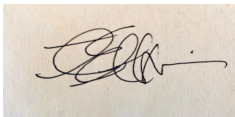
OPS received a number of comments that are not described in this letter. The 2023 rulemaking was designed to implement new legislation and clarify rules existing rules consistent with the section's guidance. A new guidance document, created in response to applicant and licensee questions related to rule compliance, will be published before the end of this year. OPS intends to update this document regularly and make any guidance offered to applicants and licensees available to all. OPS will examine changes to administrative rules in 2024 rulemaking that will be guided by additional recommendations from the Oregon Psilocybin Advisory Board. We would like to extend our gratitude to members of the Rules Advisory Committees (RACs) and individuals who participated in the public comment period for volunteering your time toward the successful implementation of the Oregon Psilocybin Services Act.

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](#).

Sincerely,



André Ourso, Administrator, Center for Health Protection



Angie Allbee, Section Manager, Oregon Psilocybin Services