



Date: November 1, 2023

TO: Interested Parties

FROM: Angie Allbee, Section Manager
Oregon Psilocybin Services

RE: Notice of proposed permanent rulemaking – OAR chapter 333, division 333, "Oregon Psilocybin Services"

The Oregon Health Authority, Public Health Division, Oregon Psilocybin Services (OPS) section is proposing to permanently amend administrative rules in chapter 333, division 333. 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.

OPS identified technical fixes to clarify and amend rules adopted in 2022. ORS 475A creates a first of its kind regulatory framework for licensed production of psilocybin products and sale of psilocybin products and services to clients. The Act required administrative rules to be adopted by January 1, 2023. The Oregon Health Authority (OHA) adopted rules in December 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. The rules are necessary to effectively implement the Act because they clarify the agency's guidance to licensees on interpretation of previously adopted rules. 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. OHA adopted rules in 2022 on curriculum requirements and approval process for psilocybin training programs. 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 rules adopted in

2022 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](#), Oregon Laws 2023, chapter 150. (SB 303). SB 303 requires licensed psilocybin service centers to collect certain data and report aggregated data to OHA on a quarterly basis. SB 303 also contains provisions that allow clients to request their data is not submitted to OHA. The data collection and reporting rules amend existing definitions and other rule sections to conform to SB 303 requirements. The rules also adopt standards for collection and maintenance of data and reporting of data. Further rules to implement SB 303 may be considered in 2024.

You are invited to review and comment on the proposed rules. If you wish to present oral comments on the proposed rules, three virtual public hearings are scheduled.

Virtual Public Hearings:

Wednesday, November 15th 6:00-7:30 p.m. PST

<https://www.zoomgov.com/j/1611251262>

Call in: 1-669-254-5252 (US)

Meeting ID: 161 125 1262

Passcode: 926366

If you plan to voice a comment at this hearing, please sign-up in advance at:

<https://forms.office.com/g/DrqkTeUBLc>

Thursday, November 16th 10:00 a.m.- 11:30 a.m. PST

<https://www.zoomgov.com/j/1604914840>

Call in: 1-669-254-5252 (US)

Meeting ID: 160 4914840

Passcode: 183416

If you plan to voice a comment at this hearing, please sign-up in advance at:

<https://forms.office.com/g/WjKLHA41C0>

Friday, November 17th 11:30 a.m. – 1:00 p.m. PST

<https://www.zoomgov.com/j/1614366556>

Call in: 1-669-254-5252 (US)

Meeting ID: 161 436 6556

Passcode: 355146

If you plan to voice a comment at this hearing, please sign-up in advance at:
<https://forms.office.com/g/9kCFj4y0ZQ>

Simultaneous interpretation in Spanish and American Sign Language (ASL) will be provided at the hearings, as well as live closed caption transcription. If you have any questions about accommodations or need any assistance to participate, please contact the Oregon Psilocybin Services team at 971-673-0322, 711 TTY or OHA.Psilocybin@odhsoha.oregon.gov and every effort will be made to respond to requests received in advance. Submitting your request as early as possible is greatly appreciated.

You may also file written comments before 5:00 p.m. PST on Tuesday, November 21, 2023, by submitting them to the Public Health Division Rules Coordinator by e-mail to: publichealth.rules@odhsoha.oregon.gov

Written comments may also be sent by regular mail to the mailing address below and must be postmarked by November 21, 2023:

OHA, Public Health Division
Administrative Rules Coordinator
800 NE Oregon Street, Suite 930
Portland, Oregon 97232

You may also send comments by fax to (971) 673-1299.

Final rules will be filed after consideration of all comments.

Please note that the [Notice of Proposed Rulemaking](#) lists an inaccurate number of psilocybin businesses in the 'cost of compliance' section. For the most current information on licensed psilocybin businesses and training programs, consult the [OPS Weekly Report on Applications for Licenses and Worker Permits](#).

For more details, please see the [full text of the proposed rules](#) and corresponding rulemaking documents at the following website:

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Administrative-Rules.aspx>

If you have any questions or would prefer a hardcopy be sent, please contact publichealth.rules@odhsoha.oregon.gov

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide information in alternate formats such as translations, large print, or braille. Contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsosha.oregon.gov.