

## Public comment: Draft rules for Oregon Psilocybin Services

From: Oregon Psilocybin Evaluation Nexus (OPEN)

OPEN Members:

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November 21, 2022

Thank you for this opportunity to provide public comments on OHA's draft rules for the Oregon Psilocybin Services Act. We submit these comments as the steering committee of OPEN - The Oregon Psilocybin Evaluation Nexus.

We are a group of colleagues from diverse disciplines and institutions that support the safe and equitable implementation of Measure 109. We are public servants, community therapists, and clinician scientists committed to public wellness. We have no financial conflicts of interest and remain steadfastly committed to avoiding commercial conflicts.

We aspire to develop an information collection system of the highest integrity, to evaluate and ultimately improve statewide psilocybin services. As of the date of this letter, we do not have any committed funding to support this aspirational project.

We respectfully submit the following comments regarding the draft rules:

**Rule 333-333-4520:** The OPEN collaboration strongly supports the Client Bill of Rights as written, particularly with regard to the right to privacy and confidentiality, and the right to refuse release of personal information to third parties *without impacting ability to receive services*.

**Rule 333-333-5000 (g):** OPEN advocates for collection of de-identified client characteristics essential for assessing equity of psilocybin services (e.g. client race/ethnicity, gender, and sexual orientation). In order to ensure Psilocybin Services are accessible for all Oregonians, we need to collect this demographic data to determine if anyone is being left out.

**Rule 333-333-5040 Informed Consent point #15:** The OPEN collaboration agrees with the spirit of this statement, which as we understand it, allows, but does not mandate reporting of de-identified data to improve services. We are concerned, however, that this rule could be used to advance commercial interests. We recommend retaining this statement in the final rules with the following suggested edits: "I understand that de-identified data collected by my facilitator or service center may be shared with people and institutions outside of the facilitator or psilocybin

service center for quality improvement, non-commercial research and other non-commercial purposes.” This would allow for collection of de-identified demographic information and core measures of best practices to support equity assessment and quality improvement efforts at the service center and program level while protecting client confidentiality and privacy. Clients should be made explicitly aware that they can opt-out of sharing their de-identified data by choosing “prefer not to answer” as a response to any/all items on forms and questionnaires. As we understand it, the Client Bill of Rights (Rule 333-333-4520) protects clients’ rights to opt-out of sharing their data, though an additional statement could be added to item 15 of the Informed Consent for added clarity (such as, “I understand I may opt-out of sharing my de-identified data by choosing not to answer any/all questions on data collection forms.”

**Rule 333-333-5040 Informed Consent point #16 (1):** The OPEN collaboration strongly supports the need for separate, written informed consent for release of any information that could potentially identify the client. OPEN adheres to internationally recognized standards for ethical research, including that clients have the right to provide or decline consent to participate in research that could potentially identify them. OPEN envisions that some subset of psilocybin services clients may be interested in contributing optional data to advance understanding of community-based psilocybin services. Such research can only occur after approval of an Institutional Review Board that oversees ethical research practices.

**Rule 333-333-5040 Informed Consent:** We recommend that the informed consent include a check-box for clients to indicate whether they would be willing to be approached about potential research opportunities (yes/no).

As bridges between the psychedelic and academic communities, we acknowledge existing tensions. Affordable and legal access to psilocybin services is a monumental step toward ending the War on Drugs and its disproportionate effects on marginalized communities. At the same time, responsible implementation and harm reduction without overmedicalization is imperative. Our team also aims to interrupt growing predatory and extractive practices when it comes to data collection in the psychedelic field. We recognize that Oregon’s psilocybin service model is a paradigm shift in multiple realms, and we believe rigorous, *unconflicted* data collection can safeguard these shifts from undue influence from outside interests.

The OPEN project, if funded, envisions three tasks:

- 1) In consultation with a diverse group of existing psilocybin practitioners: Determine the best ways to assess the success of Measure 109 (e.g., develop tools to accurately determine whether psilocybin services are being rolled out responsibly and being equitably accessed).
- 2) Gather information using these tools (utilizing a secure, encrypted software platform).
- 3) Share what we’ve learned freely and openly with participating service centers and the public (via a public-facing website where anonymous information is aggregated,

visualized, and shared); any analyses of the data will be published as open access resources.

Let's be clear about what OPEN is not:

- 1) OPEN is not a commercial effort. We envision lightening the burden of program evaluation by filling the funding gap with grants and unconflicted donations, *not* investment contracts or commerce. We pledge to remain transparent around any future sources of funding.
- 2) While we envision housing the OPEN database at OHSU and some OPEN steering committee members are OHSU faculty, OPEN is not an exclusive project at OHSU. It is a community-wide endeavor, with steering committee members from other institutions collaborating for the common good.
- 3) OPEN is not a direct collaboration with the Oregon Health Authority. We do, however, hope to create points of synergy that could *support* the OHA and reduce their administrative and financial burdens and thus reduce licensing costs. Keeping costs low means keeping M109 equitable.
- 4) OPEN has no hidden agenda. We have shared our intentions publicly at the Horizons NW conference and in recorded public Psilocybin Advisory Board meetings. OPEN has been invited to present a more detailed version of progress at an upcoming public Psilocybin Advisory Board meeting. We have no logo, no website, and no social media accounts because we have no funding, no staff, and nothing to share or disclose with the public at this point, beyond our aspirational ideas for how we can support implementation of M109.

A little more about us, as shared at the Horizon NW conference:

“OPEN is a nascent practice-based research network, designed to assess the safety of psilocybin services in community-based settings and develop a framework for future studies. The OPEN project aims to collect confidential information from Measure 109-licensed providers and their clients to assess their experience with legal psilocybin services. OPEN aims to build a rigorously designed and highly secure web-based information system that integrates data from licensed service centers, providers, and their clients. Oregon Health & Science University (OHSU) Clinical Translational Science Award will host the OPEN platform, and provide expertise on information technology, clinical, ethical, and scientific concerns.”

Our sincere hope is that the Oregon Psilocybin Services rules will be revised to support ethical data collection, as outlined above. Client, Service Center, and Facilitator data should be treated with dignity. We are confident that the confidential and encrypted methods we have outlined will support safe and equitable services across the state.

Sincerely,

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