

Oregon Psilocybin Services Section

2021 Public Listening Sessions

Summary of Questions and Answers

The Oregon Health Authority (OHA) held a series of three virtual public listening sessions in December of 2021. The listening sessions were two hours in length and open to the public. OHA staff compiled questions across the three listening sessions and summarized questions and answers in this document.

The listening sessions were recorded and can be found on our <u>Public Listening Sessions</u> <u>webpage</u>. Input from the public listening sessions will continue to inform program development, educational materials, and community engagement in 2022.

Definitions

"RAC" = Rule Advisory Committee, made up of members of the public who participate in discussions about draft rules during the rulemaking process

"May Rules" = The spring rulemaking process will result in the first set of rules being adopted by the end of May

"The Board" = The Oregon Psilocybin Advisory Board

"M109" = Ballot Measure 109, the Oregon Psilocybin Services Act

* For more definitions of terms used in this document, please refer to Section 5 of the Oregon Psilocybin Services Act (M109)

General Questions

Q: When will rules be adopted for Oregon Psilocybin Services?

A: OHA will complete two rulemaking sessions in 2022. The first round of rulemaking in February will focus on training programs and products/testing, with rules likely to be adopted by the end of May 2022. The second round of rulemaking in the fall will focus on the remainder of program rules. The final rules will be adopted by December 31, 2022 in time for OHA to begin receiving applications for licensure on January 2, 2023.

Q: Will one person be able to hold multiple license types?

A: Individuals may hold multiple licenses if they meet the eligibility requirements to apply for licensure and receive approval for licensure. An individual may not hold an interest in more than one manufacturer license or more than five service center licenses.

Q: Have there been conversations about creating equitable opportunities for minority business owners to ensure access within the market as the program is built?

A: Yes, equitable opportunities for minority business owners have been, and continue to be, discussed. OHA is working to better understand ways to address equity issues within the statutory authorities granted by M109 and within administrative rules. Although OHA is unable to prioritize licensees based on race, OHA is exploring social equity considerations for licensees.

Q: Are there any efforts to address conflicts of interest and moderate current committee members' ability to have advanced notice of details before they are made public?

A: All committee members are public officials and are responsible for complying with Oregon Government Ethics Law. All advisory board meetings and subcommittee meetings are accessible to the public. Meeting notes and recordings are also available online at: Oregon Psilocybin Advisory Board.

Q: Is the state planning to allocate any funding to support clinical research to improve the therapy and the use of psychedelic substances as a whole?

A: No. Under M109, the funds received from application and licensure fees must cover the costs of Oregon Psilocybin Services operations. There are no additional funding sources to support additional work at this time.

Q: If rules are counter-productive to a functioning system, how quickly can rule changes be made and what is the process for license holders to submit requests for rule changes?

A: The administrative rule making process requires approximately six months from start to finish for each set of rules being adopted. In the case of an emergency, the agency may choose to use a temporary rule making process that is much quicker. OHA will continually evaluate rules for efficacy.

Products & Testing

Q: What are the land use requirements for manufacturing/production?

A: M109 requires that the property owner give permission for psilocybin production. Other land use requirements may be established by local governments. Applicants will be required to produce a Land Use Compatibility Statement (LUCS) which demonstrates that the proposed use of the property is consistent with local zoning code.

Q: What are the final forms that psilocybin can take, in terms of products?

A: We will adopt administrative rules that specify which product forms will be permitted. These rules will be effective in May 2022.

Q: What will the laboratories be required to test for?

A: This will be addressed in May rules, although additional rulemaking may occur later in 2022.

Q: Will there be security requirements for manufacturers and service centers?

A: Yes. Exact requirements will be established in rule.

Q: Can people grow and use mushrooms for their own personal use?

A: M109 does not allow for personal use. M109 creates a regulatory framework for the production of psilocybin and the provision of psilocybin services.

Service Centers

Q: What are the land use requirements for a service center?

A: M109 requires that a service center be at least 1000 ft. from a school and have defined boundaries. Other land use requirements may be established by local governments. Applicants will be required to produce a Land Use Compatibility Statement (LUCS) which demonstrates that the proposed use of the property is consistent with local zoning code.

Q: What is considered the boundaries of the center?

A: Boundaries and other premises requirements for licensed service centers will be considered during rulemaking later in 2022.

Q: What will the criteria be for the Center? interior design, furniture, music system, lighting, bathrooms, etc.

A: Premises requirements for licensed service centers will be considered during rulemaking later in 2022. Generally, these rules will focus on requirements that affect public health and safety rather than items such as lighting and design.

Q: Can centers have access to the outdoors?

A: The board has recommended that service centers have access to the outdoors. Under M109, licensed service centers must have defined boundaries and cannot be located on public land. Specific requirements for service centers premises will be considered during rulemaking later in 2022.

Q: Will there be different categories of service centers?

A: No.

Q: Can the service centers operate ancillary or peripheral services that could offer additional revenue streams and help with financial viability?

A: These requirements will be considered during rulemaking in 2022.

Administration Session

Q: Will clients need a medical referral to receive psilocybin services in a service center?

A: No. M109 specifically states that a client will not be required to be diagnosed with a medical condition to receive psilocybin services. Clients must be 21 years of age or older to access psilocybin services.

Q: What is the process by which the client gets the medicine for treatment?

A: A client may purchase psilocybin products from a licensed service center for consumption during a facilitated administrative session at that service center. Licensed facilitators will not provide psilocybin products to clients.

Q: How will dosage be recommended? Will clients have a chance to voice their preference for dosage?

A: Rules specifying dosage requirements will be adopted later in 2022. Clients will have an opportunity to discuss all aspects of their administrative session, including dosage, during their preparation session with a licensed facilitator. Maximum doses may be established in rule. Clients and licensed facilitators will work together to determine dosage. These details will be established in rule.

Q: If someone is participating in multiple administration sessions within a small window of time is a separate prep session required for each administration session? A: Yes. M109 requires a preparation session to precede each administration session.

Q: Could the client choose to participate in multiple prep sessions before the administration session? What about multiple integration sessions after the administration session?

A: Details on the preparation, administration, and integration sessions will be established in rule later this year.

Q: Is the board considering micro-dosing sessions?

A: The term "microdose" is not used in M109. M109 requires OHA to establish the maximum concentration of psilocybin that is permitted in a single serving of a psilocybin

product, and the number of servings that are permitted in a psilocybin product package. Details will be established in rule later this year.

Q: Will there be a standardized screening tool for harm reduction purposes?

A: M109 requires a preparation session for clients with a licensed facilitator. A client intake form is required for this process and will include documentation of risk factors and contraindications, as well as considerations for health and safety. Details will be considered during the rulemaking process.

Q: Will sessions be able to be subsidized for those who cannot afford a session?

A: M109 does not allow OHA to use funds in this manner. Funds from application and licensure fees must cover the costs for Oregon Psilocybin Services. OHA does not have statutory authority to regulate costs of psilocybin services. Private organizations or licensed service centers and facilitators may choose to offer subsidies for lower income clients.

Q: Will groups be allowed? How large?

A: The board has recommended that group sessions be permitted. The exact requirements for group sessions will be detailed in administrative rules to be adopted later in 2022.

Q: How much will services cost?

A: Under M109, OHA cannot control the costs for training or services. The program will set application and license fees in rule and there will be a 15% sales tax on sale of psilocybin products to clients for administration sessions. Licensees and training programs will determine the cost of their services.

Training Programs

Q: What are the general requirements of a facilitator training program?

A: Training program curriculum must be approved by OHA. Application requirements for training program approval will be established in May rules.

Q: What are the requirements of the trainers themselves?

A: The requirements will be specified in May rules.

Q: When can the facilitator training programs start?

A: OHA estimates that staffing and systems will be in place to approve training programs in June of 2022. OHA will not be able to offer retroactive approval for programs operating before that time.

Q: There are already a lot of training programs out there... what is transferrable?

A: The board has recommended that some transfer of credits be allowed. Rules on transfer of credits will be discussed in the May rulemaking.

Q: How does OHA plan to acknowledge traditional and indigenous healers within the training requirements?

A: Experience in traditional healing may be considered as transferrable credits depending on what is established in May Rules.

Q: Will the training for facilitators include significant material on how to deal with mental health issues or issues related to trauma that arise during session?

A: The board has made recommendations on training curriculum, including traumainformed care, and OHA will be considering these recommendations during May rulemaking.

Q: How much will a training program cost?

A: Under M109, OHA cannot control the costs for training programs or psilocybin services. The program will set application and license fees in rule, and there will be a 15% sales tax on sale of psilocybin products to clients for administration sessions. Licensees and training programs will determine the cost of their services.

Facilitation

Q: Is there somewhere I can find information about qualifications (certification, degree, experience, etc.) for preparing to work as a Psilocybin Services Facilitator?

A: Every facilitator must complete a training program that is approved by OHA as a condition of being licensed. A high school diploma, or its equivalent, will be required without additional degrees or certifications. Additional qualifications will be discussed during May rulemaking.

Q: Does a facilitator have to have a medical license?

A: No.

Q: Will a facilitator be required to have participated themselves in a psilocybin administration session?

A: No.

Q: Will there be standardized safety protocols that facilitators will be required to follow?

A: Yes. Exact requirements will be established in rule.

Q: Are 2 licenses required for a facilitator delivering this service; one for providing psilocybin products and another for the service itself?

A: Psilocybin products are provided to clients by a licensed service center for administration sessions that take place at their location. M109 allows a person to hold both a service center and facilitator license, if that is what the licensee chooses to apply for.

Q: Will the same license apply to both solo and group sessions? Will there be different types of facilitator licenses?

A: The board has recommended that there only be one type of facilitator license. OHA will consider this recommendation before adopting May Rules.

Q: Can the psilocybin services be offered within a ceremonial or religious context? A: Yes, if psilocybin services take place at a licensed service center and is otherwise compliant with statute and rule requirements.

Q: How will OHA ensure that those who hold traditional knowledge or have experience with natural healing practices are recognized and have equitable access to licensing?

A: The board has made recommendations on training curriculum, including history of Indigenous practices, and OHA will be considering these recommendations during May rule making. Experience with traditional healing may be eligible for credit in a training program.

For more information, please go to: www.oregon.gov/psilocybin