

Licensing Subcommittee

Oregon Psilocybin Advisory Board
Minutes for May 13, 2021

I. Call to Order:

Meeting called to order by Mason Marks at 2:03pm on Thursday, May 13, 2021. The meeting was held over Zoom and the proceedings were recorded.

II. Roll Call

Members Present:

Mason Marks
Kimberley Golletz
Barb Hansen
David Hart
Rachel Knox
Sarah Present

Members Absent:

None

III. Open Issues: None

IV. New Issues:

- a. Members of the licensing subcommittee introduced themselves.
- b. Barb Hansen made the following statement citing sections of Measure 109: "The authority may not adopt rules that are more restrictive than reasonably necessary to protect the public health and safety. That's something the licensing committee and the entire advisory board should live by."
- c. The subcommittee discussed meeting times and frequency. David Hart suggested that a new meeting time be found, and the group agreed to circulate a poll to find a new time.
- d. Mason Marks discussed potential roles of the licensing subcommittee and questions it may wish to answer.
- e. David Hart asked where informed consent and transparency fit in and suggested that they likely fall under industry best practices. He stressed that these are important goals that should be part of licensing. He suggested framing them as part of consumer protection, ensuring that consumers are informed and protecting them from unscrupulous businesses and professionals. He requested that informed consent and transparency be among the stated goals of licensing.
- f. Sara Present suggested that the scope of the subcommittee duties be clarified. The group discussed the role of the subcommittee in the licensing process.
- g. The group discussed recommending the creation of a body, such as an Oregon Psilocybin Commission, to oversee plant medicine licensing in Oregon.

- h. Barb Hansen suggested thinking about regulations in terms of what clients have a right to expect and suggested a Bill of Rights for clients, which could include a right to a private room and a right to a clean bathroom, for example. David Hart suggested other rights such as a right to safety, to have their wishes respected, and to autonomy.
- i. Mason Marks presented for discussion various sections from Measure 109 of relevance to the licensing subcommittee.
 - Section 7
 - i. Public health and safety standards and industry best practices for each license type.
 - ii. Formulating a code of professional conduct with an emphasis on a code of ethics.
 - iii. Rachel Knox raised concerns regarding the two-year residency requirement for facilitators, the burden of this requirement, and its potential impact on the diversity of facilitators.
 - Section 8
 - i. Board required to establish long term strategic plan for safety, accessibility, and affordability.
 - ii. Establishing requirements for issuance, renewal, suspension, revocation, and refusal to renew licenses.
 - iii. The group clarified that the licensing subcommittee will be making recommendations to the OHA rules advisory committee that will create the Oregon administrative rules to govern the system created by Measure 109.
 - iv. Application fees.
 - Section 11
 - i. Dates that apply to the board such as the June 30, 2022 deadline for the advisory board to submit its recommendations to OHA.
 - Section 13
 - i. Four core licensing types: manufacturing, operating service center, facilitation, and testing.
 - ii. Mason Marks suggested that the subcommittee consider whether additional licensing types should be offered.
 - iii. David Hart asked whether there will be licensing requirements for individuals in the supply chain who hold and maintain psilocybin. "Presumably, it must be held in certain conditions to ensure its efficacy and safety," said Hart.
 - iv. Tom Eckert stated that delivery is covered under Measure 109's section on permitting.
 - v. The group concluded that delivery practices, safeguards, and relevant credentials would be discussed in depth at future meetings.
 - Section 14
 - i. Requirements for all license types and additional information the subcommittee may recommend is collected from applicants.
 - Section 15
 - i. Grounds for refusing to issue a license.
 - ii. Gray areas regarding substance use, incompetence, or physical incapacity and not being of good repute or moral character.

- iii. Sarah Present suggested that these sections should be vague in order to give OHA leeway to consider licensee actions on a case-by-case basis.
 - iv. Mason Marks pointed out that leaving too much discretion to a licensing board can result in discrimination against vulnerable groups such as people with disabilities. He suggested that the issue be discussed further to provide additional clarity.
 - v. Kim Golletz suggested that many of these questions show up on malpractice insurance applications and raised the section of Measure 109 providing discretion to OHA to require facilitators to secure liability insurance.
 - vi. Rachel Knox suggested that insurance has been a huge problem to solve in the cannabis industry. Further, she pointed out the importance and challenge of determining what constitutes competency and who validates it.
 - vii. David Hart said a standard of care would be needed to provide liability insurance.
 - viii. Kim Golletz asked whether establishing a standard of care is within the scope of the subcommittee's responsibilities. She suggested that the standard of care might be established by the training subcommittee and that licensure is about determining whether competence is maintained after training.
 - ix. David Hart pointed out that standards of care often differ based on geography.
 - x. Rachel Knox emphasized that standards of care for psilocybin may not be traditional and the board must consider unconventional, indigenous, and non-western perspectives on a standard of care. She pointed out that this approach was not taken by cannabis regulators, which adopted a western medical approach to the standard of care, and the result was reductive and limiting.
 - xi. Mason Marks suggested that the group might not want to define a standard in terms of what is within the standard as much as what is clearly outside of it.
 - xii. David Hart suggested establishing a baseline standard of minimum expectations and that the standard might evolve.
 - xiii. Tom Eckert agreed regarding establishing a baseline and framing standard of care in terms of safety and holding space, thereby leaving room for a variety of approaches to facilitation.
- Section 18
 - i. Determining whether to require facilities to be enclosed by a wall or fence, which the OHA may require.
 - ii. Sara Present suggested that the subcommittee clarify the duties of counties and cities versus OHA. Her understanding is that licenses are issued by OHA, and the city or county must provide a land use certification to license applicants. She suggested that the subcommittee discuss this issue further to ensure cities and counties are educated on their duties and to ensure an equitable process. She suggested that the subcommittee also consider situations in which food is served at a licensed facility and whether those premises might be licensed in a manner comparable to restaurants because food service establishments are usually licensed at the city or county level. She said the subcommittee should ensure that when psilocybin is involved, the state is issuing those licenses.

- Section 19
 - i. Requirement that applicants provide land use compatibility statement from city or county that authorizes the land use.
 - Section 21
 - i. Restrictions on financial interests in multiple licenses.
 - Section 22
 - i. Licensees can hold multiple License types.
 - Section 23
 - i. Manufacturer license.
 - Section 24
 - i. Manufacturer endorsements.
 - ii. What should different endorsements look like and what should their requirements be?
 - Section 25
 - i. Product quantity limitations.
 - Section 26
 - i. Service center operator license.
 - ii. Zoning requirements and distance from schools.
 - Section 30
 - i. Facilitator licenses: Education requirements, etc.
 - Section 40
 - i. Powers and duties of OHA related to facilitators.
 - ii. The environment in which psilocybin services can occur.
 - iii. Code of professional conduct with emphasis on code of ethics.
 - iv. Waivers of facilitator examination and waivers of licensing fees.
- j. Mason Marks asked subcommittee members to express interest in researching the topics raised earlier in the meeting.
- Rachel Knox suggested that the subcommittee seek the expertise of experienced operators in the psychedelics space. What is the mechanism for improving and ensuring that there is flexibility such that we know that we are always working towards the best type of program? How might the licensing system and the experience of licensees be reviewed on an ongoing basis by OHA or another body. We should ensure that we are continually taking in information to improve the system.
 - Barb Hansen suggested incorporating some of the data requirements into the licensing process.
 - David Hart asked whether data requirements include record keeping requirements for licensees.
 - Kim Golletz suggested that these requirements should be built into the standards for facilities and facilitators. Will there be standard kinds of things that are part of the paperwork such as consent for treatment?
 - Sara Present asked how the subcommittee might co-create requirements alongside the community that are already doing this type of work. Is there a way for us to survey them about pros and cons from their experience to drive best practices?
 - David Hart pointed out that OHA must go through a notice and comment session before it can make rules for the psilocybin industry.

- Rachel Knox suggested that the surveying of outside experts could inform the subcommittee's decision making.
- David Hart expressed concerns regarding conflicts of interest and undue influence of outside experts.
- The group discussed developing a standardized way to invite guests and assess conflicts of interests for them.
- Tom Eckert suggested the subcommittee invite experts who use open source technology for manufacturing.
- Barb Hansen expressed interest in researching service centers and facilitator licensing.
- Kim Golletz expressed interest in researching informed consent and facilitator licensing.
- David Hart asked whether it was possible to delegate subcommittee member work to assistants who are not members of the advisory board or a subcommittee. The subcommittee agreed that it was appropriate to delegate research to such assistants.
- David Hart expressed interest in researching consumer protection and informed consent as it applies to licensing.
- Sarah Present expressed interest in research service center requirements and testing laboratories.
- Mason Marks expressed interest in researching manufacturing licensing and social equity programs for psilocybin licensing.
- Rachel Knox expressed interest in researching social equity programs for psilocybin licensing.
- David Hart asked whether it was possible to ask the entities supplying psilocybin to clinical trials to speak to the subcommittee. Tom Eckert suggested that Usona might be willing to speak to the subcommittee.
- The group discussed possible methods for advisory board members to communicate across subcommittees. Tom Eckert suggested designating a member of each subcommittee to serve as a communications liaison with another subcommittee.
- Tom Eckert raised the importance of considering personnel requirements for service centers. What personnel might meet different needs of the population and provide different levels of care? He raised the possibility of having OHA endorsements for service centers or overlaying a credentialing piece onto the system.
- Rachel Knox recommended that the group eventually discuss consumer awareness about psilocybin products and what information must be provided to consumers. She emphasized that the product information must be easily accessible.

Research Assignments:

Mason Marks – Manufacturer Standards and Social Equity in Licensing

Kimberley Golletz – Facilitator Licensing

Barb Hansen – Service Center Requirements and Facilitator Licensing

David Hart – Consumer Protection and Informed Consent

Rachel Knox – Social Equity in Licensing

Sarah Present – Service Center Requirements and Laboratory Requirements

Adjournment:

The meeting was adjourned by Mason Marks at 3:40pm. The group concluded that the date and time of its next meeting would be determined through a poll distributed to subcommittee members.

Minutes prepared and submitted by: Mason Marks, May 15, 2021.