Licensing Subcommittee

Oregon Psilocybin Advisory Board

Minutes for May 24, 2021

1. **Call to Order:**

Meeting called to order by Mason Marks at 2:02pm on Tuesday, May 24, 2021. The meeting was held over Zoom and the proceedings were recorded.

1. **Roll Call**

**Members Present:**

Kimberley Golletz

Barb Hansen

David Hart

Mason Marks

Sarah Present

**Members Absent:**

Rachel Knox

1. **Open Issues:**
2. Members of the Licensing Subcommittee approved the minutes from the May 13, 2021 meeting.
3. **New Issues:**

Discussion of Licensing Subcommittee Duties and Goals

1. Mason Marks shared a list of duties and goals for the Licensing Subcommittee for group discussion.
2. Marks asked whether the group might consider recommending a mechanism for clients to file complaints to supplement the patient Bill of Rights proposed by Barb Hansen.
3. David Hart supported the discussion of a system for tracking complaints about licensees and suggested that the group also discuss a system for investigating those complaints.

Reports from Subcommittee Members on Preliminary Licensing Research

* 1. Barb Hansen facilitated a discussion on psilocybin service center licensing requirements.
     1. Hansen shared her document that paired language from sections of Measure 109 with related issues and questions that the Licensing Subcommittee may wish to consider.
     2. Hansen raised a question regarding whether a service center must be entirely located within a building or if part of it may be located outside.
     3. Hansen asked whether a service center may adjoin or be located withing a private residence, and if so, how should residential areas be separated from service center areas?
     4. Hansen asked whether group psilocybin services should be allowed, and if so, whether there should be limits on the number of participants, and what should those limits be? Should the Subcommittee recommend a ratio of facilitators to clients?
     5. Hansen asked whether clients should be permitted to access outside areas while receiving psilocybin services and whether that access should be mandated.
     6. Hansen asked whether a service center should be enclosed by a wall, fence, or other barriers such as landscaping? Should OHA require centers to be enclosed as a condition of receiving a license? Service centers cannot be mobile, but could they be in modular or mobile homes that are not on wheels? Could they be in other structures such as yurts or teepee?
     7. Hansen asked whether service centers must be accessible under the Americans with Disabilities Act (ADA).
     8. Hansen raised questions regarding service center location, land use issues, parking, and proximity to schools.
     9. Hansen asked whether a private room should be required for the administration of psilocybin services, and in a group session, should a service center be required to make at least one private room available? Should restrooms be ADA accessible and what ratio of restrooms to clients should be required of service centers?
     10. Hansen asked whether OHA should require service centers to maintain the ambient temperature within a certain range, mandate air conditioning, and require a certain level of sound proofing to protect clients from noises produced outside the service center.
     11. Hansen asked what kind of furniture should be required and made available to clients. Should kitchen facilities be available, and will clients be permitted to bring their own meals or snacks? Should a refrigerator be made available for safe food storage? How will waste disposal be handled, and should that be left to cities and counties?
     12. Hansen asked what infection control protocols should be required and how should rooms be sanitized in between client sessions?
     13. Hansen asked what the requirements for secure storage for psilocybin should be? Should there be a designated drug room with very specific storage requirements?
     14. Regarding emergencies, Hansen asked whether there should be requirements for sheltering in place. Should any emergency equipment be located on site? How might service centers contact EMS.
     15. Mason Marks suggested that service centers might be required to keep an epinephrine autoinjector on hand in case of an allergic reaction.
     16. Sarah Present recommended that the Licensing Subcommittee research Oregon regulations for healthcare facilities.
     17. David Hart suggested that making decisions regarding group psilocybin services would raise and answer several questions for the Licensing Subcommittee. He emphasized the importance of determining how many clients should be permitted to simultaneously receive psilocybin services. Should the limit be two, three, or four clients?
     18. Kim Golletz commented that there are general safety issues associated with the provision of psilocybin services, and group services present unique safety issues that the group should address.
     19. Mason Marks added that group services might keep costs down and allow people to pool their resources to more easily afford psilocybin services. He emphasized that the largest expense associated with psilocybin services could be the cost of the facilitator's time.
     20. David Hart pointed out that although group services could potentially be more cost effective, adding group services could negatively impact the efficacy of those services.
     21. Mason Marks emphasized that supporters of group services may contend that a group setting is the original mode in which psilocybin were been administered, by indigenous communities, and that the Licensing Subcommittee should consider that history in addition to economic and efficacy considerations.
     22. Kim Golletz offered to research group administration of psilocybin and other plant medicines to facilitate further discussion.
     23. Mason Marks commented that as the number of clients increases, the number of team members at the service center would also have to expand to some extent. Kim Golletz suggested establishing a required ratio of facilitators to clients.
     24. David Hart added that group services might also impact the neighborhood differently.
     25. Sarah Present suggested that the group might look to fire codes while considering requirements for the interiors of service centers. However, she suggested that for outdoor spaces, the Subcommittee will likely find fewer resources and examples.
     26. Steph Bars pointed out that psilocybin services do not constitute therapy and suggested that the term should be avoided.
     27. Kim Golletz pointed out that OHA may offer two types of facilitator licenses and that many people seeking psilocybin services will have mental health conditions and be hoping that psilocybin services will help them. She suggested that offering two types of facilitator licenses may help address concerns regarding the perception of psilocybin services as therapy. For example, OHA could offer one license for facilitators offering services to clients for wellness purposes, and a different license for facilitators capable of offering services to clients with a history of mental health conditions.
  2. David Hart discussed an informed consent document from the AIMS Institute in Seattle, which he had circulated to the Licensing Subcommittee before the meeting. He suggested that it may serve as inspiration for a more in-depth discussion of informed consent, and the group agreed to add this item to the agenda for its next meeting.
  3. Barb Hansen led a discussion on facilitator licensing requirements.
     1. Hansen shared a document that paired language from sections of Measure 109 with issues and questions that the Licensing Subcommittee may wish to consider.
     2. Hansen drew the group's attention to a section stating that "equivalent education" may be accepted in lieu of a completed training program and asked what types of training might constitute an equivalent education. Can training received in another country be classified as equivalent? What proof would be acceptable?
     3. Hansen suggested that the Subcommittee consider what should happen if an individual must temporarily drop out of a psilocybin training program.
     4. Hansen emphasized the importance of establishing grounds for refusing to issue a license to an individual or entity, and she suggested that the Subcommittee clarify the terms for refusal. How is competence evaluated and who evaluates it? Must competence be established by a judge? With respect to the use of substances, what is the meaning of the term "excess?"
     5. Hansen asked when the licensing examination requirement could be waived and whether it should ever be waived because clients may expect that their facilitators have passed an examination. Perhaps under some circumstances the examination could be offered in alternate formats?
     6. Hansen discussed establishing a code of professional conduct and industry best practices for facilitation.
     7. Hansen asked whether license renewal should occur on an applicant's birthday or if all licenses should be renewed on a specified date.
     8. Hansen stated that the Subcommittee should clarify the grounds for license suspension and revocation and the conditions under which revocation might be preferred over suspension. What kind of investigation should occur and on what timeframe? If a license is revoked, can the licensee reapply? What level of proof is required to show that a license applicant made a false statement to the OHA? Must the false statement be in writing? Since Measure 109 requires applicants to be solvent, will OHA require them to have a certain credit score? How else might solvency be evaluated?
     9. Hansen asked if a client prefers a certain type of facilitator (based on race, gender, or other factors), can the client request to be served by a specific facilitator?
     10. David Hart suggested that the group discuss requiring continuing education for facilitators to keep their training up to date.
     11. Mason Marks suggested that there may be a way to incentivize licensees to contribute to continuing education programs to help reduce the expense of the programs and increase access.
     12. David Hart recommended that the group consider including various forms of continuing education such as self-study and formal classes. He suggested that continuing education may be required to maintain a license.
     13. With respect to client choice, Mason Marks asked whether a person with a more complicated medical or psychological history should be allowed to see a facilitator who has completed the minimum requirements for licensure, which could become an issue in rural areas where there are fewer facilitators offering psilocybin services.
     14. Sarah Present commented that the availability of referral sources will be important. For instance, by analogy, some midwives may need to refer certain patients to other midwives with additional training, potentially at hospitals or other centers with more specialized personnel and equipment. She added that a system could be created to ensure that people in areas where few psilocybin services are offered could seek specialized care from experienced facilitators located elsewhere should they require it. She envisioned a community of providers with resources to serve those individuals. At a minimum, a client could access that community by phone to receive a telehealth consultation. This network could also potentially assist facilitators during the administration of psilocybin services should the need for specialized expertise be required. At a minimum, facilitators must be able to contact emergency medical services. However, it would also be helpful for facilitators to be able to reach a network of mentors who could provide more nuanced support.
  4. Mason Marks led a discussion on manufacturing standards and presented a document on good manufacturing practices for mushroom cultivation. Marks also discussed a study that examined different storage methods for fungal material and their effects on psilocybin content.
  5. Sarah Present asked whether the administration of psilocybin services should be allowed within a healthcare facility.
  6. Barb Hansen commented that some palliative care centers may wish to offer psilocybin services within their facilities.

License Types

* 1. The Subcommittee discussed what types of licenses might be offered by the OHA.
  2. Mason Marks commented that in addition to manufacturing licenses, the OHA will offer endorsements to manufacturers for each type of manufacturing activity.
  3. Marks described three potential approaches to issuing facilitator licenses:
     1. The OHA could offer a single type of facilitator license, and facilitators could seek additional certifications on top of that license. Certifications could be offered by the OHA or by external bodies such as professional organizations.
     2. The OHA could create a tiered licensing system in which a basic facilitator license is offered alongside a specialized license for facilitators with additional training.
     3. The OHA could offer a single type of facilitator license and provide the opportunity to add endorsements specialized facilitation skills through a system comparable to the manufacturing license system describe by Measure 109.
  4. Marks asked how the Subcommittee should address delivery services. Should delivery be addressed through permitting or should there be an endorsement that addresses delivery?
  5. Barb Hansen commented that the ability to facilitate group psilocybin services should be granted through an endorsement or an additional certification above the minimum requirements.
  6. David Hart expressed concern for vulnerable clients such as those with complicated medical histories or past trauma. He suggested that clients seeking psilocybin services for wellness purposes are in a different position than those seeking services for psychological conditions. He asked whether the individuals obtaining informed consent from clients will be capable of assessing competency.
  7. Kim Golletz expressed concern that offering a single license type may not adequately address concerns regarding the needs of clients with more complex histories. A two-tiered system raises the issue of routing clients to appropriate facilitators. How does one differentiate between clients on a wellness track and a mental health track? Should there be an assessment to screen people and sort them to the best facilitators for their circumstances?
  8. David Hart commented that facilitators must know their limitations. By analogy, it would be negligent for a lawyer to take on a client the lawyer is unqualified to represent. Perhaps there should be similar expectations with respect to facilitators. If a facilitator serves a client the facilitator is not qualified to serve, and a bad outcome occurs, perhaps the facilitator's license should be on the line because they must be able to screen clients effectively.
  9. Sarah Present drew comparisons between an endorsement-based facilitator licensing system and the licensing of physicians. There is a single license for physicians, but there are many medical specialties. She asked whether a facilitator possessing additional licenses, such as a license to provide psychotherapy, might qualify for an endorsement? Present asked whether offering two types of licenses would violate Measure 109's requirement that the OHA not require licensees to have more than a high school education.
  10. Mason Marks commented that an endorsement-based system may avoid potential conflicts between a two-tiered license system and the text of Measure 109. If endorsements were used, then anyone with at least a high school diploma could obtain a license if they completed the required steps.
  11. Sarah Present pointed out that offering different levels of licenses complicates the licensing system, which makes implementing the system in the specified timeline more challenging.
  12. Mason Marks commented that if the Licensing Subcommittee is tasked with promoting public health & safety and consumer protection, then the Subcommittee is obligated to consider the potential impact of the licensing system on public health & safety and consumer protection.
  13. Kim Golletz commented that one effect of offering a two-tiered licensing system is that the more specialized license may require facilitators to hold advanced degrees or certifications from other fields (to have letters after one's name), whether one is a licensed professional counselor, a social worker, a psychologist, or a psychiatrist. Golletz argued that such a system would not require people to have those letters after their name to obtain a basic facilitator's license. There would be a license for people without specialized training. However, on top of that, there would be a second license geared toward serving clients who require specialized attention, and that type of client might be served only by facilitators with this more advanced license. However, a facilitator holding the first type of license could practice while holding no more than a GED. Golletz expressed concern that training everyone to assess and mange the potential problems arising from providing psilocybin service to people with pre-existing conditions significantly increases safety concerns.
  14. Mason Marks expressed concerns regarding who would be conducting assessments. He proposed that qualified experts could design the screening instrument. However, perhaps every facilitator should be trained to implement the screening process. He argued that screening should be part of the goal of a preparatory session. By analogy, when people seek a psychotherapist, they may have a preliminary meeting with a therapist to determine whether the therapist is a good fit for the patient's needs. He suggested that facilitators should be trained and empowered to perform client screening. If screening indicates that a client has a high-risk condition, the facilitator is not qualified to serve that client, and the facilitator provides psilocybin services to that client anyway, that could be grounds for suspension of the facilitator's license. Ensuring that such guidelines are followed is the purpose of codes of conduct and professional responsibility.
  15. Kim Golletz suggested that a screening checklist administered by a facilitator might not be sufficient because clients may be incentivized to receive services from a specific facilitator even if that facilitator is not qualified to provide services to them.
  16. Mason Marks responded that a checklist in isolation might not be sufficient. However, a checklist in conjunction with proper training and evaluation to ensure proper administration of the checklist could be sufficient to ensure client safety. He emphasized that his concern regarding who administers the screening is rooted in a desire to promote equal access to psilocybin services. Training all facilitators to perform client screening could allow people in areas with few facilitators to be screened in person. Marks expressed additional concern regarding previous suggestions that a centralized matching system be used to screen clients, which would require clients to enter personal information into a central database.
  17. Kim Golletz suggested that a centralized system could potentially be accessed by telephone. She explained to other group members that the matching system was discussed in a previous meeting of the Training Subcommittee, and she clarified Marks' concerns by emphasizing that a central system might require clients to enter personal information into a database that could be accessed by the OHA, a government agency, and psilocybin remains a Schedule I drug at the federal level.
  18. Marks added further clarification that a centralized database could violate Measure 109's client confidentiality provision, which states that client information shall not be shared outside the service center. Requiring clients to share their information with the OHA could violate the relevant section of the statute.
  19. Kim Golletz asked how endorsements would protect clients from ending up in the wrong spot.
  20. Mason Marks commented that the screening process could identify information for the facilitator to act on, and the facilitator could then refer the client to a facilitator with a higher-level endorsement.
  21. Kim Golletz pointed out that service centers will be incentivized to accept clients, even if their facilitators are not qualified to serve those clients. She expressed concern that clients might receive psilocybin services from the wrong facilitators.
  22. Mason Marks commented that all providers face conflicts of interest, and that is why professional codes of conduct are created and enforced. He expressed concern regarding designing a system based on the assumption that clients will misrepresent their medical histories to gain access to psilocybin services.
  23. David Hart commented that both service centers and facilitators may be motivated to buy data from Google regarding people who search for psilocybin services and reach out to those individuals. The system created by Measure 109 will also create psilocybin tourism where people travel from out of state to receive psilocybin services. Hart emphasized the importance of implementing a system that conveys to clients that a facilitator is qualified to safely administer psilocybin to them.
  24. Mason Marks raised the possibility of voting on what types of licensing the Subcommittee will recommend to the full Board once the Subcommittee has had adequate time to consider the options.
  25. Jessie Uehling asked whether potential subcategories of facilitator licenses should be consistent with the subcategories of manufacturing licenses. Might such consistency aid the OHA's administration of the licensing system?
  26. Kim Golletz asked what the advantages of an endorsement-based facilitator licensing system might be.
  27. Mason Marks responded that an endorsement-based system might allow a wider variety of sublicenses, such as endorsements for group facilitation and for providing services to high-risk populations. Alternatively, there could be a single endorsement offered to facilitators who wish to serve high-risk communities.
  28. Kim Golletz added that one advantage of offering endorsements could be the addition of greater variety to facilitator training. Moreover, clients might find it reassuring that their facilitators have obtained endorsements in specialized areas.
  29. Mason Marks commented that endorsements could provide more flexibility than a two-tiered facilitator licensing system because additional endorsements could be added to the system in the future as the Board and the OHA learn more about how psilocybin services are best provided to clients.
  30. Jessie Uehling asked whether the subcommittee had considered linking endorsements to the credentials of facilitators.
  31. Sarah Present commented that emergency medical responders have several tiers of certification that build on each other.
  32. Kim Golletz commented that some people lacking graduate degrees may be very experienced and skilled at facilitation, and they could be amazing facilitators.
  33. David Hart expressed concern that even those talented facilitators might not be qualified to care for all clients. He expressed support for a two-tiered licensing system but suggested that the group table discussion of facilitator licenses to allow for additional research.
  34. Mason Marks asked whether the group had concerns regarding the delivery of psilocybin products.
  35. Sarah Present suggested that the group recommend that facilitators be mandatory reporters, for example, for sexual abuse.

Client Bill of Rights

1. Mason Marks initiated a discussion on the proposed Client Bill of Rights.
2. David Hart suggested the addition of a right to receive culturally appropriate care and a right to be free of sexual and financial abuse.
3. Mason Marks asked whether the number of staff present at a service center had been discussed in previous Board meetings or meetings of other subcommittees. Sara Present commented that it had been discussed at a previous meeting of the Training Subcommittee, which discussed potentially having at least two staff members present. However, no definitive conclusion had been reached.
4. Present suggested the addition of a right to be free from psychological abuse to the Client Bill of Rights.
5. David Hart clarified that it should be prohibited for facilitators to subject clients to sexual, financial, and psychological abuse before, during, and after the provision of psilocybin services. For instance, it would be inappropriate for facilitators to date their clients, to go into business with their clients, or to seek contributions from their clients.
6. Kim Golletz suggested that this prohibition should be incorporated into facilitator training and an ethical code for facilitators. Facilitators should be trained on appropriate boundaries.
7. David Hart commented that financial conflicts of interest should be disclosed to clients, and they should have a right to expect transparency from facilitators. He added that there should be a right to understand the risks, benefits, and unknowns associated with psilocybin services.
8. Mason Marks asked how the group can address potential benefits while ensuring that facilitators do not make medical claims.
9. David Hart suggested that facilitators should disclose that there are many unknowns associated with psilocybin services. Psilocybin is not an FDA approved therapy. However, there is research being conducted into its efficacy, and there are signs that it may be efficacious.
10. Mason Marks commented on a potential right for clients to access their records and potentially to request corrections in the case of errors.
11. Barb Hansen raised a potential right to refuse psilocybin services once they have begun. At what point can clients refuse and leave the service center?
12. David Hart emphasized that the right to refuse services is an important autonomy concern that might fall under the client right to autonomy.
13. Barb Hansen asked what the parameters might be for allowing clients to leave a service center if they call someone to pick them up who can ensure their safety.
14. Sarah Present asked whether clients could ask loved ones to be present during the provision of psilocybin services.
15. Kim Golletz asked whether facilitators should be permitted to record sessions for safety and whether clients can refuse to be recorded.
16. Barb Hansen suggested a right to have one's belongings secured.
17. Sarah Present suggested drafting rights and responsibilities such as a responsibility not to abuse one's facilitator.
18. Barb Hansen suggested a code of conduct for clients.
19. The subcommittee solicited comments from the public.
20. **Updated Research Assignments:**

Mason Marks – Manufacturer Standards and Social Equity in Licensing

Kimberley Golletz – Facilitator Licensing, Group Psilocybin Services

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

1. **Adjournment:**

The meeting was adjourned by Mason Marks at 3:50pm. 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 31, 2021.