

# Approved OPAB Recommendations

## INTRODUCTION

The Oregon Psilocybin Advisory Board (OPAB) was appointed by Gov. Kate Brown pursuant to Ballot Measure 109, the Oregon Psilocybin Services Act, which is now codified in ORS 475A. OPAB is an advisory board whose duties include making recommendations to the Oregon Health Authority. OPAB has organized five subcommittees to focus on specific areas of interest during the development phase, January 1, 2021, to December 31, 2022, and to provide recommendations to OHA by June 30, 2022, per statute. Approved recommendations are organized in this document by originating subcommittee and by the date of subcommittee approval. OPAB considered recommendations on 11/17/21, 12/21/21, 4/27/22, 5/25/22 and 6/22/22. In some cases, the recommendations are very lengthy or refer to separate documents. The full text of these recommendations can be found in the appendices.

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# Approved Recommendations

## Training Subcommittee

- “Curriculum” Recommendations<sup>1</sup> approved at 11/17/21 OPAB meeting.
- “Administration” Recommendations<sup>2</sup> approved at 11/17/21 OPAB meeting.
- “Supplementary” Recommendations<sup>3</sup> approved at 11/17/21 OPAB meeting.
- “Equity” Recommendations<sup>4</sup> approved at 11/17/21 OPAB meeting.
- “Equity” Recommendations<sup>5</sup> approved at 12/21/21 OPAB meeting.
- 2/10/22: Recommend that prior to a psilocybin administration session, a facilitator will work with a client to develop a transportation plan for when the psilocybin administration session ends. A facilitator will not authorize a client to operate a vehicle after completing a psilocybin administration session. If previously arranged transportation is not available after the administration session, the facilitator will help the client make other arrangements, prioritizing the client’s safety and well-being. The facilitator will not be held responsible for a violation of this requirement if they take reasonable steps to discourage the client from driving.
- 2/10/22: Recommend adoption of content for client information form in Appendix G. (Recommendation amended during 6/22/23 OPAB meeting to reformat content as yes/no questions.)
- 3/10/22: Recommend risk assessment framework to assess client suitability for psilocybin services.<sup>6</sup> (Recommendation amended during 6/22/23 OPAB meeting to reconcile content with intake form and remove items that exceed scope of practice.)
- 3/10/22: Recommend safety plan framework for clients receiving psilocybin services.<sup>7</sup>
- Training, 3/10/22: Recommend the following integration framework:  
Integration, as defined in the measure, will take place ~~as a single~~ **in at least one** session. A facilitator shall not engage in any activities with a client during the integration session that would require credentialing or licensure beyond the provider’s Psilocybin Facilitator License. A facilitator may connect a client to further services, outside the regulated psilocybin service framework, in support of a client’s ongoing integration needs. A facilitator may also self-refer a client to supportive services outside the regulated psilocybin service framework when the facilitator is credentialed or licensed to provide those services. An example would be a facilitator

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<sup>1</sup> See Appendix A for full text of recommendations

<sup>2</sup> See Appendix A for full text of recommendations

<sup>3</sup> See Appendix A for full text of recommendations

<sup>4</sup> See Appendix B for full text of recommendations

<sup>5</sup> See Appendix D for full text of recommendations.

<sup>6</sup> See appendix J for full text of risk assessment framework

<sup>7</sup> See appendix J for full text of safety plan framework

who is also a licensed psychologist and, after the formal integration session, self-refers a client to ongoing “integration therapy.”

### Products Subcommittee

- 9/23/21: Limit species to *P. Cubensis*
- 9/23/21: Direct Authority to review allowable species every 12 months
- 9/23/21: Limit production to cultivation of fruiting bodies and mycelium
- 9/23/21: Direct Authority to review allowable cultivation methods every 12 months
- 9/23/21: Prohibit use of dung and woodchips as cultivation substrate
- 9/23/21: Permit psilocybin extracts as allowable product type.
- 10/14/21: Prohibit manufacturing by chemical synthesis
- 10/14/21: Allow psilocybin to be combined with food products
- 10/14/21: Prohibit psilocybin products combined with alcoholic beverages or cannabis
- 10/14/21: Direct OHA to reevaluate all subcommittee recommendations beginning in January 2024 and at regular 12 month intervals
- 11/17/21: Equity Recommendations<sup>8</sup>
- 2/3/22: Recommend that drivers carry a manifest when transporting psilocybin products that identifies the products in transit, chain of custody, point of origin, destination and vehicle information and that psilocybin products be stored in a locked container
- 1/6/22: Recommend that labels display the following information: species, health and safety information, serving size, harvest date, unique id, food ingredient, substrate, solvents, activation time, ~~potency~~ **concentration** (quantity of psilocybin), number of servings, manufacturer info, QR code, tissue type (fruiting body vs. mycelium) and allergen information.
- 2/3/22: Require manufacturers to identify ‘best if used by’ dates for all products and include that information on the package.
- 2/3/22: Require that manufacturers determine ‘best if used by’ dates based on industry standards and reliable scientific evidence.
- 2/3/22: Recommend that OHA gather quantitative data on degradation rates of psilocybin products and factors leading to psilocybin degradation.
- 2/3/22: Require that psilocybin products be packaged in child proof packaging that does not leach harmful chemicals. 1/6/22: Recommend that OHA adopt rules to standardize psilocybin concentration in milligrams for all product types.
- 2/3/22: Recommend that manufacturers assign unique identifying numbers for each phase of cultivation (spore, inoculated substrate, and fruiting body or hyphae production) and associate those unique identifying numbers to volumetric units of substrate or liquid media.

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<sup>8</sup> See Appendix C for full text of recommendations

### **Research Subcommittee**

- 2/24/22 Dosage and Duration:
  - The maximum concentration of psilocybin per serving shall be 25 mg/serving.
  - The number of servings permitted in a psilocybin product package shall not exceed 1 serving total, though a product package may be subdivided into amounts that are less than one serving (1 serving = 25 mg).
  - Typical administration session doses should be 20-30 mg (approximately 1 serving). Administration doses less than or greater than approximately 1 serving should be specifically discussed.
  - The unique potential risks associated with substantially greater than >1 serving within a session, or repeated (defined as >5) administrations shall be specifically discussed with the client and that discussion shall be documented.

### **Equity Subcommittee**

- 1/21/22: Recommend that OHA require applicants submit a social equity plan as a condition of licensure.<sup>9</sup>
- 9/9/21: Require that licensees create and maintain an equity plan. (Licensing and Equity subcommittees adopted identical recommendations.)
- 12/17/21: Recommend that OHA prohibit the mixing of psilocybin products by facilitators and service center staff with:
  - Homemade food products
  - Pre-packaged non-intoxicating products, including but not limited to dietary supplements and nutraceuticals (excluding food products and filtered water)
  - Prescription and over-the-counter drugs
  - Pre-packaged and homemade sub-intoxicating products including but limited to hemp-derived cannabis products and cannabinoids.
  - Pre-packaged and homemade intoxicating products including but not limited to adult-use cannabis products, home grown cannabis, other hallucinogens, or beverage alcohol

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<sup>9</sup> See appendix F for full text of social equity framework

## Licensing Subcommittee

- 9/23/21: Recommend that to protect client privacy, service center operators shall not utilize audio, photo, or video surveillance within areas of a service center where clients are permitted, **without client's written informed consent which may be rescinded at any time.**
- 9/23/21: Recommend that when not being used during an administration session, all psilocybin products shall be stored within a locked room or safe. Only designated employees of the service center shall access the locked room or safe. Photo and video surveillance of the exterior and interior of the locked room or safe shall be permitted to the extent that it runs no risk of recording clients in areas where clients are permitted
- 10/7/21: Recommend that facilitators must have a reliable means to access emergency services at service centers.
- 10/7/21: Require that service centers be inspected prior to licensure.
- 10/7/21: Require that service centers submit safety and security plans as a part of their license application
- 11/4/21: Require OHA to offer endorsements with lower licensing fees for manufacturers that cultivate or produce psilocybin products on a smaller scale.
- 11/4/21: Recommend that OHA shall adopt rules that allow manufacturers to share facilities or equipment with the goals of reducing operating expenses and increasing accessibility.
- 12/2/21: Recommend that OHA shall allow psilocybin service centers to operate within, adjacent to, or adjoining an unlicensed business or organization provided that a substantial physical barrier, such as a fence, wall, or door, separates the space designated as a service center from the space that is used for the unlicensed business or organization in a manner that ensures client comfort, safety, and privacy. Unlicensed business or organization means a business or organization that is not licensed under Measure 109
- 12/2/21: Recommend that OHA shall not prohibit psilocybin service centers from operating within manufactured structures, non-commercial buildings, outdoor or other non-conventional spaces, or related structures provided that the facilities meet other requirements for licensed psilocybin service centers.
- 1/6/22: Recommend that the minimum video retention period of 30 days for required video recording.
- 9/23/21: Recommend that to protect client privacy, service center operators shall not use license plate readers, ID scanners, face recognition, behavioral analytics software, or related surveillance or biometric technology inside service centers, on properties where service centers are located, within service center parking lots, or in areas adjacent to these locations.
- 8/26/21: Require that an additional facilitator be on call for individual administration session.
- 8/26/21: Define "on call" to mean that the facilitator on call can be present at the service center within 20 minutes.
- 8/26/21: Recommend that administration sessions may be held outdoors.
- 9/9/21: Require an additional license representative to be present at the service center during administration session. This person need not be a licensed facilitator.
- 12/2/21: Recommend that a client's licensed facilitator shall always be present in the facilitation room or area and shall continuously monitor the client for the duration of an administration session. The only permitted exceptions shall be short restroom or meal breaks in which the

- client or facilitator temporarily steps out of the treatment room or area. Facilitators shall only take such breaks when the client is safe and comfortable. During short breaks, a second staff person shall monitor the client. Facilitators shall remain on the premises during meal breaks.
- 8/26/21: Recommend that group administration sessions be permitted subject to rule requirements.
  - 9/9/21: Recommend that during outdoor administration sessions, facilitators have a duty to ensure client safety comfort and privacy. The responsibilities associated with this duty included, but are not limited to:
    - Facilitators must take all reasonable efforts to ensure that areas where outdoor psilocybin administration occurs are free of reasonably foreseeable hazards that may cause physical or psychological harm or distress to clients.
    - Facilitators should ensure that outdoor areas are accessible to people with disabilities.
    - Except during client bathroom breaks, facilitators must ensure that all clients remain within visual range of a facilitator.
  - 11/4/21: Recommend that before a psilocybin product is dispensed to a client, the client shall be provided with a product information sheet that includes all label information in an easy-to-read format. Alternates to the standard product information sheet shall be made available to clients with disabilities.
  - 11/4/21: Recommend that psilocybin product labels shall contain an easily recognizable symbol or warning that indicates that they contain psilocybin.
  - 11/4/21: Recommend that The OHA should review psilocybin product labels before products are offered for sale.
  - 11/4/21: Recommend that the ingredients of psilocybin products should be included on all product labels in a manner consistent with current U.S. food labeling practices. Additional information such as dosage, solvents used, and the potential for potentiation or attenuation of psilocybin effects shall also be listed. Common allergens shall be listed in bold at the top of each label.
  - 11/4/21: Recommend that licenses issued by the OHA under Measure 109 shall not be transferrable.
  - 10/21/21: Recommend that once licenses are accepted, the Licensing Subcommittee ~~should take on the role of licensing oversight, which~~ will review licensing requirements on an ongoing basis and make recommendations to the OHA. As with all OPAB subcommittees, OPAB members may submit a request to join the Licensing Subcommittee.
  - 10/21/21: Recommend that OHA adopt the following language on license penalties: Denial, suspension, or revocation of licenses; restrictions on admission; penalties.
    - (1) The Oregon Health Authority may assess a civil penalty and, pursuant to ORS 479.215, shall deny, suspend, or revoke a license, in any case where the State Fire Marshal, or the representative of the State Fire Marshal, certifies that there is a failure to comply with all applicable laws, lawful ordinances and rules relating to safety from fire.
    - (2) The authority may:
      - (a) Assess a civil penalty or deny, suspend, or revoke a license of psilocybin manufacturer, testing laboratory, service center, or facilitator in any case where it finds that there has been a substantial failure to comply with ORS [sections that pertain to Measure 109].
      - (b) Suspend or revoke a license issued under ORS [sections that pertain to Measure 109] for failure to pay a civil penalty imposed under ORS [relevant sections].

- 10/21/21: Recommend that a psilocybin service center, or person acting in the interest of the center, may not take any disciplinary or other adverse action against any employee or facilitator who in good faith brings evidence of inappropriate care or any other violation of law or rules to the attention of the proper authority solely because of the employee or facilitator's action as described in this subsection.
- 10/21/21: Recommend that OHA adopt the following language on license responsibility: Service center staff and bylaws; rules.
  - (1) The licensee of a psilocybin service center shall be responsible for the operation of the facility, the selection of the staff and the quality of services rendered in the facility. The governing body shall:
    - (a) Ensure that all personnel for whom state licenses, registrations or certificates are required are currently licensed, registered or certified;
    - (b) Ensure that psilocybin facilitators licensed to practice in the facility are granted privileges consistent with their individual training, experience and other qualifications;
    - (c) Ensure that procedures for granting, restricting and terminating privileges exist and that such procedures are regularly reviewed to ensure their conformity to applicable law;
- 8/26/21: Allow group administration sessions without limiting the total number of clients in a group, provided that the service center is compliant with building occupancy and other applicable state and local requirements.
- Licensing, 1/6/22: Recommend maximum client to facilitator ratio for group sessions of 8:1 for perceptual doses and 10:1 for subperceptual doses and **require back up facilitator who is able to be present at the service center within 15 minutes.**<sup>10</sup>
- 1/6/22: Recommend that to reduce costs and increase the accessibility of psilocybin services in Oregon:
  - Group preparation sessions shall be permitted;
  - Facilitators shall be permitted to conduct individual and group preparation sessions remotely, provided that the client agrees and has opportunities for one-on-one interaction with the facilitator;
  - Group integration sessions shall be permitted and
  - Facilitators shall be permitted to conduct individual and group integration sessions remotely, provided that the client agrees and has opportunities for one-on-one interaction with the facilitator.
- Licensing, 1/6/22: Recommend that to promote equity and accessibility, while keeping costs down for facilitation students and training programs candidates for facilitator licenses:
  - Shall be permitted to complete all portions of core facilitator training online through either synchronous or asynchronous learning;
  - Shall be permitted to complete up to 50% of practical facilitator training online through synchronous or asynchronous learning; and
  - Shall be permitted to complete 100% of practical facilitator training online if at least 50% of the practical training is completed synchronously.
- Licensing, 9/9/21: Recommend requiring fiduciary duties of loyalty, care and confidentiality that facilitators owe to clients.

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<sup>10</sup> Note: License SC recommended 3:1 ratio on 8/26/21; that recommendation was rejected at 5/25/22 OPAB

- 12/2/21: Recommend that supportive touch, such as holding a client's hand or placing a hand on a client's shoulder, shall be permitted provided that the informed consent of the client has been appropriately obtained and documented before the administration session begins. Sexual or romantic contact between facilitators and clients or contact that may reasonably be construed as sexual or romantic, shall be prohibited and shall be grounds for an investigation and potential license revocation.
- 1/6/22: Adopt 1/2/22 draft of the ethical principles/code of conduct for psilocybin facilitators for consideration by the full Psilocybin Advisory Board.<sup>11</sup>
- 10/21/21: Recommend that the Client Bill of Rights should be posted in a prominent place visible to clients in every service center.<sup>12</sup>
- 12/2/21: Recommend that clients may leave an administration session before it has concluded. However, in such cases, the facilitator shall advise the client that they are leaving before the session has concluded (against the advice of the facilitator), record this information in the client record, ask the client to sign a form acknowledging that they are leaving against the facilitator's advice, and take reasonable efforts to ensure that the client has a trusted person transport them home safely. Though clients may leave an administration session before it has concluded, facilitators may not prematurely conclude an administration session. An administration session is concluded prematurely if continuing the session is necessary to ensure the safety of the client and the public.
  - 12/2/21: Recommend that the client informed consent document shall be updated to inform clients of the requirements of the preceding motion as part of the informed consent process.
- 11/4/21: Approve draft informed consent document presented during meeting and move the document to the full Psilocybin Advisory Board for consideration.<sup>13</sup>
- 12/2/21: Recommend that to reduce the costs associated with psilocybin services, and maximize accessibility of the Oregon model, there shall be no minimum or maximum duration for administration sessions. The length of each administration session may depend on several factors such as the dose and type of psilocybin products administered, the goals of the client, whether the client has trustworthy transportation to take them home, and the degree to which the administered psilocybin products are affecting the client's physical abilities and cognitive function. Considering these factors, the facilitator shall determine when an administration session has concluded, and if, in the facilitator's professional judgement, continuing an administration session is unnecessary to ensure the safety of the client and the public, then the facilitator may conclude the administration session and shall record the time at which the session concluded in the client record. Framing the required duration of administration sessions in this manner leaves room for the administration of subperceptual doses of psilocybin products while allowing administration sessions to be completed in less time (compared to the time required to complete sessions in which higher doses of psilocybin products are administered).
- 10/7/21: Recommend that there be no waivers for the licensing exam.
- 10/21/21: Require that to receive a psilocybin facilitator license, candidates must pass a multiple-choice exam (the licensing exam) that evaluates knowledge of concepts included in the

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<sup>11</sup> See Appendix E for code of conduct document

<sup>12</sup> See Appendix J for complete text of Client Bill of Rights as adopted by OPAB 5/25

<sup>13</sup> See Appendix D for informed consent document

training curriculum, the text of Measure 109, documents produced by the licensing subcommittee, and rules adopted by OHA.

- 10/21/21: Recommend that the licensing exam should be developed and maintained by OHA and OPAB and its subcommittees. The Licensing Subcommittee may seek the advice of outside experts who may contribute to the process as needed.
- 10/21/21: Recommend that candidates should be permitted to take the licensing exam at home using remotely proctored administration software that protects candidate privacy and is accessible to people with disabilities.
- 10/21/21: Recommend that the licensing exam should be made available in multiple languages and in alternate formats that promote accessibility.
- 10/21/21: Recommend that the cost of registering for the licensing exam should be no higher than is necessary to maintain the testing program, and fee waivers should be offered to increase accessibility

## **Appendix A—Training Subcommittee Recommendations Adopted by OPAB on 11/17/21**

### DEFINITION

*For Training Subcommittee recommendations, the terms “program” and ‘training program’ shall mean a comprehensive training program.*

### ADMINISTRATION RECCOMENDATIONS

1. *As part of their enrollment and application process, training programs shall require applicants to submit information and materials that include, but are not limited to, a signed authorization permitting the program to conduct a criminal background check, letters of reference, a description of educational background, and a written statement demonstrating commitment to entering the field and serving the community with integrity.*

2. *Programs shall provide Core Training that consists of at least 120 hours. At least 25% of Core Training hours shall take place in an in-person teaching format. At least 50% of Core Training not conducted in-person shall be conveyed through online synchronous learning. Synchronous Learning means that students learn from their instructor at the same time as their fellow students.*

3. *Core Training will devote specified minimum hours to each of the following subject areas:*

- *Historical, Traditional, and Contemporary Plant Medicine Practices and Applications (12)*
- *Diversity, Equity, and Inclusion in relation to Psilocybin Services (12)*
- *Safety, Ethics and Responsibilities of a Psilocybin Facilitator (10)*
- *Psilocybin Pharmacology, Neuroscience, and Clinical Research (12)*
- *Core Psilocybin Facilitation Skills (16)*
- *Conducting a Psilocybin Preparation and Orientation Session (16)*
- *Conducting a Psilocybin Administration Session (20)*
- *Conducting Psilocybin Integration (14)*
- *Group Psilocybin Facilitation (8)*

4. *Programs shall require students to complete practicum training. The goal of practicum training is to provide students the opportunity to facilitate and observe the facilitation of non-ordinary states of consciousness. Over time, and as the number of licensed Service Centers and qualified supervisors allows, practicum training shall include placement at a Practicum Site where students shall observe and facilitate psilocybin services under the supervision of a Practicum Site Supervisor. In cases in which a*

*Practicum Site is not reasonably available or accessible to students, a training program will identify and facilitate alternative training for students to fulfill the practicum requirement and describe to the Oregon Health Authority how this alternative training reasonably approximates training at a Practicum Site. Students shall complete a minimum of 40 hours of practicum training, including at least 30 hours of direct practice, and at least 10 hours of consultation relating to the student's direct practice.*

*a. Practicum Site: A licensed Psilocybin Service Center or other designated site approved by the Oregon Health Authority to provide practicum training.*

*b. Practicum Site Supervisor (Site Supervisor): An onsite practicum supervisor of assigned trainees, affiliated with a Practicum Site. It is the primary responsibility of the Site Supervisor to develop the trainee's practicum skills and evaluate a trainee's practicum performance, focusing on direct services with clients / participants.*

*5. Partial Training Programs may be approved by the Oregon Health Authority to offer specific Core Training to students while not providing all Core Training. Partial Training Programs must clearly identify to prospective students that they do not offer all required Core Training. If a program grants Accelerated Training hours to students, it must also accept transfer credits from Partial Training Programs. Partial training programs are not subject to the requirement that their students complete practicum training. 14*

*6. Training programs can either categorically accept or not categorically accept transfer hours from all Partial Training Programs. Training programs cannot accept transfer hours from one or some Partial Training Programs while denying transfer hours from others. 15*

*7. Comprehensive training programs shall have more than one Lead Educator on staff. All presenters of the curriculum affiliated with a training program, whether Lead Educators, contracted specialists, or guest speakers, shall have significant relevant experience and/or education in the subject areas on which they are presenting. Partial Training Programs are not required to have more than one Lead Educator.*

*a. Lead Educator: An educator affiliated with a training program who provides Core Training to students and tracks the progress of students throughout the program.*

*8. Each training program shall identify a Program Director who has authority to confer student enrollment and program completion.*

*9. Training programs shall maintain a level of training for students such that students who successfully complete the program's training could reasonably expect to possess the knowledge and skills required to pass the state licensing exam and practice in good standing as a licensed facilitator.*

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14 Equity subcommittee considered an identical recommendation on 11/3/21

15 Equity subcommittee considered an identical recommendation on 11/3/21

10. *Training programs shall train students in CPR and First Aid or ensure that students have current certification prior to program completion.*

## CURRICULUM RECCOMENDATIONS

1. *Programs shall provide students with an overview of historical and current views and practices involving the role of fungi and plant medicines in various wisdom traditions, including indigenous and shamanic traditions, and in identifying the key differences and shared principles across cultures in relation to plant medicine use.*
2. *Programs shall train students in the ethical dimensions around working across diverse social locations and cultures, while highlighting the potential for psilocybin services to address and redress inequities and stigma resulting from the current structure of health care systems and delivery of healthcare services, particularly in relation to BIPOC community members and persons who, through identity, experience, or geography, have lacked meaningful access to behavioral health and wellness care.*
3. *Programs shall train students in pharmacology related to psilocybin, supporting students to understand:*
  - *Pharmacodynamics and pharmacokinetics of psilocybin*
  - *How various medications and supplements, including MAO inhibitors and SSRI's, can interact with psilocybin*
  - *The metabolism of psilocybin and psilocybin products*
4. *Programs shall train students in basic neuroscience relating to psilocybin, supporting students to understand:*
  - *The concept of neuroplasticity and neurogenesis*
  - *The primary effects of psilocybin on the brain, including connectivity in and between areas in the brain, such as effects on the Default Mode Network*
  - *Current theories on mechanisms of action of psilocybin*
5. *Programs shall train students in key areas of research, including, but not limited to:*
  - *Depression and Treatment Resistant Depression*
  - *Substance Use Concerns*
  - *End of Life / Palliative / Existential Distress*
  - *Anxiety*
  - *Trauma*
  - *Spirituality*
  - *Enhancements relating to measures of wellness, such as well-being, pro-social behavior, creativity, eco-mindedness, openness, and connectedness*
  - *Emerging research in the field*

6. *Programs shall train students on the Oregon Psilocybin Services Act and related laws, regulations, and professional standards as they pertain to the rights and ongoing professional obligations of licensed Facilitators.*
7. *Programs shall train students to develop an awareness of personal motives for doing this work, with an understanding of problematic motives.*
8. *Programs shall train students in ethical issues related to psilocybin facilitation, following Oregon's Facilitator Code of Ethics.*
9. *Programs shall train students to demonstrate an awareness of ethical considerations relating to equity and reciprocity, including an understanding of what cultural appropriation means and its impact in people's lives.*
10. *Programs shall train students in how to prepare clients for psilocybin use in a manner that ensures informed consent, safety planning, and promotes an understanding of the boundaries between the facilitator and the client.*
11. *Programs shall train students to recognize their scope of practice, how to relate scope of practice to a Client Information Form, how to identify clients in need of referral to specialized treatment services, and how to provide such referrals in a timely manner.*
12. *Programs shall train students to have the capacity to evaluate a standardized Client Information Form to help determine whether and under what circumstances a client is an appropriate candidate for psilocybin services, what should be included in safety planning, and whether a client's needs fall under a facilitator's scope of practice.*
13. *Programs shall train students to have the capacity to conduct an intake interview for the purpose of establishing a trusting alliance with a client and evaluating a client's readiness for psilocybin services.*
14. *Programs shall train students to determine a client's goodness of fit with a facilitator, based on information on a standardized Client Information Form, a facilitator's scope of practice, the strength of the alliance between the client and facilitator, and a facilitator and client's assessment of the appropriateness of psilocybin services for the client at the current time.*
15. *Programs shall train students to understand various dosing strategies and considerations, taking into account:*
  - *Experiential differences relating to differing dosages*
  - *Physiological considerations in relation to dosage*
  - *Delivery mechanisms of psilocybin*
  - *Use of secondary doses*



16. Programs shall train students in the foundations of traumatic stress (individual and systemic), including how it's stored in the body, how it can manifest during the psilocybin experience, and what to do in these circumstances. Programming will help students to:

- Understand that trauma is embedded in the body
- Identify repressed trauma rising to the surface of consciousness during a psilocybin experience
- Identify intergenerational trauma and traumatic stress resulting from systemic oppression
- Create safety for trauma resolution
- Understand the risks associated with re-traumatization resulting from the psilocybin experience
- Use self-regulatory skills in response to a client's trauma reaction

17. Programs shall train students in skills needed to serve as an empathic presence for clients, including an ability to sustain a nondirective facilitation approach and a nonjudgmental and accepting disposition, to suspend attention evenly over the course of a session, to communicate clearly and compassionately, to respond to distress with calmness, and to monitor interpersonal boundaries.

a. *Nondirective Facilitation: An approach to facilitation in which the facilitator maintains a consistent, warm, and affirming disposition with a client, while avoiding giving the client direct advice or directly interpreting a client's statements or behaviors. The goal of nondirective facilitation is for clients to discover things about themselves for themselves with minimal guidance from a facilitator. Pace and direction is controlled by the client. An exception would be when safety is at stake, at which point it may be incumbent on a facilitator to become directive in the service of safety.*

18. Programs shall train students to identify and facilitate a variety of subjective psilocybin experiences, including experiences relating to bodily sensations, cognitive processes, emotional states, spiritual and mystical states, and traumatic memories.

19. Programs shall train students to demonstrate skills necessary to safely and effectively facilitate non-ordinary states of consciousness during a personal process of transformation, including, but not limited to:

- Reflective listening
- Discerning when to intervene and when to step back during a client's experience
- Resisting the urge to impose meaning upon a client's experience
- Ethically navigating power differentials between facilitator and client
- Demonstrating a capacity to create a safe container for difficult or intense thoughts, emotions, and experiences
- Understanding when and how a client may need additional support or a higher level of care

20. *Programs shall train students to develop an understanding of the optimal use of environmental components within a psilocybin administration session, including, but not limited to, space, lights, smells, decor, comfort, access to bathroom, and minimization of outside-session distractions.*

21. *Programs shall train students in a trauma-informed manner on how to safely manage and reduce potential harms related to difficult or adverse behavioral or medical responses that may arise as a result of psilocybin ingestion.*

- a. *Adverse Behavioral Response means behavior engaged in by a*
- b. *client during an administration or integration session that endangers*
- c. *the safety of the client, the Facilitator, or others whom the client encounters or may reasonably encounter.*
- d. *Adverse Medical Response means a physiological reaction of a client during an administration session the continuation of which could lead to medical harm.*

22. *Programs shall train students to develop characteristics and skills related to effectively working with challenging behaviors during session, such as:*

- *Calmness*
- *Empathic presence and nonjudgmental listening*
- *Non-directive communication skills*
- *Knowing when and how to be directive in support of safety*
- *Recognizing signs of medical distress and knowing when and how to seek support if there are safety concerns beyond the facilitator's scope of practice*

23. *Programs shall train students to demonstrate an understanding of skills, processes, and criteria involved in completing a psilocybin administration session, including an ability to discern when and how to initiate and document completion of the administration session, and how to facilitate this transition with a client.*

24. *Programs shall train students on proper integration tools, techniques, and resources available to help clients process their psilocybin experiences.*

25. *Programs shall train students to articulate the goals of an integration session, including, but not limited to:*

- *Exploration of negative feelings from psilocybin session*
- *Facilitation of positive internal and external changes*
- *Enhancement of existing supportive relationships*
- *Maintenance of trust and positive connection between client and facilitator*

26. *Programs shall train students to use open-ended questions that support effective integration, including those relating to:*

- *Memories from the psilocybin experience*
- *Positive and challenging aspects of the psilocybin experience*
- *Role of previously identified intention during the experience*
- *How the experience might affect a client's relationships*
- *How the client can incorporate new insights and breakthroughs into daily life*

27. *Programs shall train students to demonstrate skills required to facilitate an effective and safe psilocybin group session, including, but not limited to:*

- *Screening a participant for compatibility with group format*
- *Facilitating group rapport*
- *Establishing a sense of safety within the group*
- *Discussing group agreements, including confidentiality, boundaries, ethics, and communication rules*
- *Facilitating group cohesion, belonging, and safety*
- *Identifying when an individual within a group requires one-to-one support, removal from a group, or additional intervention*

#### SUPPLEMENTARY RECCOMENDATIONS

1. *Programs shall train students on maintaining appropriate boundaries between facilitators and clients, the risk of emotional and sexual abuse, the potential harm to clients, and the consequences for facilitators.*

2. *Programs shall train students in professional ethics, including fraud, financial exploitation, the risks of financial conflicts of interest, and when and how to disclose those conflicts.*

3. *Programs shall train students on the importance of accurate record keeping and how to maintain appropriate client records including the importance of maintaining client privacy and data security.*

4. *Programs shall train students in the fiduciary duties that facilitators owe clients and the consequences of breaching those duties.*

5. *Programs shall train students to understand and explain all aspects of the client informed consent form and the appropriate timing and procedures for obtaining informed consent from clients.*

6. *Programs shall train students to understand and explain the client bill of rights and the related responsibilities of facilitators.*

7. *Programs shall train students in the legal requirements of Oregon's Measure 109.*

8. *Programs shall train students on how to proactively make psilocybin services accessible to people with disabilities.*

*9. Programs shall train students on appropriate handling, storage, and dispensing of psilocybin products.*

*10. Programs shall train students in appropriate emergency procedures for obtaining medical assistance for clients and assisting vulnerable clients during emergencies.*

## **Appendix B—Equity Subcommittee’s Training Recommendations Adopted by OPAB on 11/17/21**

### **MOTIONS:**

#### EQUITY IN CORE MATERIALS (See attached document for detail and defintions)

- 1) *Orient learners to the meanings of cultural equity and racial justice, and to the ethics of relational care and reciprocity, and use these core competencies as the framework to develop and present all core modules.*
- 2) *Teach “cultural equity” as a core module, and include in this module a historical accounting of systemic inequity and intergenerational trauma.*
- 3) *Teach “historical, traditional knowledge and practices” as a core module.*
- 4) *Teach Trauma Informed Care, broader concepts of trauma including s the physiology of trauma, and how physiology generally shapes all experiences including the experience of trauma.*
- 5) *Teach community- and self-care, addressing vicarious trauma, vicarious resilience, empathic stress, compassion fatigue, and compassion satisfaction.*
- 6) *The Psilocybin Services Program, by rule or by policy, should orient Facilitator Training Programs and their learners to Measure 109 and its impacts on and intersection with Measure 110.*
- 7) *Require training in basic CPR for all facilitators and look into the opportunities and implications of dual tracking with Traditional Health Workers or Community Health Workers.*

#### STUDENT MASTERY OF EQUITY IN CORE MATERIALS (See attached doc for detail and defintions)

- 1) *Recommend that OHA require training programs to have a means to measure student proficiency in cultural equity, racial justice, and the ethics of relational care, and reciprocity*

## Appendix B—Equity Subcommittee Recommendations Adopted by OPAB on 11/17/21

### DETAIL:

General question to consider: How do we institutionalize and codify the ways in which Facilitator Training Programs demonstrate equity?

Note: items highlighted indicate terms or concepts requiring further development. Additional notes and details about these items can be found in the footnotes that accompany them.

### Ensuring Equity In Core Materials

OAR should require Facilitator Training Programs to:

- Orient learners to the meanings of **cultural equity**<sup>1</sup> and **racial justice**<sup>2</sup>, and to the ethics of relational care and reciprocity, and use these core competencies as the framework to develop and present all core modules.
- Teach “cultural equity” as a core module, and include in this module a historical accounting of systemic inequity and intergenerational trauma, particularly highlighting:
  - Cultural equity and its relationship to **health equity**<sup>3</sup>
  - Cultural equity and its relationship with environmental and racial justice
    - The rationalization of the Controlled Substances Act of 1970 and psilocybin prohibition
    - The War on Drugs of 1971 including who it impacts and its effects on cultural and health equity today
    - Social power and privilege, their misuse, and who they impact and their effects on cultural and health equity today
  - **Decolonization**<sup>4</sup> and **cultural appropriation**<sup>5</sup>

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“Cultural equity” means [the embodiment of values, policies, and practices that ensure that all people, especially those who have been historically marginalized based on race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances, are represented in the development of social pathways to health

equity] <sup>2</sup> “Racial justice” means [the restitutive fairness in the treatment of racially marginalized people by way of eliminating discriminatory and systemic barriers and creating new pathways for the same in order to ensure health equity for people of all races] <sup>3</sup>

“Health equity” means [the assuredness of access to full health and wellbeing for all people despite differences and disadvantages created by designations of race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances]. See [OHA’s definition of Health Equity](#). <sup>4</sup>

“Decolonization” means [unlearning the thinking, practices, and societal systems that assert western superiority over traditional and Indigenous governance, knowledge and practices. Decolonization requires dismantling systems and structures that assert power and control, and cause harm by the dominant culture, making repairs for the damages done, and returning to a culture which honors and centers Indigenous sovereignty and justice]

- Teach “historical, traditional knowledge and practices” as a core module and include in this module the following topics:
  - Historical, traditional knowledge and practices including: origin, Indigenous lineage, ceremonial and other traditional practices across cultivation and preservation, harvesting and preparation, and administration and experience
    - The impact of historical, traditional knowledge and practices on today’s modes and standards of use
    - Western exposure and 20th century research, study, and practices
- Cover **Trauma Informed Care**<sup>16</sup>, broader concepts of trauma including the physiology of trauma, and how physiology generally shapes all experiences including the experience of trauma.
- Cover community- and self-care, addressing vicarious trauma, vicarious resilience, empathic stress, compassion fatigue, and compassion satisfaction.

The Psilocybin Services Program, by rule or by policy, should orient Facilitator Training Programs and their learners to Measure 109 and its impacts on and intersection with Measure 110.

The Psilocybin Services Program, by rule, should require training in basic CPR for all facilitators and look into the opportunities and implications of dual tracking with Traditional Health Workers or Community Health Workers.

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<sup>16</sup> “Trauma Informed Care” means [ ] vs. “Trauma Focused Care” which means [ ]

## Ensuring Student Mastery of Equity in Core Materials

OAR should require that Facilitator Training Programs:

- Have a means to measure student proficiency in cultural equity, racial justice, and the ethics of **relational care**<sup>17</sup> and reciprocity. Proficiency should demonstrate the following:
  - Value and respect for cultural, individual, and role differences, including those due to race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances.
  - Awareness and knowledge of cultural equity and racial justice, the difference between the two, and the meaning of inclusion, including contextual and systemic dynamics related to inequities due to race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances.
  - Awareness and skills to become accountable and create **repair**<sup>18</sup> when they have misused or abused their privileges due to race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances.

## Ensuring Equity in Program Business and Operating Practices

OAR should require that Facilitator Training Programs:

- Develop and maintain **social equity plans**<sup>19</sup>—plans encompassing internal and external equity strategies—as a condition of approval. Social equity plans should, at minimum, present a well-defined mission and describe the ways Programs will 1) integrate equity (e.g., DEI) throughout their internal practices, policies, and programming; 2) participate in and support the Psilocybin

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17 “Relational care” means [to support the personal needs, growth, and wellbeing of others, particularly of those going through temporal crises such as houselessness, illness, marginalization, stigmatization, ostracization., etc.]

18 Some models of repair include, but are not limited to, [ ]

19 Criteria and administrative oversight details TBD

Service Program's equity efforts; and 3) monitor, measure, and report against proposed key performance indicators.

- Advise new trainers applying to their Programs to demonstrate through their CV how they have been involved in promoting equity, diversity and inclusion and list what they have done in these areas.
- Maintain continuing education for their leadership and staff in the areas of cultural equity, decolonization and racial justice.
- Meet social equity plan KPIs, maintain continuing education, report the evaluations of student proficiency in equity, and report student satisfaction assessments as a condition for Program renewal.

The Psilocybin Services Program, by rule or by policy, should prioritize the approval of Facilitator Training Programs that have a diverse group of trainers (according to race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances); and that have diversity target goals and strategies for the recruitment and retention of diverse staff trainers in their social equity plans.

## **Ensuring Equity in Economic Opportunity**

OAR should require that the Psilocybin Services Program:

- Prioritize Oregon-based and Oregon-owned Facilitator Training Programs, Programs that are owned by culturally marginalized people and those directly impacted by the War on Drugs, and Programs that demonstrate diversity in their trainers and staff. Programs that demonstrate all three criteria should have a highest priority for acceptance.
- Charge application fees to non-Oregon Programs that build a fund to support the development and maintenance of Programs owned by culturally marginalized people and those directly impacted by the War on Drugs so that these Programs may succeed.  
Examples of support include:
  - Grants and low interest rate small business loans
  - Technical assistance and business support services
- Require Programs to identify their business relationships and funding sources, including connections with venture capital.

## Ensuring Equity in Training Access

OAR should require that the Psilocybin Services Program:

- Charge application fees to non-Oregon Programs that build a fund to support culturally and economically disadvantaged students' enrollment in Facilitator Training Programs.

Examples of support include:

- Grants and scholarships

The Psilocybin Services Program, by rule or by policy, should work to provide access to Facilitator Training Programs through public and private sector agencies and organizations that offer free training programs available to culturally marginalized people.

OPAB should work to build connections and rapport with accreditation organizations so that in the future there may be federal accreditation of the Programs to provide access to federal student loan and grant money.

OAR shall require that Facilitator Training Programs:

- Offer translation services for programmatic documents and lectures for students for whom English is a second language, or offer reduced fees so students may purchase interpretation themselves.
- Offer academic and physical accommodation in Facilitation Training Programs for people living with disabilities to guarantee academic equity.
- Offer reduced fees for applicants with disabilities who are receiving state assistance.
- Offer other forms of experiential learning to those who are unable to undergo a facilitated psilocybin experience due to contraindicated medical conditions.

## Ensuring Equity in Community

The Psilocybin Services Program and OPAB should work to answer these additional questions:

- How does the Psilocybin Services Program integrate, support, and make accessible community-based peer support groups and networks for clients, facilitators, and Service Center staff, especially those consisting of culturally marginalized people?

- What role, if any, can the Psilocybin Services Program play in helping people, and especially those identifying as culturally marginalized, learn how to establish peer support groups to be made available for clients, facilitators, and Service Center staff?
- How does the Psilocybin Services Program facilitate connections between clients, facilitators, Service Center staff, Service Centers, and community-based peer support groups, and in a way that doesn't over professionalize community-based services?
- How are facilitators and Service Centers protected when referring clients to community-based peer support groups?
- How can the Psilocybin Services Program facilitate learning from and sharing with community-based peer support groups?

## **Appendix C—Equity Subcommittee’s Product Recommendations, Adopted by OPAB 11/17/21**

1. *Recommend that rules create a list of prohibited additives and ingredients.*
2. *Direct OHA and the Psilocybin Services Program to maintain a list, with scientific citations, of allowable and prohibited food, food ingredients, and additives that may potentiate, attenuate, or affect the onset of action or duration of action of psilocybin.*
3. *Recommend that administrative rules should make permissible, and carefully regulate and ethically examine, psilocybin product innovation, such as but not limited to innovations in formulation and routes of delivery, that improves accessibility to clients with disabilities, gastrointestinal intolerances, or other physical or mental barriers to ingestion.*
4. *Recommend that OHA “Make permissible, carefully regulate, and ethically examine additives that may be common or necessary in formulating products intended for variable routes of administration to ensure bioavailability, predictability, safety, shelf stability, and tolerability.”*
5. *Recommend that OHA “Make permissible, carefully regulate, and ethically examine manufacturing technologies such as but not limited to nanoemulsion techniques, or medical devices in the development of combination products (e.g., inhalers, transdermal patches, or suppositories) that may be common or necessary in formulating products intended for variable routes of administration to ensure bioavailability, predictability, safety, shelf stability, and tolerability.”*
6. *Recommend that OHA allow psilocybin products using the following delivery methods: ingestible, pulmonary, transmucosal, and transdermal.*
7. *Recommend that OPAB “Direct OHA and the Psilocybin Services Program to evaluate psilocybin products every twelve months beginning in 2024, and report:*
  - a. *Its findings regarding the cultural, economic, safety, and social impacts of currently allowable psilocybin products;*
  - b. *Its response to an accompanying annual public comment period;*
  - c. *The announcement of newly allowed or newly excluded psilocybin products, foods, food ingredients, or other additives;*
  - d. *A review of completed, ongoing, and prospective clinical trials and FDA approval status for natural and/or synthetic psilocybin products, and their implications on the Oregon Psilocybin Services Program; and*
  - e. *An analysis of the opportunities and limitations of allowing or excluding chemical synthesis in the manufacture of psilocybin products in the Oregon Psilocybin Services Program, and the cultural, economic, safety, and social impacts of those opportunities and limitations.*

8. *Recommend that OHA “Avoid prohibiting foods, food ingredients, or additives solely on the basis of being liable to potentiate, attenuate, or affect onset of action or duration of effect, as these effects are not inherently adverse.”*
9. *Recommend that OHA “Prohibit foods, food ingredients, or additives based on their liability to produce adverse effects, toxicity, and/or known and dangerous drug-drug interactions.”*
10. *Recommend that OHA “Prohibit concentrations of foods, food ingredients, or additives based on their liability, at or above that concentration, to produce adverse effects, toxicity, and/or known and dangerous drug-drug interactions.”*
11. *Recommend that OHA “Require the accurate labeling of all foods, food ingredients, and additives in psilocybin products, which should be accompanied by appropriate disclaimers such as potential potentiation or attenuation, acceleration or delay in onset, or shortened or extended duration of action of psilocybin.”*
12. *Recommend that the Products Subcommittee and Psilocybin Advisory Board examine harm-reduction considerations for products or substances clients may consume prior to, during, or after administration services.*
13. *Recommend that OHA “Make permissible ‘remediation’ pathways for over-production other than destruction such as: Supplying a non-profit Service Center, Supplying research studies, Further processing into shelf-stable forms for storage and distribution at a later date.”*
14. *Recommend that OHA “Allow the mixing of psilocybin products by facilitators and authorized Service Center staff with pre-packaged food products and filtered water.”*

## **Appendix D - Equity Subcommittee's Training Recommendations, Adopted by OPAB 12/21/21**

- 1) The "outline of instruction that training provides must submit as a condition of course approval shall include how the courses will be made accessible in addition to other equity accommodations and considerations. Considerations should include but are not limited to:
  - a) Offering translation services for program documents and lectures for students for whom English is a second language or offer reduced fees so students may purchase interpretation themselves.
  - b) Offering academic and physical accommodations for people living with disabilities to guarantee academic equity.
  - c) Offer reduced fees for applicants with disabilities who are receiving state assistance.
  - d) Offering other forms of experiential learning to those who are unable to undergo a facilitated psilocybin experience due to contraindicated medical conditions.
- 2) That the Psilocybin Services Program
  - a) Integrate, support and make accessible community-based peer support groups and networks for clients, facilitators and service center staff, especially those consisting of culturally and racially marginalized people.
  - b) Help people, especially those identifying as culturally and racially marginalized, learn how to establish peer support groups to be make available for clients, facilitators, and service center staff.
  - c) Facilitate connections between clients, facilitators, service center staff, service center, and community-based peer support groups in a way that doesn't over professionalize community-based services.
  - d) Identify way to protect facilitators and service centers when referring clients to community-based peer support groups. e. Facilitate learning from and sharing with community-based peer support groups.
- 3) That the Psilocybin Services Program should identify public and/or private sector agencies and organizations that cover the cost of training programs to culturally and racially marginalized people.
- 4) That the Psilocybin Services Program should identify pathways to federal accreditation for training programs to provide access to federal student loan and grant funds.

## **Appendix E—Proposed Informed Consent Document, 11/4/21**

### **INFORMED CONSENT TO RECEIVE PSILOCYBIN SERVICES**

#### Introduction:

In the State of Oregon, psilocybin services are delivered during three different sessions: preparatory, administration, and integration. You should receive this informed consent form at the start of your preparatory session. During the session, your facilitator will discuss the form with you. Please ensure that you read and understand every section because you must sign the form before the preparatory session concludes. If you do not understand any part of this document, please ask your facilitator for clarification before signing.

#### Statement on Data Collection:

While receiving psilocybin services, you may be asked to contribute information for research purposes. Efforts will be made to protect the security and confidentiality of your information, such as the deidentification of your data, consistent with standards of medical care and research. However, there is a risk the information could be used to identify you and reveal that you have received psilocybin services. If you agree to share your information, then data collected about you by your facilitator may be shared with people and institutions outside the psilocybin service center. If you would prefer that your information not be shared for these purposes, then you should not agree, and your information will only be shared if permitted or required by law. Your decision will not affect your ability to receive psilocybin services.

I have been informed of and understand the following:

(Please initial each item below)

1. \_\_\_\_ I have been provided with a copy of the Psilocybin Services Client Bill of Rights, my facilitator has explained it to me, and I understand my rights as a client.
2. \_\_\_\_ I understand that psilocybin services do not constitute medical diagnosis or treatment.
3. \_\_\_\_ I understand that Psilocybin has not been approved by the FDA for marketing as a drug, and the federal government currently classifies psilocybin as a Schedule I controlled substance.

- a. According to the Drug Enforcement Administration (DEA), Schedule I controlled substances have (1) a high potential for abuse; and (2) no currently accepted medical use.
  - b. Federal law prohibits the manufacture, distribution, and possession of psilocybin even in cities and states that have modified their laws to allow its possession or use.
  - c. Despite its federal Schedule I status, research suggests that psilocybin is very unlikely to be addictive. The Food and Drug Administration (FDA) has designated psilocybin a "breakthrough therapy" for major depressive disorder and treatment resistant depression, which means psilocybin may be a significant improvement over current FDA approved therapy. Additionally, randomized controlled clinical trials and peer reviewed medical literature suggest that psilocybin may improve symptoms of depression, anxiety, end of life distress, various forms of trauma, and problematic substance use. Participants also report improvements in mental and spiritual wellbeing.
4. \_\_\_\_ I understand that while existing research has shown promising results, the risks, benefits, and drug interactions of psilocybin are not fully understood, and individual results may vary. During clinical trials, participants may have received more preparatory, administration, and integration sessions, and clients should use caution when using the results of research to predict the nature of their experience when receiving psilocybin services.
  5. \_\_\_\_ I understand that some people find psilocybin administration sessions challenging and uncomfortable. Common potential side effects include mild and transient headache, fatigue, anxiety, confusion, increased blood pressure, elevated heart rate, paranoia, perceptual changes, altered thought patterns, reduced inhibitions, unmasking of repressed memories and traumas, and altered perception of time and one's surroundings. If they occur, these side effects are usually mild and temporary. However, because the potential risks and benefits of psilocybin administration are not fully understood, there may be unanticipated side effects.
  6. \_\_\_\_ I understand that less common, and potentially more serious side effects may include dizziness, fainting, and changes in heart rhythm (arrhythmia) such as QT prolongation.
  7. \_\_\_\_ I understand that if I am taking prescription medications or have a chronic medical condition including, but not limited to, heart disease, kidney disease, or liver disease, I should check with my doctor before being administered psilocybin.

8. \_\_\_\_ I understand that people diagnosed with certain mental health conditions, such as schizophrenia and bipolar disorder, may be at increased risk for serious side effects during or following the administration of psilocybin.
9. \_\_\_\_ I understand that some people are allergic to mushrooms, and psilocybin is sometimes derived from mushrooms. If I have a known mushroom allergy, I should check with my doctor before being administered psilocybin.
10. \_\_\_\_ I understand that the effects of psilocybin during pregnancy and breastfeeding are unknown.
11. \_\_\_\_ I understand that facilitators may use different types of touch while providing psilocybin services and that certain types of touch may be unavoidable. My facilitator has had a thorough discussion about which types of touch are acceptable to me prior to the start of my psilocybin administration session.
12. \_\_\_\_ I understand that if I disclose instances of child or sexual abuse to my facilitator, or information that may put me or another person at risk of imminent harm, my facilitator may be required by law to report my statements to police and other authorities.
13. \_\_\_\_ I agree not to drive, operate heavy machinery, or engage in any activities that require alertness or quick responses for at least 24 hours after psilocybin administration.
14. \_\_\_\_ I understand that being administered psilocybin is completely voluntary and I may decide not to receive psilocybin at any time.
15. \_\_\_\_ I understand that if I agree to share my information for research purposes, then data collected by my facilitator may be shared with people and institutions outside the psilocybin service center. Efforts will be made to protect the security and confidentiality of my information, such as the deidentification of my data, consistent with standards of medical care and research. However, there is a risk the information could be used to identify me and reveal that I have received psilocybin services. If I do not want my information to be used for research, then I should decline to share my data. I may still receive psilocybin services, and my data will only be shared to the extent permitted or required by law.
16. \_\_\_\_ I understand that for my own safety, leaving a psilocybin service center during an administration session once it has begun is not recommended. Doing so could expose me to safety and legal risks.
17. \_\_\_\_ I understand and have been informed of the potential benefits, risks, and complications of psilocybin services with my facilitator to the extent that they are known.

18. \_\_\_\_ I have had the opportunity to ask questions regarding anything I may not understand or that I believe should be clarified.

\_\_\_\_\_  
Name (Print)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

# Appendix F—Proposed Facilitator Code of Conduct, 1/6/22

Draft 1-2-2022

## Ethical Principles/Code of Conduct for Psilocybin Facilitators

### 1. General principle.

Beneficence and nonmaleficence: All facilitators shall strive to benefit others, to do no harm, and to safeguard the welfare of clients.

### 2. Fiduciary Duties.

Fiduciary duties are intended to protect the more vulnerable parties in relationships where one party has greater expertise and influence. Facilitators owe clients fiduciary duties including, but not limited to, the duties of loyalty, care, and confidentiality.

*Duty of Loyalty:* While acting in the role of fiduciary, facilitators have a duty to put their clients' interests above their own. When soliciting a client's consent for psilocybin services, facilitators shall have a duty to disclose all information that is material to the client's decision, including but not limited to, any personal or financial interests unrelated to the client's welfare that may affect the facilitator's judgement. Should such information arise after consent is obtained, the facilitator has an ongoing duty to disclose it to the client.

*Duty of Care:* Facilitators have a duty to use the degree of skill, knowledge, and care that other reasonably careful licensed facilitators would use in the same or similar circumstances. Facilitators shall understand the laws and regulations governing the provision of psilocybin services, comply with the facilitator's professional code of conduct, and complete the continuing education necessary to maintain the requisite level of skill, knowledge, and care.

*Duty of Confidentiality:* Facilitators have a duty to maintain the confidentiality of client information. When disclosure of client information may be permitted under Section 56 of the Oregon Psilocybin Services Act, facilitators should attempt to maintain the confidentiality of client information to the greatest extent possible, and if compliance can be achieved without disclosing client information, the facilitator should avoid disclosure.

### 3. Misconduct and Responsibility for the Acts of Others

It is professional misconduct for a facilitator to:

- a. Violate this code of conduct, knowingly induce another to do so, or to do so through the acts of another;
- b. Commit a criminal act that reflects adversely on the facilitator's honesty, trustworthiness or fitness to provide psilocybin services;

c. Engage in conduct involving dishonesty, fraud, deceit, or misrepresentation;

A facilitator shall be responsible for another facilitator's violation of this code of conduct if:

a. The facilitator orders or, with the knowledge of the specific conduct, observes, condones, or approves the conduct involved; or

b. The facilitator has direct supervisory authority over the other facilitator and knows of the conduct at the time when its consequences can be avoided or mitigated but fails to take reasonable remedial action.

Facilitators who observe or ratify the misconduct of another facilitator shall report the misconduct to the OHA within 7 calendar days.

#### **4. Privacy and Confidentiality.**

Facilitators have an obligation to protect confidential client information obtained during their work.

Unless required by law, disclosures of client information shall be made only with a client's written consent. Facilitators shall not disclose confidential client information when consulting with colleagues or with other clients.

Limits of confidentiality should be discussed with clients, including under what conditions confidential information is legally required to be released.

#### **5. Competence.**

Facilitators shall demonstrate successful completion of an OHA approved training program that meets training standards set by OHA.

Facilitators shall only provide services within the boundaries of their competence (scope of practice), based on education, training, and licensure.

Facilitators shall undertake relevant education, training, supervision, and consultation when providing techniques or services that are new to them.

Facilitators shall participate in ongoing training or continuing education to maintain competence.

#### **6. Contacting Emergency Services.**

Facilitators shall acknowledge that due to the stigmatization and current legal status of psilocybin, contacting police and other emergency responders can pose unique risks to client safety and privacy. Accordingly, facilitators shall have safety plans in place that reduce the need to contact emergency responders. Nevertheless, facilitators must learn to distinguish benign side effects of psilocybin services from medical emergencies, and when true emergencies arise, they shall contact emergency responders. In those circumstances, facilitators have ongoing fiduciary duties to clients requiring facilitators to minimize potential harms to clients associated with contacting and involving first responders.

#### **7. Dual/Multiple Relationships.**

When a facilitator sees a client with whom they have an existing relationship, or sees a person closely associated with a client, this creates a dual relationship. The conflation of personal relationships with the provision of psilocybin services can be problematic and may impair the facilitator's objectivity or effectiveness.

Facilitators should not provide services to people over whom they have supervisory, evaluative, or other authority (e.g., students, employees).

When a facilitator serves a client with whom they have a previous or existing relationship, great care should be taken to delineate between professional and personal roles and respect and understand the vulnerable position of clients receiving psilocybin services.

A facilitator shall not offer or render psilocybin services as a means of establishing a personal relationship with clients.

## **8. Record Keeping.**

Facilitators shall create and maintain records of services provided to meet service center requirements, to document client response to psilocybin services, for accurate billing, and for the maintenance of licensure.

Facilitator records shall include:

- Completed Client Information Form
- Completed Informed Consent Form for each round of psilocybin services
- Start and stop time of each preparatory, administration, and integration session
- The identity, dose, and batch number of the psilocybin product(s) administered during each administration session
- Adverse outcomes

## **9. Maintenance, dissemination, and disposal of confidential records**

Facilitators shall store client information in accordance with the following rules:

- Client records must be stored and maintained for a minimum of 5 years.
- To prevent unauthorized access and protect client confidentiality, records shall be stored in a manner that meets or exceeds HIPAA standards.
- With reasonable notice, facilitators shall allow clients to access, review, and correct their records.
- Records should only be destroyed in a manner that maintains client confidentiality, such as a commercial shredding service.
- After maintaining a client's records for 5 years, facilitators shall destroy those records upon receiving a written request from clients for their records' destruction.

## **10. Fees and Financial Arrangements.**

Agreement between client and facilitator regarding fees, and any other financial arrangements, shall be recorded in writing prior to the provision of psilocybin services.

## **11. Advertising and other public statements.**

Facilitators shall not make false, deceptive, or misleading statements and shall take reasonable efforts to prevent others from making false, deceptive, or misleading statements on their behalf. Facilitators providing public advice (in person, in print, or on the internet, etc.) shall take precautions to ensure statements are based on training and experience and are consistent with this code of ethics.

Facilitators shall not solicit testimonials from clients.

## **12. Resolving Ethical Issues.**

Facilitators and members of the public shall submit complaints to an ethics/licensing committee that receives complaints from the public, adjudicates/investigates complaints, and has the power to revoke licenses or mandate remedies.

## **13. Special considerations for non-ordinary states of consciousness**

Clients may be especially open to suggestion, manipulation, or exploitation, and because the effects of psychedelics can persist for months, this state of vulnerability may be prolonged, which requires increased attention to safety and consent.

Psilocybin facilitation has the potential for stronger, more subtle, more complicated transference (strong feelings a client projects onto a provider; for example, as a parental figure) and counter transference (strong feelings a provider feels toward a client). This potential dynamic requires facilitators to be self-awareness, to engage in self-reflection and self-examination, and when possible, to participate in supervision/peer support for facilitators.

## **14. Non-Directive Approach to Facilitation of Psilocybin Services**

Facilitators shall provide psilocybin services, which consist of preparation, administration, and integration sessions, in a non-directive manner. The non-directive approach to facilitation is characterized by maintenance of a consistent, warm, and affirming disposition with clients, while avoiding giving clients direct advice or directly interpreting their statements or behaviors. The goal of nondirective facilitation is for clients to discover things about themselves for themselves with only minimal guidance from a facilitator. The pace and direction of facilitation are controlled by clients, while facilitators serve in a supportive role. An exception would be when safety is at stake, at which point facilitators shall become directive only in the service of safety.

## **15. Use of Touch**

Clients may want or benefit from a facilitator's reassuring touch during the administration session. Facilitators shall complete training regarding the appropriate use of touch and demonstrate an acceptable level of understanding regarding the context and boundaries for appropriate touch. Facilitators shall discuss the use of touch with clients before the start of each administration session, and permission to use touch shall be requested and recorded.

## **16. Romantic and Sexual Relationships**

No romantic relationships, sexual contact, or sexual intimacy with clients is permitted during any stage of psilocybin services including preparatory, administration, and integration sessions. In addition, sexual contact or romantic relationships with clients, or their partners or immediate family members, is prohibited for one year after the facilitator-client relationship has been formally terminated.

## **17. Storage and Diversion of Psilocybin Products**

Facilitators shall store psilocybin products in accordance with OHA administrative rules and shall have a duty to prevent their adulteration, contamination, or diversion from psilocybin service centers.

## **18. Acknowledgements**

This code of conduct was inspired by ethical codes of the American Counseling Association, the American Psychological Association, and the Multidisciplinary Association for Psychedelic Studies (MAPS).

## Appendix G—Proposed Social Equity Framework, adopted by Equity Subcommittee 1/21/22

### CONSIDERATIONS FOR MANUFACTURING & SERVICE CENTER LICENSE HOLDERS

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OHA shall require that applicants for manufacturing and service center licenses develop Social Equity Plans as part of their application for licensure.

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OHA shall require that licensed manufacturers and service centers maintain Social Equity Plans as a condition of renewal.

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Social Equity Plans shall encompass internal and external equity strategies and shall be commensurate to the size of the organization.

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At minimum, Social Equity Plans shall include a well-defined mission and description of the ways license holders will accomplish the following:

- Integrate DEJI throughout their internal practices, policies, and programming
- Participate in and support any Psilocybin Services Program's equity efforts, including the implementation and support of any future equity program
- Monitor, measure, and report against stated key performance indicators (KPIs) as defined in the Social Equity Plan

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Social Equity Plans shall include a forecast of incremental KPIs (milestones) that advance the license holders' Social Equity Plan.

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License holders shall submit an annual report detailing the implementation and management of their Social Equity Plans, including the following:

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- Plan summary
  - Narrative of activity to date
  - Evaluation of each KPI
  - Successes
  - Challenges
  - Assessment of internal and external impact
  - Future plans and opportunities
  - Opportunities for policy and regulation changes

OHA shall report and highlight SEP impacts (spotlight, rank on efficacy and best practices)

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OHA shall review SEPs each renewal period, provide an assessment of the plan's efficacy and the organization's achievement of stated goals, and make a determination on whether the organization's license may be renewed, put on an improvement plan, or discontinued.

#### CONSIDERATIONS FOR FACILITATOR LICENSE HOLDERS

Require continuing education in cultural equity, racial justice, and health equity as part of facilitator renewals.

Require continuing education in ethics as part of facilitator renewals.

OHA shall require that applicants for facilitator licenses develop Social Equity Plans as part of their application for and maintenance of licensure.

## **Appendix H—Proposed Informed Consent Framework, adopted by Training Subcommittee 2/13/22**

The Client Information Form shall collect information from the client that is necessary to enable a facilitator to determine whether the client should receive psilocybin services, whether additional consultation, referral, resources, or support is needed in order for the client to receive psilocybin services, and to assist the service center and facilitator in meeting public health and safety standards during the administrative session. This information shall include:

- Client medical and mental health history
- History of recent suicidal ideation, intent, or attempts
- Trauma history, including childhood trauma, as well as recent traumatic events
- History of recent psychological destabilization
- Substance use history, including current use and any history of problematic use
- History of experience with psilocybin or other altered states (including client response to those experiences)
- Client’s support network and current living situation
- Client’s history of treatment for mental health issues (including past and current therapy)
- Client’s experience with any kind of self-work, meditation, or other contemplative and/or spiritual practices
- Client’s current medication list
- Medical devices that client is currently using (Example: catheter)
- Medication that must be taken during administrative session
- Medication that may need to be taken during administrative session (Example: epi pen)
- Whether the client will need assistance from another person, such as a health aide or translator, during the administrative session
- Mobility concerns
- Languages spoken, including languages that the client grew up with

# **Appendix I—Full Text of Training Subcommittee Recommendations 3/10/22**

## **Risk Assessment Framework 3/10**

**OPAB Risk assessment document edited 3/10/22**

**Eligible for services now/Not eligible for services now but may have a reconsideration of eligibility in the future.**

**All clients will receive safety planning for their unique needs**

**Standardized screening tools will be used to create a clear and numerical cut off for safety concerns that does not require extensive training to conduct.**

**Create a package of resources that all people who receive facilitation may have access to.**

**Hard No's: with the possibility of reconsideration at a later date**

Active psychosis

Immediate risk for harm to self or others

Pregnancy

The current OR RECENT (1-2 months) use of contraindicated meds

Current impaired decision making capacity including intoxication (assure there is training to identify)

Clearly unsafe living situation (needs definition beyond DV) always provide definitions of DV and give resources as not all people will disclose

**Requires further screening? : with the possibility of reconsideration at a later date**

Standardized Screening Battery \*The following screening measures are utilized to assist facilitators in providing accurate information to clients regarding risk levels/factors and to guide the safety planning process.

Suicidality: Columbia-Suicide Severity Rating Scale (C-SSRS)

Mania: Hypomania Symptom Checklist-32 (HCL-32)

Alcohol/Substance Use: Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)

Childhood Trauma: Adverse Childhood Experiences Scale (ACES)

Social Support: Multidimensional Scale of Perceived Social Support (MSPSS)

Severity of Psychological Distress: Brief Symptom Inventory (BSI)

Depression Severity: Patient Health Questionnaire-9: (PHQ-9)

Resilience: Satisfaction with Life Scale (SWLS)

**Hospitalizations for risk of harm to self or others: requires further screening** (What are the risks or protective factors?) (3 month timeframe since hospitalization, medications are stable, demonstration of safety net)

**Chronic heavy substance use?** (amphetamines, cocaine are higher risk) (what is daily use like and what is the impact on metabolism?, and also how is the client presenting the day of the session? What screening tools?)

**dementia** and end of life care and decision making capacity

**Significant medical illness Naive to non-ordinary states of consciousness**

**Multiple meds**

**Significant trauma folks with long term and recalcitrant mental health concerns**

**Cannabis?** How do we address in screening and informed consent?

Crisis Lines/Support Services

Fireside Project-Psychedelic Support Hotline: call (623) 473-7433 or text 62 FIRESIDE

National Suicide Prevention Lifeline: (800) 273-8255

Substance Abuse and Mental Health Services Association: (800) 662-HELP (4357)

National Domestic Violence Hotline: (800) 799- SAFE (7233)

National Sexual Assault Telephone Hotline: (800) 656-HOPE (4673)

National Alliance on Mental Illness (NAMI) Helpline: (800) 950-NAMI (6264)

Veterans Crisis Line: (800) 843-4564

LGBT National Hotline: (888) 843-4564

## Safety Planning Framework 3/10

Safety planning is the process of identifying potential reactions or responses that may arise following psilocybin administration, as well as what resources or support you can utilize if you notice those reactions occurring. Having a plan laid out in advance can improve safety outcomes and increase feelings of safety during an administration session. This form should be filled out with your facilitator prior to engaging in a psilocybin administration session.

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**Warning Signs.** These are emotions, thoughts, sensations, moods, behaviors, images that may lead to difficulty coping. Identify what happens in your body or mind when you begin to feel distress (e.g., emotional or physical sensations). There might also be situational provocations such as seeing someone/something, witnessing unfair treatment, and/or a distressing memory. What do you experience in response to these cues? Examples might be a racing heart, chest tightness, sweating, narrowing of visual field, inability to concentrate. Please describe in your own words.

Warning signs:

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**Coping Strategies.** What can you do on your own that promotes safety? What helps you manage stress? Examples might be journaling, drawing, dancing, meditation, exercise, a warm bath, reading, laughing, etc. What might get in the way of engaging in these coping strategies? Coping strategies are personal and meaningful and there isn't one "right way".

Coping strategies:

**Useful Distractions.** What options are there to temporarily distract from the stressor? Develop a list of activities that may offer relief. It may involve changing your current “headspace” or environment. If you enjoy being outside, write down “go for a walk”. If you have a favorite feel-good movie, write that down. Is there music that brings you joy? Think of simple interventions you can do easily and quickly. Write those things down.

Useful distractions:

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**People to Contact.** Who is available to support you? List anyone you fully trust or feel safe around. These could be friends, family members, or community/peer support resources who could be available to talk to or spend time with. Write down their phone numbers and/or addresses.

Your people:

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**Professional Contacts.** Develop multiple layers of support. Identify a medical/psychological care team (e.g., therapist, psychiatrist, primary care provider, other care providers), spiritual supports, recovery groups, psychedelic integration specialists, peer support groups, free or low-cost resources, county crisis lines, local crisis mobile units, walk-in clinics, and hospitals. Write down phone numbers and addresses.

Contacts:

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**Remove Means.** Address plans for removing means of self-harm: Flush medications, remove firearms or other high-risk items identified as potentially causing harm.

Describe:

## **Crisis Lines/Support Services**

Fireside Project-Psychedelic Support Hotline: call (623) 473-7433 or text 62 FIRESIDE

National Suicide Prevention Lifeline: (800) 273-8255

Substance Abuse and Mental Health Services Association: (800) 662-HELP (4357)

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Veterans Crisis Line: (800) 843-4564

LGBT National Hotline: (888) 843-4564

## Appendix J – Client Bill of Rights, Licensing 10/21/21

Client Bill of Rights Clients receiving psilocybin services in Oregon have the following rights:

1. To be treated with dignity and respect while receiving psilocybin services.
2. To receive culturally competent care.
3. To be free from physical, sexual, psychological, and financial abuse before, during, and after receiving psilocybin services.
4. To be fully informed of, and helped to understand, the risks associated with psilocybin services.
5. To make decisions autonomously, free of coercion and undue influence.
6. To be fully informed of the benefits and risks associated with psilocybin services.
7. To refuse psilocybin services once they have begun.
8. To privacy and confidentiality and to control how their information is processed and used.
9. To decline to participate in research or share information with third parties, except as required by law.
10. To a full accounting and explanation of all facilitator conflicts of interest and the costs associated with receiving psilocybin services before receiving those services.
11. To have belongings stored securely while receiving psilocybin services.
12. To access their client records after providing reasonable notice to a facilitator or service center and to correct information that ~~they believe~~ is inaccurate.
13. To request a private room in which to receive psilocybin services.
14. To be monitored and supported by a licensed facilitator for the duration of psilocybin services until it is safe for the client to be transported home or transferred to the care of a responsible friend or family member.
15. To receive psilocybin services from the same licensed facilitator for the duration of those services.
16. To access service centers, therapy rooms, and psilocybin services that are welcoming and accessible to people with disabilities.
17. To have access to a clean, single occupancy restroom for the duration of psilocybin services.
18. To discuss this Bill of Rights with licensed facilitators and service center operators without facing discrimination or retaliation.
19. To report violations of this Bill of Rights to the Oregon Health Authority, or other appropriate governing body, without facing discrimination or retaliation.

~~To report violations of these rights, please contact the Oregon Health Authority~~