Oregon Psilocybin Advisory Board

June 22, 2022 1:00 p.m. to 4:00 p.m. To Join via Zoom:

https://www.zoomgov.com/i/16054780370

Meeting ID: 160 5478 0370

What it the purpose of the meeting?

The purpose of the meeting is to conduct board business. A copy of the agenda is provided with this notice. Go to Oregon.gov/psilocybin for current meeting information.

May the public attend board and subcommittee meetings?

Yes, members of the public, interested parties, and the media are invited to attend all board and subcommittee meetings. Public comments will be heard if stated on the agenda. For the courtesy of all participants on the call, keep your device muted during all times of the meeting until you are given an opportunity to speak during a scheduled public comment period.

What if the board enters into executive session?

Prior to entering executive session, the board chairperson will announce the nature of and the authority for holding an executive session in accordance with ORS 192.660. Board member and designated participants shall be allowed to attend the executive session. All other audience members are not allowed to attend the executive session. No final actions or final decisions will be made in executive session. The board will return to open session before taking any final action or making any final decisions.

Representatives of the news media who are interested in attending an executive session are asked to contact the Oregon Psilocybin Services team by emailing OHA.Psilocybin@dhsoha.state.or.us or calling (971)341-1713 by 5:00 p.m. the day before the scheduled meeting to make arrangements to attend an executive session.

Who do I contact if I have questions or need special accommodations?

A request for accommodations for persons with disabilities should be made at least 48 hours in advance of the meeting. For questions or requests, contact the Oregon Psilocybin Services team by emailing OHA.Psilocybin@dhsoha.state.or.us or calling (971)341-1713.

Attendance

Ali Hamade

Andre Ourso

Angela Carter

Angie Butler

Atheir Abbas

Barb Hansen

Chris Stauffer

David Hart

Jessie Uehling

Kevin Fitts

Kimberly Golletz

Margaret Philhower

Nathan Rix

Rachel Knox

Sarah Present

Stephanie Barrs

Todd Korthuis

Tom Jeanne

Agenda Item	Description	Presenter	Time
Meeting Convenes	Welcome and Roll Call, 5 minutes	Dr. Atheir Abbas, <i>OPAB</i> <i>Chair</i>	1:00 p.m.

Welcome new	Introductions, 10 minutes	Angie Allbee,	1:05
OPAB members		OHA-OPS	p.m.
	Angie Butler, 5 minutes	Section	
	Chris Stauffer, 5 minutes	Manager	
OHA Updates	Oregon Psilocybin Services Update, 5 minutes	Angie Allbee,	1:15
		OHA-OPS	p.m.
		Section	
		Manager	
Approval of	Approval of April Minutes, 5 minutes	Dr. Atheir	1:20
Minutes		Abbas, OPAB	p.m.
		Chair	
Vote on	Vote on Recommendations, 70 minutes	Dr. Atheir	2:20
Recommendations		Abbas, OPAB	p.m.
	#1: Client Information Form	Chair	
	1. Licensing, 11/4/21: Approve draft informed consent document presented during meeting	Dr. Angie	
	and move the document to the full Psilocybin Advisory Board for consideration. or	Carter, OPAB	
	2. Training, 2/10/22: Recommend adoption of content for client information form.	Vice Co-Chair	
	Note: complete text of both forms is included on following pages		
	Proposed Informed Consent Document, Licensing, 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.

Proposed Informed Consent Document, Licensing, 11/4/21

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. 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 (arrythmia) 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.	
Proposed Informed Consent Document, Licensing, 11/4/21	
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	

could be used to i not want my infor data. I may still re extent permitted 16 I understand	medical care and research. However, there is a risk the information identify me and reveal that I have received psilocybin services. If I do rmation to be used for research, then I should decline to share my eceive psilocybin services, and my data will only be shared to the or required by law. If that for my own safety, leaving a psilocybin service center during an ession once it has begun is not recommended. Doing so could expose legal risks.	
Proposed Informed Cons	sent Document, Licensing, 11/4/21	
complications of p known. 18 I have had th	d and have been informed of the potential benefits, risks, and psilocybin services with my facilitator to the extent that they are he opportunity to ask questions regarding anything I may not at I believe should be clarified.	
Name (Print)		
Signature	 Date	
Proposed Informed Cons	sent Framework, Training Subcommittee 2/13/22	
enable a facilitator to det	orm shall collect information from the client that is necessary to termine whether the client should receive psilocybin services, ultation, 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 speaking

#2: Risk Assessment and Safety Planning

1. Training, 3/10/22: Recommend risk assessment framework to assess client suitability for psilocybin services.¹ (Full text below)

 $^{^{\}rm 1}\,\mbox{See}$ appendix J for full text of risk assessment framework

OPAB Risk assessment document adopted 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 2. Training, 3/10/22: Recommend safety plan framework for clients receiving psilocybin services. (Full text below)

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.

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:

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:	
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:	
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:	
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)

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

#3(A): Products

- 1. Licensing, 3/3/22: Recommend that to promote access to psilocybin products and services for all people in Oregon 21 years of age and over for whom they are appropriate (a stated goal of Measure 109), the OHA shall not limit permissible psilocybin products to those that are orally consumed. Some people with disabilities have difficulty chewing or swallowing, and alternatives to orally consumable products shall be made available to ensure that people with disabilities have equal access to psilocybin services. (Note: This motion is out of order. OPAB considered an identical motion at November 2021 meeting, and OHA has adopted rules.)
- 2. Products, 1/6/22: Recommend that OHA adopt rules to standardize psilocybin concentration in milligrams for all product types.
- 3. Products, 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.
- 4. Equity, 12/17/21: Recommend that OHA stratify allowed psilocybin products into two categories:
 - a) Hallucinogenic psilocybin products (hallucinogenic doses)
 - b) Sub-hallucinogenic psilocybin products (micro doses)

#3 (B): Dosage, Duration and Frequency

- 1. Licensing, 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).
- 2. Products, 1/6/22: Recommend 10 mg of psilocybin as max quantity per serving for extracts, .5 gram as max quantity per serving for fruiting body and mycelium products.
- 3. Research, 2/24/22:
 - a. The maximum concentration of psilocybin per serving shall be 25 mg/serving.
 - b. 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).
 - c. 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.
 - d. 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.

#4: Product Handling

- 1. Training, 2/10/22: Recommend that during a psilocybin administration session, a licensed psilocybin service center will deliver a psilocybin product or products to a participant of psilocybin services. The participant's facilitator will be present when the client ingests the product(s), but will not prepare, handle, or administer the product(s), unless the facilitator is also the service center operator
- 2. Equity, 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.
- 3. Pre-packaged and homemade intoxicating products including but not limited to adult-use cannabis products, home grown cannabis, other hallucinogens, or beverage alcohol

#5: Integration Session

1. Training, 3/10/22: Recommend the following integration framework: Integration, as defined in the measure, will take place as a single 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 who is also a licensed psychologist and, after the formal integration session, self-refers a client to ongoing "integration therapy."

#6: Facilitator Exam and Training

- 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 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 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
- 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.
- 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. (Note: this motion is out of order. OPAB considered an identical motion at the November 2021 meeting, and rules have been adopted by OHA.)

3/3/22: Approving only comprehensive training programs that offer both core training and practicum training privileges wealthy established training programs outside of Oregon at the expense of Oregonians who wish to start their own training programs. To further the goals of making psilocybin services safe, accessible, and affordable (a stated goal of Measure 109), the OHA shall approve partial training programs in addition to comprehensive training programs. (Note: this motion is out of order. OPAB

	 considered an identical motion at the November 2021 meeting, and rules have been adopted by OHA.) 3/2/22: Administering psilocybin during practicum training requires training programs to either become licensed psilocybin service centers or to have close ties with a licensed service center. Therefore, requiring psilocybin to be administered during practicum training unless special condition apply privileges wealthy established training programs who already have those relationships. To further the goals of making psilocybin services safe, accessible, and affordable (a stated goal of Measure 109), the OHA shall not deny approval to training programs that administer substances other than psilocybin during practicum training to simulate or approximate the effects of psilocybin. Alternatively, training programs may administer no substances and use role play to simulate a psilocybin administration session. No special conditions need apply, and training programs need not obtain the permission of OHA, to utilize these alternatives during practicum training. If alternative substances are utilized during practicums, the programs will comply with state laws governing their use. (Note: this motion is out of order. OHA has adopted rules.) 		
Break	Break (if time allows), 5 minutes	All	3:30 p.m.
Subcommittee Reports	Subcommittees Reports to Board (if time allows), 5 minutes Equity SC	SC Chairs: Dr. Rachel Knox and Dr. Angie Carter, Equity SC Co- Chairs	3:35 p.m.
	Research SC	Dr. Atheir Abbas and	

		Dr. Todd Korthius, Research SC Co-Chairs	
Oregon Psilocybin Advisory Board Comment Period	Oregon Psilocybin Advisory Board Member Comment Period (if time allows), 10 minutes	Dr. Atheir Abbas, OPAB Chair	3:40 p.m.
Public Comment Period	Comments from the Members of the Public (if time allows), 10 minutes	OHA Oregon Psilocybin Services Team	3:50 p.m.
Adjourn	Meeting adjourns	Dr. Atheir Abbas, <i>Chair</i>	4:00 p.m.