November 21st, 2022

Re: Draft Administrative rules to implement <u>ORS chapter 475A, the Oregon Psilocybin Services</u>
Act

To: Oregon Psilocybin Services Section, Oregon Health Authority,

Thank you for the opportunity to comment on OHA's draft administrative rules for the Oregon Psilocybin Services Act. We are a collaborative of psilocybin subject matter experts and advocates working together to promote high standards of safety in Oregon's new psilocybin program. We believe in the power of this program to improve the lives of Oregonian's, and we also recognize that strong safety standards will help to assure the success of this effort.

We believe that there are important opportunities for strengthening safety requirements in the current draft rules. Based on our collective knowledge, experience and professional expertise, we urge you to incorporate the following recommended changes.

333-333-3200 | **Facilitator Exam:** No time frame nor other limits are specified for when an applicant can retake a test after failing. We recommend requiring people who fail the test for a facilitator license wait a minimum of 30 days before retaking (rather than the 48 hours previously in draft rule) and be limited to taking the test no more than 3 times per year.

333-333-5020 | Group Preparation Sessions: We recommend group preparation sessions include the discussion of safety considerations such as adverse reactions from peers, sexual encounters, appropriate boundaries around touch, using consent model when interacting with others, etc. Draft rule should explicitly state this as a requirement.

333-333-5040 [Informed Consent: The required informed consent language should include specific information about known interactions/ risks of psilocybin, including for those with:

- History of hospitalizations for risk of harm to self or others
- Serious or persistent mental illness
- Personal or family history of serious mental illness
- Chronic heavy substance use
- Dementia
- Hypertension, cardiac conditions, and vascular disease
- Epilepsy
- The informed consent language should also include a statement such as: "The effects of Psilocybin mushrooms on a fetus and breastfeeding/chestfeeding infants are unknown."
 Pregnancy tests will not be required for screening, and some clients will simply not know they are pregnant while receiving services, but they should be reminded to think about the chance/risk of this during the consent process.

333-333-5050 | Client Information Form: The Client Information Form is our area of highest concern for safety. As it stands in draft rule, this form does not sufficiently gather important

information needed to assess client risk. First, in order to protect the safety of clients, the reasons for exclusion from services should be expanded to include:

- Pregnancy or lactating (to be revisited after 1 year of OPS operation)
- Active psychosis
- Immediate risk of harm to self or others
- Current or recent use of contraindicated medications (a list which should be updated at least annually based on recommendations by a committee of clinical experts)

In addition, the required elements on the client intake form need to be expanded to support safety. Additional screening / health assessment by a licensed medical or behavioral health professional should be required (rather than voluntary) when a facilitator identifies a significant potential safety risk. Facilitators should also be provided further guidance to help understand and identify risks. Clients with any of the following identified risks should require additional screening/safety planning by a licensed professional:

- History of hospitalizations for risk of harm to self or others;
- Serious and persistent mental illness;
- Family history of serious mental illness;
- Anyone taking a MAOI or antipsychotic
- Chronic heavy substance use
- Dementia
- History of clinically significant cardiovascular disease
- Epilepsy
- Clearly unsafe living situation

Please see our <u>Recommended Client intake form</u> as an example of a form that incorporates these recommendations.

333-333-5080 | **Safety and Support Plans:** The Safety Workgroup recommended all clients have a safety plan (not just those with identified risk). This updated draft rule language reflects that recommendation generally but specificity about required elements in the safety plan should be added.

Add additional service center requirements:

 Require emergency escalation plans: The Safety Workgroup recommendation is for all service centers to also be required to have an emergency escalation plan for when a safety or other emergency occurs with a client during an administrative or integration session. Currently, draft rules require emergency plans only for natural disasters or power outages.

Again, we thank you for the opportunity to provide this input and are grateful for your efforts to develop a safe and successful Oregon psilocybin program.

Respectfully,

Alex Cardenas, MD, Executive Director, American Psychedelic Practitioner Association

Rebecca Martinez, Founder & Director, Alma Institute

Tyler Norris, MDiv, Chair, Board of Trustees, Naropa University

Hanifa Nayo Washington, Co-Founder, Chief of Strategy, Fireside Project

Bruce Goldberg, MD, Former Director, Oregon Health Authority

Diana Quinn, ND, Training Director, Alma Institute

Bonny Koeber, MD, The Leela School Psilocybin Facilitator Program

Hannah McLane, MD, MA, MPH, SoundMind Founder & Director

Jessie Uehling, PhD

Brian Pilecki, PhD, Portland Psychology, Fluence

Thomas Eckert, MS, Founder and Program Director, InnerTrek

Jason Luoma, Psychologist, Portland Psychotherapy

Elizabeth M. Nielson, PhD, Psilocybin-Assisted Therapy Certificate Program Director, Co-founder & Chief Visionary Officer, Fluence

Benjamin Brubaker, Coordinator, Subtle Winds Training Program & Service Center

Daniel Golletz, Ph.D., Psychologist

Casey Frieder, DC, Program Director, The Leela School of Awakening

Matthew Hicks, ND, MS, Synaptic Institute

Charles Jasper, PhD, The Oregon Center for Psychedelic Somatic Therapy

Juan Quesada, LMFT retired, Kaiser

Rachel Aiden, CEO, Synthesis

David Esselman, MBA, BrainFutures

Chris White, MD, Eugene, Oregon

Gina Gratza, LMFT, Psychotherapist & Lead Educator, InnerTrek

Mike Bonetto, Partner, Tenfold Health

Myles Katz, Chief Business Development, Synthesis

Nate Howard, Director of Operations, InnerTrek

Ingmar Gorman, Psychologist, Fluence

Jason Foster, MA, InnerTrek Lead Educator

Brandon Maldonado, Mending Mindcelium Method

Sam Chapman, Executive Director, Healing Advocacy Fund

Tony Betz, Future Facilitator

Tyler Van Osdol