



## Summary Analysis of Oregon Psilocybin Services Draft Rules

Henry Harbin, MD

BrainFutures Board Member

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Here are summaries of our analysis and opinions on several topics in the draft rules for Oregon Psilocybin Services. Quotes from the draft rules are noted in blue text. These opinions do not constitute a legal opinion and are based solely on review of these draft regulations.

There are five key areas where the proposed rules do not require adequate disclosure of risks and create safety concerns, confusion, contradictions, and concerns about monitoring compliance with regulations, each of which is explained in greater detail below:

- A. Psilocybin is not for mental health treatment
- B. Clear and specific guidance on the facilitator's role
- C. Confusion of Facilitator Role and Scope for Licensed Health Care Professional vs Non-licensed Health Care Professionals
- D. Lack of clarity around dispensing limits
- E. Lack of full disclosure of risks in the Client Bill of Rights and Informed Consent

### A. Psilocybin Is Not for Mental Health Treatment

The regulations are clear that giving psilocybin in Oregon under this statute is NOT for the treatment of any mental health or substance use disorder. Multiple sections of the regulations make this clear as quoted below. However, other sections require service centers to make quasi clinical/medical claims of effectiveness of psilocybin for treating mental health disorders, which is contradictory and will likely lead to confusion for clients and facilitators.

#### Informed Consent (333-333-5040)

I understand that psilocybin services do not require medical diagnosis or referral and that psilocybin services are not a medical or clinical treatment.

#### Dishonest Conduct (333-333-6040)

Making representations or claims that the psilocybin product has curative or therapeutic effects

#### Advertising Restrictions (333-333-6100)

(1) Advertising for psilocybin products and services may not:

(e) Make claims that psilocybin products and services have curative or therapeutic effects or make other health claims<sup>1</sup> that are not supported by the totality of publicly available scientific evidence (including evidence from studies conducted in a manner that is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims.

### **Contradictions to the above requirements:**

There are multiple statements above that clarify that “psilocybin services are not a medical or treatment and in fact that its **“Dishonest Conduct”** to

### **(c) [Make] presentations or claims that the psilocybin product has curative or therapeutic effects**

These above statements are contradictory to these requirements below in section 333-333-5040 (Informed Consent):

3.b. Despite its federal Schedule I status, research suggests that psilocybin is very unlikely to be addictive. **Additionally, research and other information suggests that psilocybin may improve symptoms of depression, anxiety, end of life distress, various forms of trauma, and problematic substance use.**

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.

## **B. Clear and Specific Guidance on the Facilitator’s Role**

There are several specific requirements for facilitators that should provide helpful consumer protection. For example, criminal background checks (even though several types of prior criminal acts are exempt), minimum training requirements and standards and passage of a test. However, these clear-cut requirements are in contrast to the confusion and contradictions of the scope of practice of facilitators outlined in Part C below.

### **Specific Examples of How a Facilitator Should Protect Consumers**

#### **Facilitator Conduct (333-333-5120)**

(5) Except when acting as a practicum site supervisor under OAR 333-333-3070, a facilitator shall not provide psilocybin services to clients over whom may have supervisory, evaluative, or other authority.

(6) Facilitators may provide supportive touch during administration sessions with prior written consent. Supportive touch is limited to the facilitator placing their hands on a client’s hand or shoulder. A facilitator shall not use any other forms of touch, not permit another person to use any other form of touch during an administration session.

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<sup>1</sup> Emphasis added.

(8) A facilitator shall not engage in any romantic relationships, sexual contact, or sexual intimacy with a client during the provision of psilocybin services including preparatory, administration, and integration sessions.

(9) A facilitator shall not engage in any romantic relationships, sexual contact, or sexual intimacy with clients, or client's partners or immediate family members, for a period of one year following the last date that the facilitator provided psilocybin services to the client.

(10) Except for payments for psilocybin services, a facilitator may not engage in any financial transactions with clients or the clients' partners or immediate family members until the facilitator has ceased providing psilocybin services to the client

(11) If a facilitator is a mandatory report of abuse under Oregon law, the facilitator must disclose their status and obligations to a client at the beginning of the client's first preparation session.

### **C. Confusion of Facilitator Role and Scope for Licensed Health Care Professional vs Non-licensed Health Care Professionals**

#### ***Challenges for a Licensed Health Care Professional Who Is a Facilitator***

The regulations state that both licensed and unlicensed facilitators are certified in the same manner. Both types of facilitators must follow this scope of practice definition:

(333-333-1010): "Scope of practice" means practice boundaries related to psilocybin facilitation and avoiding the unlicensed practice of other disciplines including but not limited to medicine or psychotherapy.

There are several concerns about this definition. How is any facilitator going to know what are all the functions of licensed practitioners in Oregon? How will this prohibition be monitored for compliance?

Additionally, this is the requirement for a licensed health care professional (333-333-5130(3)):

**If a facilitator holds a professional license in another field, the facilitator shall not exercise the privileges of that license while providing psilocybin services to clients.**

Additionally, the regulations state this:

(333-333-5130(1)): A facilitator shall not engage in any conduct that requires additional professional licensure while providing psilocybin services to clients, including but not limited to diagnosing and treating physical or mental health conditions.

This requirement appears to be unimplementable. How does a licensed health care professional disavow their expertise and training and their licensure status? Is this ethical? Will this drive away licensed health care professionals from becoming facilitators in Oregon?

This requirement appears even more confusing in light of the tasks that facilitators are required to do in the screening of consumers for a psilocybin session and their role in these sessions. As described below, many of the screening questions for a facilitator are clearly clinical/medical questions and the decisions and conclusions require clinical/medical judgment. If a licensed health care professional acting as an

Oregon licensed facilitator makes a judgment that a person based on these required screening questions is not safe for psilocybin sessions, are they supposed to NOT use their licensed expertise to make this judgment? Will they need to disclose to a consumer that they are not using their clinical medical knowledge? Is this even possible?

### ***Challenges For a Licensed Facilitator Who Is NOT a Licensed Health Care Professional***

Here are key quotes from the regulations:

#### **Client Information Form (333-333-5050) [Screening questions]**

3. The client information form must include the following questions, and a client must answer each question by indicating “yes” or “no”:

- (a) Have you taken the prescription drug Lithium in the last 30 days?
- (b) Are you currently being treated by a medical, clinical, or other healthcare provider for a medical, mental health, or behavioral health condition?
- (c) Have you ever had an allergic reaction to consuming mushrooms or other fungi?
- (d) Are you currently taking any medications that might need to be consumed during an administration session?
- (e) Do you have a recent history of causing harm, or wanting to cause harm, to self and others?

(4) The client information form must include the following questions, and a client may provide a narrative answer to these questions or may choose not to answer.

- (a) Would you like to share anything about your medical history, including current medications, that you feel would be helpful for an administration session?
- (b) Would you like to share anything about your mental health history, including traumatic experiences or past history of causing harm, or wanting to cause harm, to self or others, that you feel would be helpful for an administration session?
- (c) Would you like to share anything about your history of substance use, including current substance use, that you feel would be helpful for an administration session?

These appear to be good questions to ask a potential consumer, but there appears to be a mismatch between the minimum required expertise or training of either the licensed Service Center staff or the Licensed Facilitator who is not a licensed health care professional to interpret the answers to many of these clearly medical issues. Asking and understanding the answers to these questions requires some level of medical/clinical experience or knowledge. Is it reasonable to ask a non-health care professional licensed Facilitator to make these types of judgements?

Similarly, is it reasonable to ask a non-health care professional facilitator to “[evaluate the answers to questions listed in section \(3\) of this rule to determine whether or not the client should participate in an administration session?](#)” Interpreting this list of medical questions and then deciding about whether it is safe or appropriate to undergo psilocybin experience seems to require significant clinical/medical knowledge and experience.

An additional challenge arises in the requirement for facilitators without medical training to “[utilize their training to distinguish between typical side effects of consuming psilocybin and medical emergencies.](#) In

the event of a medical emergency, a facilitator must contact emergency responders or other appropriate medical professionals immediately” (Facilitator Conduct (333-333-5120)).

#### **D. Lack of clarity around dispensing limits**

The proposed rules allow clients to consume psilocybin products more than once over the course of the administration session yet prohibit facilitators from assisting clients with medication or psilocybin products. This creates confusion about who is authorized to make dosage decisions, which is clearly a medical decision.

#### **Consumption Limits (333-333-5240)**

- (1) A service center licensee or license representative may not allow a client to consume more than 50 mg of psilocybin products during an administrative session.
- (2) A service center licensee or license representative may permit a client to consume more than one psilocybin product during an administration session as long as the total amount of psilocybin contained in the products is 50 mg or less.
- (3) Clients who want the options to consume more than one psilocybin product during their administration sessions up to a total of 50 mg of psilocybin, must provide written consent prior to the beginning of their administration session.”

However, Licensed Facilitators are told: “A facilitator shall not:

- (a) Assist a client with taking medication” or
- (d) “assist a client with consuming psilocybin products”

Yet a service center “licensee or license representative” are required to both monitor psilocybin dosages and more importantly to establish the appropriate dosage level (within certain levels)

- (1) A service center licensee or license representative may permit a client to consume more than one psilocybin product during an administration session as long as the total amount of psilocybin contained in the products is 50 mg or less

Confusion arises if a licensed facilitator is explicitly prohibited from assisting a client with medication. It isn’t clear who at the Service Center is qualified to make these dosage decisions? Decisions around dosage limits are clearly of a medical nature but there is a lack of clarity as to who specifically has the authority to make these decisions.

#### **E. Lack of disclosure in the (333-333-4520) Client Bill of Rights and (333-333-5040) Informed Consent**

There are many positive and clear requirements in the regulations contained in the Client Bill of Rights and the Informed Consent items. However, there are no requirements about key safety and ethical issues in regard to the roles of the facilitators. No disclosure is required for a consumer to know the expertise and training of their facilitators. Shouldn’t a consumer know that a facilitator asking very personal, clinical, and medical questions is NOT a licensed health care professional and if they conclude

that psilocybin is safe that this isn't the judgement of a licensed health care professional? Likewise, if they do know that the facilitator is a licensed health care professional, should not the consumer know that this facilitator is barred from using his or her professional expertise to make these decisions?