

Deep Dive Into The Oregon Psilocybin Services Act Session 1: Microdosing



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“Microdose”

- ▶ The term “microdose” does not appear in the Act
- ▶ Dosage
 - Very low dose
 - Sub-hallucinogenic
 - Sub-threshold or near-threshold perceptible
 - Typical psilocybin microdose is < 0.1g to 0.5g of dried mushrooms
- ▶ On a regular basis or at regular intervals

The Act – Dosage

- ▶ The Act does not set any minimum or maximum dosage requirements for psilocybin products.
- ▶ The Oregon Health Authority (OHA) has the power and duty to adopt rules as necessary to carry out the intent and provisions of the Act. (8(2)(c))
- ▶ OHA must adopt rules establishing:
 - Maximum concentration of psilocybin permitted in a single serving of a psilocybin product; and
 - Number of servings that are permitted in a psilocybin product package. (109)

The Act – Relevant Definitions

▶ “Psilocybin products” means:

- Psilocybin-producing fungi; and
- Mixtures or substances containing a detectable amount of psilocybin. Psilocybin products does not include psilocybin services. (5(12))

▶ “Psilocybin services” means services provided to a client before, during, and after the client’s consumption of a psilocybin product, including:

- A preparation session;
- An administration session; and
- An integration session. (5(16))

The Act – Relevant Definitions

- ▶ “Administration session” means a session held at a psilocybin service center at which a client purchases, consumes, and experiences the effects of a psilocybin product under the supervision of a psilocybin service facilitator. (5(1))
- ▶ “Client” means an individual that is provided psilocybin services in this state. (5(2))
- ▶ “Preparation session” means a meeting between a client and a psilocybin service facilitator that must occur before the client participates in an administration session. (5(9))
- ▶ “Psilocybin service center” means an establishment at which administration sessions are held and at which other psilocybin services may be provided. (5(13))
- ▶ “Psilocybin service facilitator” means an individual that facilitates the provision of psilocybin services in this state. (5(15))

The Act – Relevant Definitions

▶ “Client information form”

- Client must complete and sign the form before the client participates in an administration session
- OHA will prescribe the form
- Will solicit from the client information necessary to enable the service center operator and the facilitator to determine: (i) whether the client should participate in an administration session (including information that may identify risk factors and contraindications); and (ii) if so, to assist the service center operator and the facilitator in meeting any public health and safety standards and industry best practices during the administration center
- Will contain health and safety warnings and other disclosures to the client (7(3)(b); 35)

PAB – Relevant Recommendations to the OHA

- ▶ Oregon Psilocybin Advisory Board (PAB) must make recommendations to the OHA on:
 - Requirements, specifications and guidelines for holding and verifying the completion of an administration session (7(3)(a))
 - Contents of a client information form that a client must complete and sign before the client participates in an administration session (7(3)(b))
 - Public health and safety standards and industry best practices (7(4); 7(8))
 - Whether group administration sessions should be available (7(8)(a))
 - Circumstances under which an administration session is considered complete (7(8)(c))

Policies of the OHA and the Act

► OHA

- Improve the lifelong health of Oregonians
- Increase the quality, reliability, and availability of care for all Oregonians
- Lower or contain the cost of care so it is affordable to everyone

► Act

- Improve the physical, mental, and social well being of all Oregonians (2(1)(b))
- Make psilocybin services a safe, accessible, and affordable option for all persons 21 years of age and older for whom psilocybin may be appropriate (2(1)(c))

OHA Rules – Outright Prohibition

- ▶ Require a minimum concentration of psilocybin that must be consumed by a client during an administration session

OHA Rules That Will Affect Whether Microdosing Will Be a Viable Business Option

- ▶ Whether there will be a maximum number of administration sessions that a client may participate in during a given time period
- ▶ Whether there will be a minimum length of time that must elapse before an administration session can be completed
- ▶ Preparation sessions
 - Whether a preparation session is required before each administration session
 - Whether preparation sessions may take place online
 - Whether there will be a minimum length of time that must elapse between the completion of a preparation session and an administration session

OHA Rules That Will Affect Whether Microdosing Will Be a Viable Business Option

▶ Client information form

- Whether a client must complete and sign a client information form before each administration session
- Whether microdosing is a risk factor that requires the client to consult with a medical or other professional before participating in multiple microdosing sessions during a given time period (7(3)(b)(A))

▶ Group administration sessions (7(8(a)))

- Whether group administration sessions will be available
- If so, whether one facilitator can supervise multiple clients
- If so, the maximum client-to-facilitator ratio

OHA Rules – Blueprint for Maximum Viability

- ▶ No minimum concentration of psilocybin that must be consumed by a client during an administration session
- ▶ Client information form
 - Not required for each individual microdose session (or if required, a procedure for a short “verification that nothing has changed” form)
 - Microdosing not a risk factor that requires the client to consult with a medical or other professional

OHA Rules – Blueprint for Maximum Viability

- ▶ Substantial discretion between facilitator and client regarding preparation sessions
 - Frequency: Not required for each individual microdose session (or if required, a procedure for a short “verification that things are going well” preparation session)
 - Meetings: Preparation sessions may take place online
 - Requirements: No unduly burdensome requirements to complete the preparation session
 - Length of time before an administration session: No (or alternatively, a reasonable minimum) length of time between the completion of a preparation session and an administration session

OHA Rules – Blueprint for Maximum Viability

- ▶ Substantial discretion between facilitator and client regarding administration sessions
 - Frequency: No maximum (or alternatively, a reasonable maximum) number of administration sessions that a client may participate in during a given time period
 - Requirements: No unduly burdensome requirements to complete the administration session
 - Length: No minimum (or alternatively, a reasonable minimum) length of an administration session
- ▶ Group administration sessions
 - Permitted
 - Relatively high client-to-facilitator ratio for microdose sessions

Timeline

▶ Products and facilitator training

- February 14-25, 2022 – Rules Advisory Committees (RACs) convened
- March / April 2022 – OHA publishes draft rules (*Microdosing?*)
- April 2022 – Public comment on draft rules
- May 2022 – Rules become effective

▶ Other subject areas

- June 30, 2022 – PAB makes rule recommendations to OHA
- July 2022 – Listening sessions
- September 2022 – RACs convened
- October / November 2022 – OHA publishes draft rules
- November 2022 – Public comment on draft rules
- December 30, 2022 – Rules for remaining subjects become effective

Disclaimer

The information in this document is for general educational purposes only.