

Oregon Psilocybin Services Act Measure 109 (2020)

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General Overview

- ▶ **Regulatory framework of supervised psilocybin therapy**
 - Oregon Health Authority (OHA)
 - Oregon Psilocybin Advisory Board
- ▶ **21 years of age and older**
- ▶ **Purchasing, consuming, and experiencing the effects of psilocybin**
 - Only at a licensed service center
 - Only under the supervision of a licensed facilitator
 - Only after the completion of a preparation session
- ▶ **Two-year development program before licenses are issued**
- ▶ **No homegrown**

Psilocybin Licenses

▶ Types

- **Manufacturer**
- **Service center operator**
- **Facilitator (individual)**
- **Laboratory**

▶ OHA

- **Prescribe application forms**
- **Process applications**
- **Conduct background checks**
- **Issue, renew, suspend, and revoke licenses**

Psilocybin Licenses

▶ Restrictions on multiple licenses

- No more than one product manufacturer
- No more than five service center operators

▶ Residency requirements

- Manufacturers and service center operators
 - If a legal entity, Oregon residents must own more than 50% of the ownership interests
 - If an individual, must be an Oregon resident
- Facilitators must be Oregon residents
- Oregon resident means a resident for two or more years
- Expire on January 1, 2025

Psilocybin Services

- ▶ **Services provided to a client before, during, and after the consumption of a psilocybin product**
- ▶ **Facilitator**
 - **21 years of age or older**
 - **High school diploma or equivalent education**
 - **Complete education and training approved by OHA**
 - **Pass examination approved by OHA**
 - **Subject to code of professional conduct and ethics**
- ▶ **Client**
 - **21 years of age or older**
 - **Must have a facilitator**
 - **No medical preconditions required**

Psilocybin Services

▶ Sessions

- Preparation
- Administration
- Integration

▶ Preparation session

- Client must attend with facilitator before each administration session
- Client completes a client information form
 - Solicitation of information about client, including identification of risk factors and contraindications
 - Health and safety warnings
- Facilitator must certify completion

Psilocybin Services

▶ Administration session

- Purchase, consume, and experience the effects of a psilocybin product
- Must occur at a psilocybin service center
- Facilitator present throughout entire process
- Facilitator must certify completion

▶ Integration session

- Must be offered by facilitator after completion of administration session
- Client may, but need not, participate
- If client participates, facilitator must certify completion

Manufacturing

- ▶ **Manufacturing**
 - Includes cultivation, production, and processing
 - Endorsements for different types of activities
 - Manufacturer may hold multiple endorsements
- ▶ **OHA must adopt rules restricting quantities at a licensed premises**
- ▶ **No outdoor manufacturing**
- ▶ **Products tested by laboratory**
- ▶ **Packaging, labeling, and dosage requirements**
- ▶ **Tracking system for psilocybin products**

Service Centers

- ▶ **Service centers**
 - **Clients purchase psilocybin products**
 - **Clients consume and experience the effects of psilocybin**
- ▶ **Preparation sessions and integration sessions may, but need not, occur at service centers**
- ▶ **May employ facilitators or contract with third-party facilitators**
- ▶ **Collect retail sales tax**
- ▶ **Tracking system for psilocybin products**
- ▶ **Not located within 1,000 feet of school**

Retail Sales Tax

- ▶ **15% tax on retail sale of psilocybin products**
- ▶ **Collected at point of sale by service center operator**
- ▶ **Tax on psilocybin products only (not psilocybin services)**
- ▶ **Remitted to Oregon Department of Revenue**
- ▶ **Tax revenues appropriated to OHA**

Advertising

- ▶ **No advertising of psilocybin products to public**
- ▶ **Advertising of psilocybin services by service center operators and facilitators**
 - **Permitted but regulated**
 - **May not**
 - **Appeal to minors**
 - **Promote excessive use**
 - **Violate code of professional conduct by facilitators**
 - **Present risk to public health and safety**

Confidentiality

► Clients

- **No disclosure of client's personally identifiable information by licensee without client's consent**
- **Exceptions**
 - **Client initiates legal action against licensee**
 - **Client intends to commit harmful criminal act**
 - **Client reveals abuse or neglect of a minor**
 - **Licensee responds to OHA inquiry**

► Licensees

- **Personally identifiable information exempt from public disclosure laws**
- **Exceptions**
 - **Facilitators and sole proprietor owners**
 - **Request for information by law enforcement agency**

Local Jurisdictions

- ▶ **M109 preempts local charters and ordinances**
- ▶ **Local jurisdictions may opt out**
 - **City or county initiative petition**
 - **Majority vote**
 - **Elections held at time of statewide general election**
- ▶ **May adopt reasonable time, place, and manner regulations**
- ▶ **No local licenses**
- ▶ **No local taxation**

Two-Year Program Development Period

- ▶ **January 1, 2021 – December 31, 2022**
 - **Extensive preparation for regulatory framework**
 - **No licenses issued**
 - **No changes to criminal laws**
- ▶ **OHA publishes studies, research and educational information**
- ▶ **Oregon Psilocybin Advisory Board established**
- ▶ **OHA adopts rules and regulations**

Oregon Psilocybin Advisory Board

▶ Advisory Board established within OHA

- 14-16 members appointed by Governor
- 3 members affiliated with the OHA

▶ Duties

- Make recommendations to OHA
 - Health and safety standards and industry best practices
 - Code of professional conduct for facilitators
 - Education, training, and examinations for facilitators
 - Rules and regulations
- Develop long-term strategic plan for safe, accessible, and affordable psilocybin therapy
- Monitor and study federal laws
- Attempt to discuss M109 with US Attorney for Oregon

Timeline

- ▶ **February 28, 2021 – Governor appoints members of Advisory Board**
- ▶ **March 31, 2021 – Advisory Board holds first meeting**
- ▶ **June 30, 2021 – Advisory Board makes recommendations to OHA on studies, research, and educational information**
- ▶ **July 31, 2021 – OHA publishes studies, research, and educational information**

DONE!

Timeline

- ▶ **June 30, 2022 – Advisory Board makes recommendations to OHA**
 - Rules and regulations
 - Long-term strategic plan
 - Federal laws and policies
- ▶ **December 31, 2022 – OHA adopts rules and regulations and prescribes forms**
- ▶ **January 2, 2023 – OHA begins receiving license applications**
- ▶ **First half of 2023 (est.) – First licenses issued**

What M109 Does Not Do

▶ Reduce criminal penalties for

- **Manufacture or use by persons under 21**
- **Delivery by or to persons under 21**
- **Persons who possess, manufacture, or deliver psilocybin outside of regulatory framework**

▶ Amend or affect

- **Medical assistance programs**
- **Health insurance policies**
- **DUI laws (which already prohibit drugged driving)**
- **Laws pertaining to employment matters**
- **Laws pertaining to landlord-tenant matters**

Federal Law

- ▶ **No expressly stated policies or enforcement priorities for psilocybin**
- ▶ **General principles for federal prosecution**
 - **Resources are finite**
 - **Appropriate discretion used before prosecuting a federal case**
 - **Consideration of civil law enforcement as an alternative**
 - **Focus enforcement efforts on federal violations implicating federal priorities**
 - **Seriousness of the crime**
 - **Deterrent effect of criminal prosecution**
 - **Cumulative impact of particular crimes on the community**

Federal Law

- ▶ **US Attorney District of Oregon's enforcement priorities for marijuana**
 - **Overproduction and interstate trafficking**
 - **Protecting Oregon's children**
 - **Prevent diversion of marijuana to other states**
 - **Violence, firearms, or other public safety threats**
 - **Organized crime**
 - **Protecting federal lands, natural resources, and Oregon's environment**

Oregon Psilocybin Advisory Board

▶ **Oregon Psilocybin Advisory Board (PAB)**

- Election of chairs and co-chairs
- Creation of subcommittees

▶ **LOTS OF MEETINGS!**

▶ **LOTS OF IDEAS!**

▶ **OHA Website Page: <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Oregon-Psilocybin-Services.aspx>**

PAB and Subcommittees

▶ PAB

- **Chair – Tom Eckert**
- **Co-Vice Chairs**
 - **Atheir Abbas**
 - **Angela Carter**

▶ Subcommittees

- **Equity – Co-Chairs: Angela Carter and Rachel Knox**
- **Licensing – Chair: Mason Marks**
- **Products – Chair: Jessie Uehling**
- **Research – Co-Chairs: Ali Hamade and Todd Korthuis**
- **Training – Co-Chairs: Angela Carter and Tom Eckert**

Rulemaking Process

► State of Oregon

- Angela Allbee (OHA) – Oregon Psilocybin Services Section Manager
- Jesse Sweet (OHA) – Policy Analyst Oregon Psilocybin Services
- Brittany Hall (OHA) – Public Health Division Rules Coordinator and Legislative Assistant
- Shannon O’Fallon (Oregon Department of Justice)

► OHA Presentation to PAB at 7/28 Meeting:

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/OPS%20PAB%20Board%20Presentation%207.28.21%20FINAL.pdf>

► Rules

- Final draft rules (public comment period; statutory notice requirements)
- Final rules (adopted after public comment; no significant changes to final draft rules)
- Temporary rules (good for 180 days without public comment)

Rulemaking Process

- ▶ **Jesse Sweet will take lead on preparing initial drafts of rules**
- ▶ **Rules Advisory Committees (RACs) will be formed**
- ▶ **OHA will take PAB and RAC recommendations into consideration**
- ▶ **Primary directives**
 - **Equity and access**
 - **Harm reduction**
- ▶ **Chronological priorities**
 - **Facilitator education and training**
 - **Psilocybin products**

Recent Topics of Discussion

► Products Subcommittee

- Recommendations approved by PAB at 9/22/21 PAB meeting
 - Limit cultivation to species *Psilocybe cubensis* only
 - Direct OHA to review allowable species for cultivation every 12 months beginning January 2024
 - Limit psilocybin production to cultivation of fruiting bodies and mycelium
 - Direct OHA to review allowable production methods every 12 months beginning January 2024
 - Prohibit use of dung and woodchips as substrates for cultivation
 - Permit extracts as an allowable psilocybin product
- Other topics of discussion for subcommittee
 - Methods of extraction
 - Additives to extracts

Recent Topics of Discussion

► Training Subcommittee

- **33 proposed training program motions to be voted on by subcommittee**
- **Topics**
 - **Application and enrollment**
 - **Accelerated trainee credit**
 - **Program components**
 - **Personnel**
 - **Program curriculum**
 - **Student evaluation**
 - **Program completion**
 - **Licensure and renewal**
 - **Continuing education**
 - **Handling complaints**
 - **Program fidelity**
 - **Solvency**
 - **Inter-program collaborations**
 - **Others**

Recent Topics of Discussion

- ▶ **Licensing Subcommittee – Approved many recommendations (not yet approved by PAB)**
 - **Administration sessions**
 - **Group sessions**
 - **Maximum 3:1 client to facilitator ratio for group sessions**
 - **No limit on number of clients in a group session**
 - **Outdoor sessions**
 - **Additional “on call” facilitator for individual sessions (within 20 minutes of service center)**
 - **Advertising**
 - **Permit advertising of psilocybin products (*NOTE: M109 prohibits advertising products to the public*)**
 - **Prohibit certain advertising (false and misleading; medical claims; targeting minors)**
 - **Facilitator duties**
 - **Obligations to ensure client safety and privacy**
 - **Fiduciary duties of loyalty, care, and confidentiality**
 - **Licensees must create and maintain an “equity plan”**

Recent Topics of Discussion

▶ Licensing Subcommittee – Other topics of discussion for subcommittee

- Service center requirements
- Manufacturing facility requirements
- More administration session issues:
 - Codes of conduct for facilitators
 - Rules regarding “touch” between facilitators and clients

▶ Equity Subcommittee

- Adopted recommendations regarding facilitator training (not yet approved by PAB)
- Currently working on making recommendations on products and licensing

Not Discussed Yet

► What has not been discussed

- Financial interests
- Residency requirements
- Reach out to US Attorney for Oregon
- Certain aspects of the client information form, including information solicited from the client (should client participate; identification of risk factors and contraindications)
- Circumstances under which an administration session is complete
- Dosages (microdosing?)

What Might The Industry Look Like (Crystal Ball Predictions; Wild Speculation)

- ▶ **Potentially high client demand**
- ▶ **Manufacturers**
 - Much smaller scale than cannabis
 - Fewer types of products than cannabis
 - Products less important than service centers, facilitators, and services in general
- ▶ **Service Centers**
 - Significant capital investment
 - Different types
 - Serious clinical and mental health
 - Destination resorts
 - No frills
 - Variety of settings, themes, and marketing niches
- ▶ **Facilitators**
 - Many facilitators due to relatively low barriers to entry
 - Variety of facilitation approaches, themes, and marketing niches

Business and Legal Issues

- ▶ **Federal illegality – Potentially no guidance at all**
- ▶ **Banking**
- ▶ **Internal Revenue Code Section 280E**
 - **Manufacturers – Yes**
 - **Service centers – Yes, although potential for services to be a separate line of business?**
 - **Facilitators – Arguably no**
- ▶ **Bifurcation of pricing for psilocybin products and services**
 - **Products subject to Oregon sales tax; services are not**
 - **Further bifurcation of pricing for specific services for Section 280E purposes?**
 - **Preparation session**
 - **Consumption portion of administration session**
 - **Post-consumption portion of administration session**
 - **Integration session**

Business and Legal Issues

▶ Entity organizational structures

- Residency requirements
- Financial interest disclosures to OHA
- Tax classification
- Service centers owned and operated by two affiliated co-licensees for separate lines of business?

▶ Securities offerings; risk factors

▶ Federal trademarks

- Products – No
- Services – Possibly?

Business and Legal Issues

▶ Local jurisdictions

- Opt out
- Land use and zoning

▶ Real estate

▶ Insurance

▶ Attorney ethics

Disclaimer

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