Washington State Health Care Authority

Report to the Legislature

# Washington Psilocybin Stakeholder Workgroup

## Preliminary Report

Engrossed Substitute Senate Bill 5693; Section 211(99)(e); Chapter 297; Laws of 2022

December 1, 2022

# Washington Psilocybin Stakeholder Workgroup

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# Executive Summary

In its 2022 session, the Washington Legislature included a budget proviso in SB 5693 (2021-2023 fiscal biennium supplemental operating appropriations) that directed the Health Care Authority (HCA) to provide a report on psilocybin services and opportunities in consultation with a group of specified stakeholders. An excerpt of SB 5693 can be found in Appendix A. The Stakeholder Workgroup has been tasked to:

1. Review the Oregon Health Authority's proposed rules for the regulation of psilocybin and assess the impact the adoption of substantially similar laws and rules or Senate Bill No. 5660 would have in Washington state, and identify specific areas where a different approach may be necessary or desirable;
2. Review systems and procedures established by the liquor and cannabis board to monitor manufacturing, testing, and tracking of cannabis to determine suitability and adaptations required for use with psilocybin if Washington adopts legislation substantially similar to the Oregon psilocybin services act or Senate Bill No. 5660;
3. Review the social opportunity program proposed in Senate Bill No. 5660 for the purpose of recommending improvements or enhancements to promote equitable access to a potential legal psilocybin industry within an operable administrative framework;
4. Assess functional requirements of Senate Bill No. 5660 that would exceed the expertise and capacity of the Department of Health and identify opportunities for development or collaboration with other state agencies and entities to meet the requirements; and
5. Discuss options to integrate licensed behavioral health professionals into the practice of psilocybin therapy under the framework of Senate Bill No. 5660 where appropriate.

The Washington Legislature specified that the Stakeholder Workgroup be chaired by the Director of HCA or her designee and the group shall consist of:

- the director of the liquor and cannabis board or designee
- the director of the department of agriculture or designee
- the following representatives with knowledge of psilocybin:
    - a military veteran, or similar
    - up to two recognized indigenous practitioners
    - an individual with expertise in disability rights advocacy
    - a member of the nursing profession
    - a psychologist
    - a mental health counselor, marriage and family therapist, or social worker
    - a physician
- a health researcher with expertise in health equity
- a representative of the cannabis industry with knowledge of regulation of cannabis businesses in Washington
- an advocate from the LGBTQIA community with knowledge of the experience of behavioral health issues within that community
- a member of the psychedelic medicine alliance of Washington
- up to two members with lived experience of utilizing psilocybin

The Stakeholder Workgroup membership can be found in Appendix B. HCA contracted with the Center for Evidence-based Policy ("the Center") to provide technical assistance in support of this project, manage and facilitate the Stakeholder Workgroup, and draft two reports summarizing the Stakeholder Workgroup's deliberations to be submitted to the Legislature by HCA. This is the first of two reports and outlines progress made toward the key tasks listed above. A workplan of the Stakeholder Workgroup can be found in Appendix C.

# Workgroup Tasks

This report summarizes the initial work completed by the Psilocybin Stakeholder Workgroup to address the five key tasks of the legislation. To this point, the workgroup has had four meetings and completed actions related to tasks one, two, four, and five. Future meetings, scheduled through 2023, will address the remaining key task. Actions completed and workgroup feedback related to the final task will be summarized in the final report, due December 2023. The table below summarizes the work plan:

## Key tasks

| Workgroup task | Workgroup actions | Date |
|---|---|---|
| 1. Review the Oregon Health Authority's (OHA) proposed rules for the regulation of psilocybin and assess the impact the adoption of substantially similar laws and rules or Senate Bill No. 5660 would have in Washington State and identify specific areas where a different approach may be necessary or desirable. | • Reviewed OHA implementation at first workgroup meeting<br>• Workgroup proposed areas where a different approach may be necessary or desirable | June 30, 2022 |
| 2. Review systems and procedures established by the liquor and cannabis board to monitor manufacturing, testing, and tracking of cannabis to determine suitability and adaptations required for use with psilocybin if Washington adopts legislation substantially like the Oregon psilocybin services act or Senate Bill No. 5660. | Jim Morgan, CFO of Liquor and Cannabis Board (LCB), presented the LCB's processes around tracking and licensing cannabis at second workgroup meeting | August 4, 2022 |
| 3. Review the social opportunity program proposed in Senate Bill No. 5660 for the purpose of recommending improvements or enhancements to promote equitable access to a potential legal psilocybin industry within an operable administrative framework. | Initial work group feedback:<br>Means testing sliding scale fee approach<br>Group sessions for therapy to reduce costs<br>Group sessions and telemedicine for extended integration<br>Encourage providers to accept vouchers/scholarships | October 31, 2022 |

| | | |
|---|---|---|
| | Integrate SOP into the lottery applicant process<br><br>Funding for public health and education campaigns<br><br>Topic scheduled for Stakeholder Workgroup discussion at February 2023 meeting | February 2023 |
| 4. Assess functional requirements of Senate Bill No. 5660 that would exceed the expertise and capacity of the Department of Health and identify opportunities for development or collaboration with other state agencies and entities to meet the requirements. | Presentation from the Department of Health on its Transformational Plan, existing regulatory framework, health professional oversight and regulation, and DOH responsibilities under SB 5660<br><br>Presenters included:<br><br>Lacy Fehrenbach, MPH, CPH Chief, Prevention, Safety and Health Washington State Department of Health;<br><br>Christie Spice, MPH Deputy Assistant Secretary for Policy Health Systems Quality Assurance Division Washington State Department of Health<br><br>Marlee O'Neill, JD Executive Director Pharmacy Quality Assurance Commission Washington State Department of Health | December 2, 2022 |
| 5. Discuss options to integrate licensed behavioral health professionals into the practice of psilocybin therapy under the framework of Senate Bill No. 5660 where appropriate. | See above – Department of Health presentation | December 2, 2022 |

# Workgroup Task 1

**Review the Oregon Health Authority's (OHA) proposed rules for the regulation of psilocybin and assess the impact the adoption of substantially similar laws and rules or Senate Bill No. 5660 would have in Washington state, and identify specific areas where a different approach may be necessary or desirable**

## Action Taken

To review Oregon Health Authority's proposed rules and regulations, HCA and the Center did the following:

- Prepared a memo for Stakeholder Workgroup members in advance of the first meeting outlining Oregon's Measure 109, implementation process, and the most recent rules and regulations.
- Conducted a survey before the first meeting to gauge Stakeholder Workgroup familiarity with Oregon's psilocybin program.
- Included in the first workgroup meeting presentations by Angie Allbee, Manager of Oregon Psilocybin Services Section, OHA, and Sam Chapman, Executive Director, Healing Advocacy Fund, a nonprofit organization involved in the design of Measure 109. Full presentations can be found in Appendix D.

## Related Materials

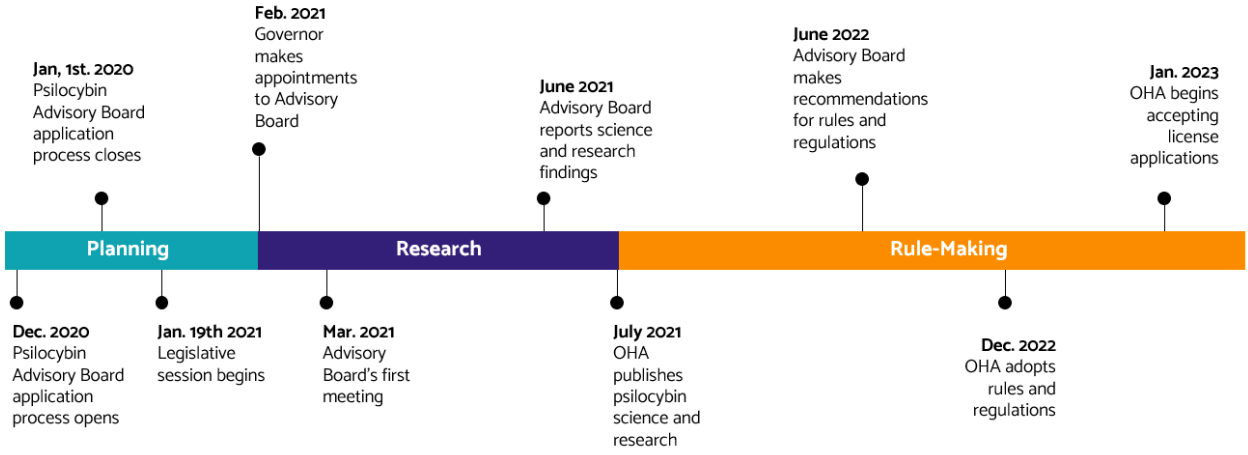
The following overview of Oregon's Measure 109 is excerpted from the memo sent to workgroup members in advance of the first workgroup meeting on June 30, 2022.

### Executive Summary

#### Measure 109

- Passed in Oregon in November 2020 with 56% voter support
- What it did:
    - Established a regulatory framework within the Oregon Health Authority that will allow trained facilitators to administer psilocybin-assisted therapy at licensed service centers
    - Established the Governor-appointed Oregon Psilocybin Advisory Board
    - Imposed a two-year development period before initial licenses are granted
    - Requires the establishment of a training and licensure system for psilocybin facilitators, psilocybin manufacturers, and testing labs
    - Requires the establishment of a tracking system for psilocybin products
- Does not allow for:
    - Retail sales
    - Off-site consumption or possession
    - Branding or advertising
    - Unregulated or untracked psilocybin production, delivery, or inventory
    - Therapy centers near schools
    - Access for minors

## Measure 109 Implementation Timeline




## Oregon Psilocybin Advisory Board

### Board Members

| Board Member | Position | Subcommittee |
|---|---|---|
| Andre Ourso | Public Health Director Designee | |
| Dr. Tom Jeanne | State Health Officer Designee | Research |
| Barb Hansen | Oregon Health Policy Board Designee | Licensing |
| Ali Hamade | State Employee w/ Public Health Expertise | Research |
| Dr. Sarah Present | Local Health Officer | Licensing |
| Kevin Fitts | Addictions Medicine Specialist | Equity |
| Dr. Kimberley Golletz | Licensed Psychologist | Licensing, training |
| Dr. Todd Korthius | Licensed Physician | Research |
| Mason Marks (since resigned) | Licensed Naturopath | Licensing, product, training |
| Jessie Uehling | Myocologist | Product, research |
| Dr. Angela Carter | Harm Reduction specialist | Equity, product, training |
| Dr. Atheir Abbas | Psychopharmacologic Specialist | Research |
| Nathan Rix | OLCC | |
| David Hart | Oregon DOJ | Product |

| | | |
|---|---|---|
| Tom Eckert (since resigned) | Chief Petitioner Designee | |
| Stephanie Barrs | Public, Family Nurse Practitioner & Psychiatric Mental Health Nurse Practitioner | Product, training |
| Dr. Rachel Knox | Public, Endocannabinologist and Cannabinoid Medicine Specialist. | Equity, licensing, product, research, training |

## Training Update

- Oregon Psilocybin Services (OPS) released **its online platform** where training programs can complete and submit for approval their facilitator training program curriculum.
- Higher Education Coordinating Commission (HECC) will be licensing psilocybin facilitator training programs which are considered "career schools".

## Rules Update

- OHA has adopted the **first subset of rules** related to psilocybin products and testing and training programs.
- Highlights:
    - Manufacturer requirements
        - A manufacturer must design and manufacture all psilocybin products to be consumed by a client orally or delivered via another enteral method.
        - A manufacturer is prohibited from designing or manufacturing psilocybin products that can be delivered to clients through any method other than orally or another enteral method. A manufacturer is prohibited from designing or manufacturing psilocybin products that include but not limited to, transdermal patches, inhalers, nasal sprays, suppositories, and injections.
    - Training
        - Curriculum application requirements and approval process
        - Training instructor qualifications and program performance
        - Core training program requirements:
            - 120 hours of instruction
            - For virtual training, at least 50% must be through online synchronous learning
        - Requirements of Psilocybin Training Curriculum Modules
        - Practicum requirements
            - 40 hours of practicum training and 30 hours of direct practice and at least 10 hours of consultation relating to direct practice
            - Must be in person
    - Product Testing
        - Speciation testing: A manufacturer must order a test for a batch taken from the first harvest lot recorded in a calendar year to ensure that the lot consists only of Psilocybe cubensis.

- Other testing: potency, solvent, pesticide, contaminant, heavy metals
- Second rulemaking process will occur for the remainder of the rules in Fall 2022.

## Legislation Comparison

The following graphic compares key elements of Washington SB 5660, SB 5693, and Oregon's Measure 109.

**WA SB 5660 (did not pass)**

- Would establish safe, legal, and affordable psilocybin centers for Washington citizens over 21.
- Would create a Washington psilocybin advisory board within department to provide advice and recommendations to the department.
- Would impose an 18 month program development period.
- Would direct the Department to adopt rules in following areas: education and training requirements, testing, establishment of a tracking system.

**WA SB 5693 (passed)**

- Provide report on psilocybin services wellness and opportunities in consultation with stakeholders.
- Review social opportunity program proposed in SB 5660 for purpose of recommending improvements or enhancements.
- Access functional requirements of SB 5660 that would exceed expertise and capacity of HCA (in collaboration with other state agencies and entities).
- Integration of licensed behavioral health professionals under framework of SB 5660.

**Unique to WA SB 5660**

- **Social opportunity program (DOH):** establish equity and help remedy harms resulting from historical injustice and the disproportionate and targeted enforcement of drug-related laws on poor and marginalized communities.
- Department may not prohibit use of naturally grown mushrooms that meet quality and safety standards or mandate the use of patented products or procedures.
- Must create micro tier manufacturing endorsement with lower fees to reduce barriers to access.
- Must establish rules for circumstances in which psilocybin services can be administered in home of client who is medically unable to travel to center.

**Unique to OR Measure 109**

- Limited to Psilocybe cubensis species only.
- Doesn't allow for consumption outside service sites.
- 15% tax on price of psilocybin products sold at OHA licensed service centers.

## Resources

- WA SB 5660 (did not pass)
- WA SB 5693 (Psilocybin Stakeholder Workgroup starting on page 315)
- Oregon Measure 109 Details
- Oregon Psilocybin Services
- Oregon Psilocybin Rules
- Oregon Psilocybin Services Section Community Interest Survey Findings: 2022 Report
- Oregon Psilocybin Advisory Board Rapid Evidence Review and Recommendations
- Oregon Psilocybin Services Spring 2022 Newsletter

## Workgroup Feedback

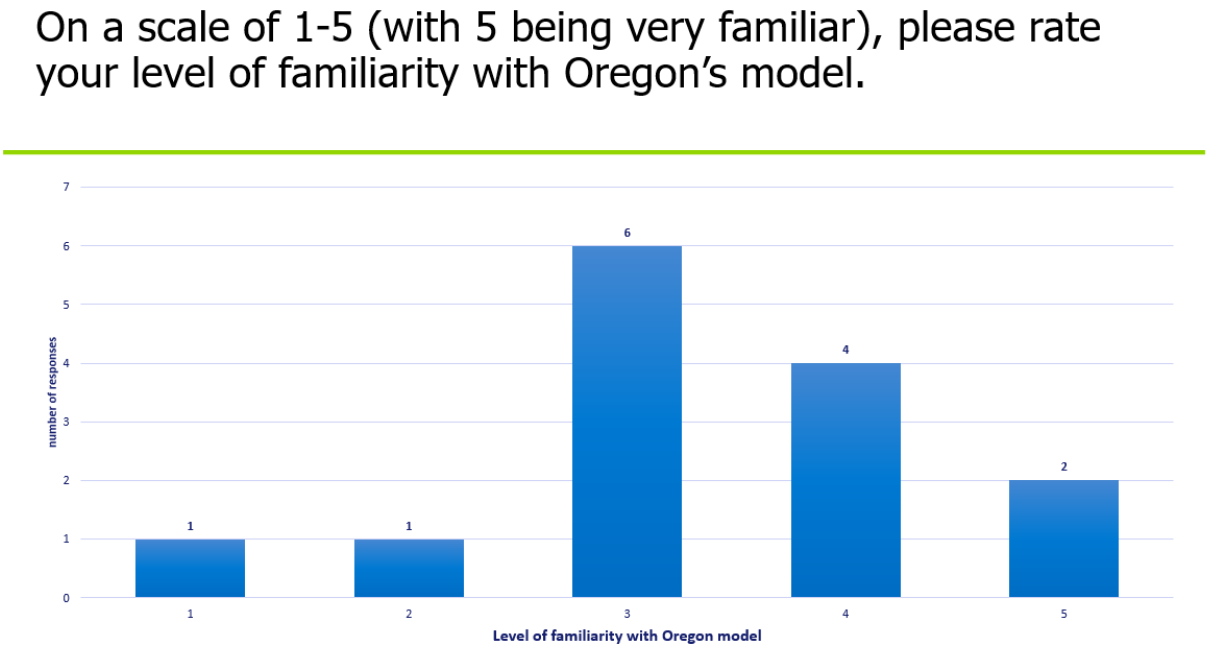
Most of the workgroup participants were familiar with Oregon's Measure 109 design and implementation. Specific feedback on Oregon's Measure 109 was gathered through a survey before the first workgroup meeting and a facilitated discussion was conducted during the meeting.

## Key Themes from Meeting #1 (June 2022)

In advance of the first workgroup meeting, the Center surveyed workgroup participants on their thoughts related to a potential regulatory framework for Washington and their familiarity with Oregon's psilocybin program. The results of this survey are summarized in the Survey Findings section below and full results are included in Appendix E. Themes arising from discussion of the survey are summarized in the Discussion Themes section below.

### Survey Findings

Fourteen of the 20 workgroup participants responded to the survey. Most respondents were familiar with Oregon's psilocybin model with only two respondents saying they were not familiar with the model. Results are shown below.




### Elements of Oregon's model that members want to duplicate:

- 2-year implementation period
- General satisfaction with facilitator licensing and training design
- Requiring only a high-school diploma for admission to training programs
- Promote access to psilocybin during end-of-life care

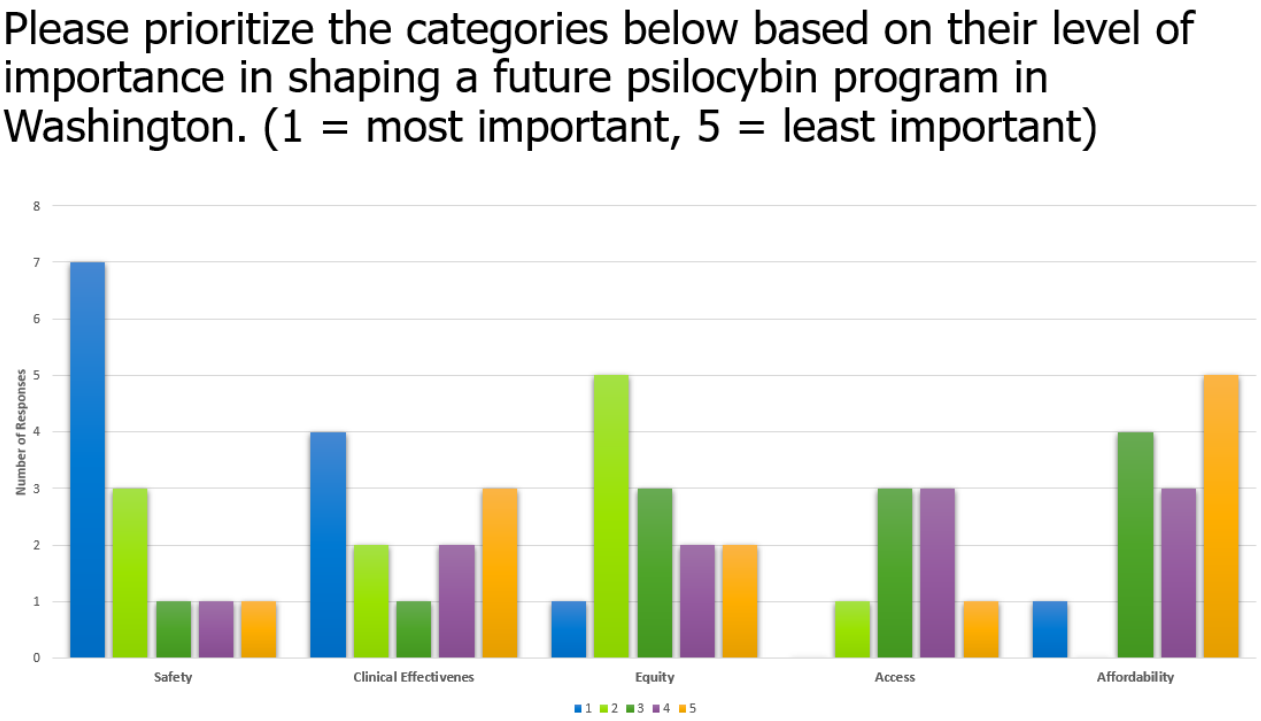
### Elements of Oregon's model that members want to avoid or modify:

- Lack of policy and procedure around microdosing
- Required on-site consumption
    - Workgroup members would like to recommend an allowance for at-home administration for people with mobility access issues
- Members would like to include exemptions for personal, religious, or indigenous use which is **not** included in Oregon's policy

- Prohibition of interstate transport
- Members would like to include more protections for equitable access and incorporate cost analysis to ensure sessions remain affordable for average consumer

## Designing Washington's Psilocybin Program

Workgroup members were asked to prioritize categories based on their level of importance in shaping a future psilocybin program in Washington. Results were:




## Workgroup members were also offered the chance to add categories they would like to see prioritized in the design of Washington's psilocybin program. Additional recommendations were:

- Research
- Respecting indigenous practices
- Equity, access, and affordability could be combined or defined as separate priorities
- Safety and clinical effectiveness also might have overlapping qualities that need to be defined
- Flexible regulation that allows for innovation

## Opportunities in Designing Psilocybin Program

- Could be solution to unmet needs of psychiatric conditions
- Potential to improve mental health and wellbeing of Washingtonians
- Reduction of crime and prevention of mental illness
- Washington could serve as thought leader for other states looking to improve upon Oregon's model
- Could simplify or clarify regulation to allow for enhanced research and innovation

## Challenges and Concerns in Designing Psilocybin Program

- Department of Health would have no framework for approving controlled substance registration applications
- Cost-accessibility issues
- Interaction with behavioral health license boards
- How to ensure diversity of practitioners to meet population needs
- Developing regulatory framework for growth and manufacturing and safety assurance when dealing with schedule 1 substance
- Developing regulatory framework that allows for research and innovation

## Discussion Themes

Workgroup participants emphasized the following areas of interest and future development of psilocybin regulation in Washington.

## Additional Policy Scope Concerns

- Washington should consider how microdosing practices could occur in system
- Washington should consider decriminalization efforts in tandem with any state model
- Washington should look to other states for their decriminalization policies

## Feedback on Oregon Model

- Positive feedback on Oregon's facilitator education requirement of high school diploma only
- Mixed feedback on Oregon's limitation to one species only

## Designing Washington's Psilocybin Program

- Any recommendations in the final report should be broad and consider all populations (dual diagnoses, wellness, spirituality, post-traumatic stress disorder (PTSD), etc.)
- Have explicit regulatory language that psilocybin training programs do not need approval from Washington's Student Achievement Council
- Consider designing a tiered training program designed for different populations:
    - General wellness
    - Spiritual experience
    - Dual behavioral health diagnoses
- Washington should offer variety of facilitator training programs to prioritize access and safety

## Other Workgroup Suggestions

- Safety concerns related to interactions with other pharmaceuticals
- Recommendation that workgroup specifically define equity, access, and affordability
- Need time to circle back on workforce considerations like discussions with state licensure boards for practitioners

# Workgroup Task 2:

**Review systems and procedures established by the liquor and cannabis board to monitor manufacturing, testing, and tracking of cannabis to determine suitability and adaptations required for use with psilocybin if Washington adopts legislation substantially like the Oregon psilocybin services act or Senate Bill No. 5660**

## Action taken

The second workgroup meeting, held on August 4, 2022, featured a presentation by Jim Morgan, Chief Financial Officer for the Washington Liquor and Cannabis Board (LCB). The presentation included an overview of the history of cannabis tracking systems in the state and highlighted key similarities and potential differences between psilocybin and cannabis. The following is a summary of the LCB's presentation:

### History of Tracking Systems

- First system was a pharmaceutical tracking system that was rebranded and repackaged for cannabis but didn't meet the needs of LCB's program.
- Second system was challenging in terms of usability and support and was more complicated than needed. System went beyond what was required in statute and rule.
- The current system launched in December 2021. It was built by LCB (aka a home-grown system) and designed specifically to meet required regulatory responsibilities. The LCB reviewed statute, rules, and what was necessary to meet overarching goals when designing the system.
    - Current system has a database that was developed to collect data from licensees every week
    - Licensees submit comma-separated value (CSV) files and upload through an online portal
    - System conducts initial error checking and validation on CSV files before accepting licensee submission
    - The LCB can run queries from the database and produce reports

### Similarities Between Cannabis and Psilocybin Tracking

- Licensing procedures will be necessary and will need to be tailored for different industry participants (manufacturers, facilitators, etc.)
- Both are Schedule 1 drugs

### Differences Between Cannabis and Psilocybin Tracking:

- When regulating cannabis, LCB is regulating a commercial, retail industry. Psilocybin may not use a retail model.
- Cannabis is processed into wide range of commercial products to be sold through 500 retailers to anyone over 21.
- Medical cannabis is directed toward medical patients but is still sold through retail stores.
- A majority of LCB's cannabis processes are around licensing, regulatory compliance, and collecting taxes from licensees.

# Workgroup Feedback

## Key Themes from Meeting #2 (August 2022)

In addition to the presentation from the LCB, the second workgroup meeting included a facilitated discussion of survey responses from the workgroup members. The survey was sent out ahead of time and major findings are described below.

### Survey Findings

Thirteen of the 20 workgroup members responded to the survey that was sent out in advance of the second workgroup meeting. The survey was designed using discussion themes from the first workgroup meeting including priority issues raised by members when discussing how Washington could adapt Oregon's Measure 109 approach. Topics included microdosing policies, clinical vs. wellness model, training program structures, insurance coverage options, and design and implementation of Oregon's Measure 109. A summary is below, and full results are in Appendix F.

**Microdosing:**

- There was strong support for including a recommendation in the final report on microdosing procedures and policies with average support being 4.0 out of 5.0
- Possible policies including reducing waiting period during implementation session and allowing microdoses to be obtained only through qualified providers like cannabis retail stores

**Clinical vs. wellness model:**

- Workgroup members preferred recommending a wellness model over a clinical model for psilocybin. The average support ranking for a wellness model was 4.2 (out of 5.0) and the ranking for a clinical model was 2.61 (out of 5.0)
- Respondents noted that a clinical model would better address equity issues related to access
- Another respondent advocated for both models – wellness model for sessions with less than 3 grams of psilocybin and clinical model for sessions with more than 3 grams
- Some respondents noted they would agree with a medical model if it was the only option for implementation

**Training program structures:**

- Respondents were mixed on their support for a tiered training structure designed to targeted different populations (general wellness, spiritual experiences, mental health diagnoses, etc.). The average support ranking of the group was 3.61 (out of 5.0)
- Workgroup members pointed out there was no research support for tiered training
- There was support for following Oregon's training model of allowing anyone with a high-school diploma to complete training

**Insurance coverage options:**

- Support was high for including a recommendation in the final report that psilocybin be covered by private insurance and had an average ranking of 4.38 (out of 5.0).
- Support was also high for including a recommendation in the report that Medicaid explore legal and financial policies for covering psilocybin sessions with state funding. The average support ranking was 4.54 (out of 5.0).

**Design and implementation of Oregon's Measure 109:**

- Workgroup members showed favorable support (average ranking of at least 3.5 out of 5.0) for the following aspects of Oregon's Measure 109 design and implementation:
    - 2-year implementation period;
    - passing decriminalization policy concurrently; and
    - requiring only a high school diploma for facilitators.
- Workgroup members showed less than favorable support (average ranking of less than 3.5 out of 5.0) for the following aspects of Oregon's Measure 109 design and implementation:
        - limiting to P.cubensis species of psilocybin only;
        - limiting consumption to on-site only;
        - not including exemptions for religious, personal, or indigenous use; and
        - not specifically targeting populations with addiction, PTSD, and end-of-life diagnoses.

## Discussion Themes

Workgroup participants emphasized the following areas of interest during the second workgroup meeting. Discussion between workgroup members was related to Oregon's psilocybin program and how the model should or shouldn't be changed to apply to Washington. A summary of key themes is below.

**Equity considerations**

- Could we look to international studies for example of equity models
- Washington has history in courts related to religious and spiritual freedom which will be important to pay attention to within this area
- Need to consider how workforce shortages may also impact access

**Microdosing policy**

- Potential policy consideration for allowing individuals to access microdoses through a service center and not requiring administration on-site at the service center
- Decriminalization of psilocybin would help address microdosing
- Would need to consider regulatory framework of microdosing policy if the workgroup wants to include it in the final report
    - One suggestion was to make microdoses available by prescription only

**Clinical vs. wellness model**

- The wellness model includes access to the clinical model but not the other way around so the state should make the gate as big as possible
- If the Workgroup does support the wellness model it will be met with questions on if the wellness model is consistent with having to go to specific locations for psilocybin journey
- Whatever model is recommended the state need ways to capture data long-term so we can see effects to target treatments

**Tiered training structure**

- There needs to be training specific to populations – for example if someone with complex PTSD has an episode during the session
    - Oregon is looking at increasing hours or building offshoot programs for specialization, but Washington should consider what people are looking for, what needs of clients are, and what the scope is for facilitators
- Underground and ceremonial experience should be considered for training program requirements
- Need to consider if licensed medical professionals can lose license for participating in state training programs (as may be the case in Oregon)

**Insurance Coverage**

- Action that requires DEA rescheduling or approval should not be considered
- Look to ketamine clinics around the country doing drug-assisted sessions and if insurance can be used for certain sections of that clinical process
    - Look to Colorado who created partnerships with Medicaid to cover ketamine services

# State Legislative Summary

The second workgroup meeting also featured a presentation by the Center regarding 21 state legislative actions or ballot initiatives related to psilocybin programs. A summary of the legislation can be found below with full details in Appendix G.

# Workgroup Task 3:

**Review the social opportunity program proposed in Senate Bill No. 5660 for the purpose of recommending improvements or enhancements to promote equitable access to a potential legal psilocybin industry within an operable administrative framework.**

## Action to be taken

The workgroup will discuss the social opportunity program and overall equity recommendations at its upcoming February 2023 meeting.

# Workgroup Task 4:

**Assess functional requirements of Senate Bill No. 5660 that would exceed the expertise and capacity of the Department of Health and identify opportunities for development or collaboration with other state agencies and entities to meet the requirements.**

## Action taken

At the Stakeholder Workgroup meeting on December 2, the Stakeholder Workgroup heard from the Department of Health on its Transformational Plan, existing regulatory framework, health professional oversight and regulation, and overall department responsibilities under SB 5660. Presenters included: Lacy Fehrenbach, MPH, CPH Chief, Prevention, Safety and Health Washington State Department of Health; Christie Spice, MPH Deputy Assistant Secretary for Policy Health Systems Quality Assurance Division Washington State Department of Health Marlee O'Neill, JD Executive Director Pharmacy Quality Assurance Commission Washington State Department of Health.

The Department of Health's full presentation can be found in Appendix H.

# Workgroup Task 5:

**Discuss options to integrate licensed behavioral health professionals into the practice of psilocybin therapy under the framework of Senate Bill No. 5660 where appropriate.**

## Action taken

At the Stakeholder Workgroup meeting on December 2, the Stakeholder Workgroup heard from the Department of Health on its Transformational Plan, existing regulatory framework, health professional oversight and regulation, and overall department responsibilities under SB 5660. Presenters included: Lacy Fehrenbach, MPH, CPH Chief, Prevention, Safety and Health Washington State Department of Health; Christie Spice, MPH Deputy Assistant Secretary for Policy Health Systems Quality Assurance Division Washington State Department of Health Marlee O'Neill, JD Executive Director Pharmacy Quality Assurance Commission Washington State Department of Health.

The Department of Health's full presentation can be found in Appendix H.

# Appendix A: Legislation

CERTIFICATION OF ENROLLMENT
ENGROSSED SUBSTITUTE SENATE BILL 5693

67th Legislature
2022 Regular Session

(99)(a) $50,000 of the general fund—state appropriation for 39 fiscal year 2022 and $150,000 of the general fund—state appropriation for fiscal year 2023 are provided solely for the authority to provide a report on psilocybin services wellness and opportunities in consultation with stakeholders as described in this subsection.

(b) The director of the authority, or the director's designee, must chair the stakeholder group.

(c) The stakeholder group must include, but not be limited to, the following members:

(i) The secretary of the department of health or the secretary's designee;

(ii) The director of the liquor and cannabis board or the director's designee;

(iii) The director of the department of agriculture or the director's designee; and

(iv) As appointed by the director of the authority, or the director's designee:

(A) A military veteran, or representative of an organization that advocates on behalf of military veterans, with knowledge of psilocybin;

(B) Up to two recognized indigenous practitioners with knowledge of the use of psilocybin or other psychedelic compounds in their communities;

(C) An individual with expertise in disability rights advocacy;

(D) A member of the nursing profession with knowledge of psilocybin;

(E) A psychologist with knowledge of psilocybin;

(F) A mental health counselor, marriage and family therapist, or social worker with knowledge of psilocybin;

(G) A physician with knowledge of psilocybin;

(H) A health researcher with expertise in health equity;

(I) A representative of the cannabis industry with knowledge of regulation of cannabis businesses in Washington;

(J) An advocate from the LGBTQIA community with knowledge of the experience of behavioral health issues within that community;

(K) A member of the psychedelic medicine alliance of Washington; and

(L) Up to two members with lived experience of utilizing psilocybin.

(d) The authority must convene the first meeting of the stakeholder group no later than June 30, 2022.

(e) The authority must provide a preliminary brief report to the governor and appropriate committees of the legislature by December 1, 2022, focusing on (f)(i), (ii), and (iii) of this subsection, and a final report by December 1, 2023. The authority may form subcommittees within the stakeholder group and adopt procedures necessary to facilitate its work.

(f) The duties of the authority in consultation with the stakeholder group shall include, but not be limited to, the following activities:

(i) Review the Oregon health authority's proposed rules for the regulation of psilocybin and assess the impact the adoption of substantially similar laws and rules or Senate Bill No. 5660 would have in Washington state, and identify specific areas where a different approach may be necessary or desirable;

(ii) Review systems and procedures established by the liquor and cannabis board to monitor manufacturing, testing, and tracking of cannabis to determine suitability and adaptations required for use with psilocybin if Washington adopts legislation substantially similar to the Oregon psilocybin services act or Senate Bill No. 5660;

(iii) Review the social opportunity program proposed in Senate Bill No. 5660 for the purpose of recommending improvements or enhancements to promote equitable access to a potential legal psilocybin industry within an operable administrative framework;

(iv) Assess functional requirements of Senate Bill No. 5660 that would exceed the expertise and capacity of the department of health and identify opportunities for development or collaboration with other state agencies and entities to meet the requirements; and

(v) Discuss options to integrate licensed behavioral health professionals into the practice of psilocybin therapy under the framework of Senate Bill No. 5660 where appropriate.

(g) The department of health, liquor and cannabis board, and department of agriculture must provide subject matter expertise and support to stakeholder group and any subcommittee meetings of the stakeholder group. For the department of health, subject matter expertise includes an individual or individuals with knowledge and experience with rulemaking, with the regulation of health professionals, and with the regulation of health facilities.

(h) Meetings of the stakeholder group under this section shall be open to participation by members of the public.

(i) Stakeholder group members participating on behalf of an employer, governmental entity, or other organization are not entitled to be reimbursed for travel expenses if they are elected officials or are participating on behalf of an employer, governmental entity, or other organization. Any reimbursement for other non-legislative members is subject to chapter 43.03 RCW.

# Appendix B: Workgroup Members

## Workgroup members

| | |
|---|---|
| Dr. Charissa Fotinos (Chair), Health Care Authority | Dr. Tony Rousmaniere, Clinical Psychologist |
| Dr. Sunil Aggarwal, AIM Institute | Dr. Caitlein Ryan, The Cannabis Alliance |
| Ada Danelo, Summit Law Group | Dr. Nathan Sackett, University of Washington |
| Germaine D'Anniballe, Nursing Commission | Paul Stamets, Fungi Perfecti |
| Lacy Fehrenbach, Department of Health | Kody Zalewski, Psychedelic Medicine Alliance of Washington |
| Kate Foster, RN, Bellingham Patient Navigator | Dr. Judy Zerzan, Health Care Authority |
| Jeremy Grisham, Department of Veteran Affairs | Jill Wisehart, Department of Agriculture |
| Dr. Jae Kennedy, Washington State University | Jim Morgan, Liquor and Cannabis Board |
| Emma Knighton, American Psychedelic Practitioners Association | Dr. John Roll, Washington State University |
| Seth Maier, Military Veteran | Dr. Alvina Marris, Clinical Psychologist, Colville Tribal Member |
| Dr. Tana Silvas, Research Scientist | |

# Appendix C: Workplan

## Washington Psilocybin Stakeholder Workgroup Scope and Workplan

### Background

In the 2022 session, the Washington Legislature directed its Health Care Authority (HCA) to provide a report on psilocybin services and opportunities in consultation with a group of specified stakeholders.

### Scope

Over the course of 6 meetings, the Stakeholder Workgroup will consider the following:

1. Review Oregon rules
2. Review systems and procedures of Washington Liquor and Cannabis Board Technical Assistance
3. Review social opportunity program
4. Identify necessary expertise and capacity to implement functional requirements in Senate Bill 5660
5. Identify possible options to integrate licensed behavioral health professional

**Deliverables**

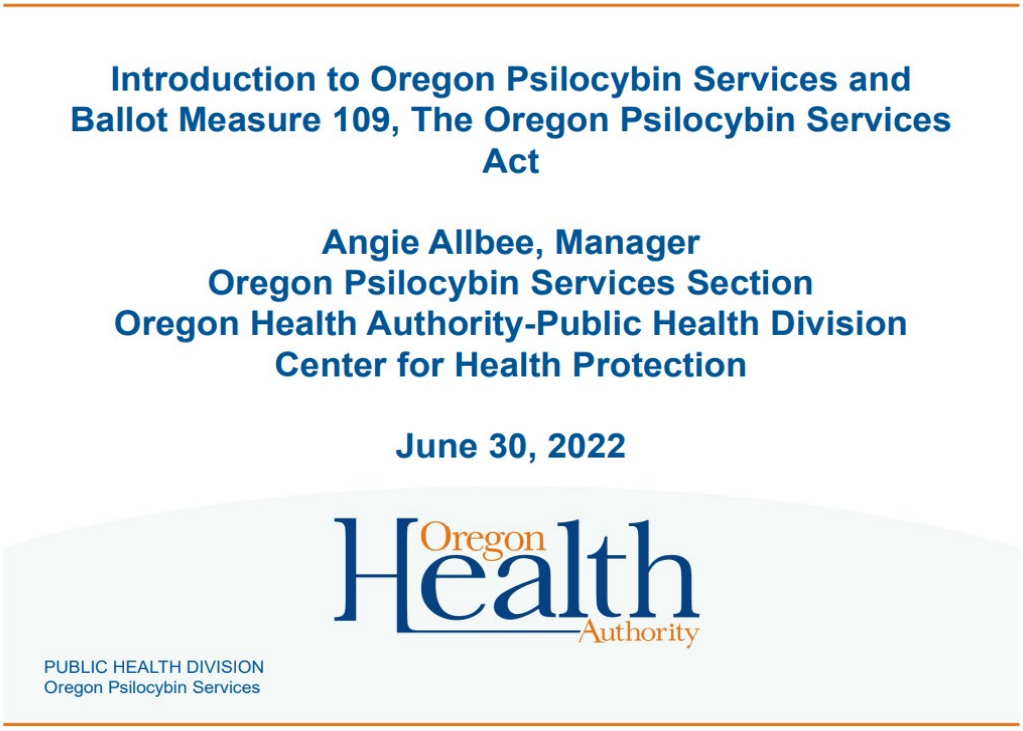
- Meeting agendas, meeting materials, and meeting summaries for all Psilocybin Stakeholder Group meetings
- Preliminary Brief Report by on December 1, 2022
- Final Report by December 1, 2023

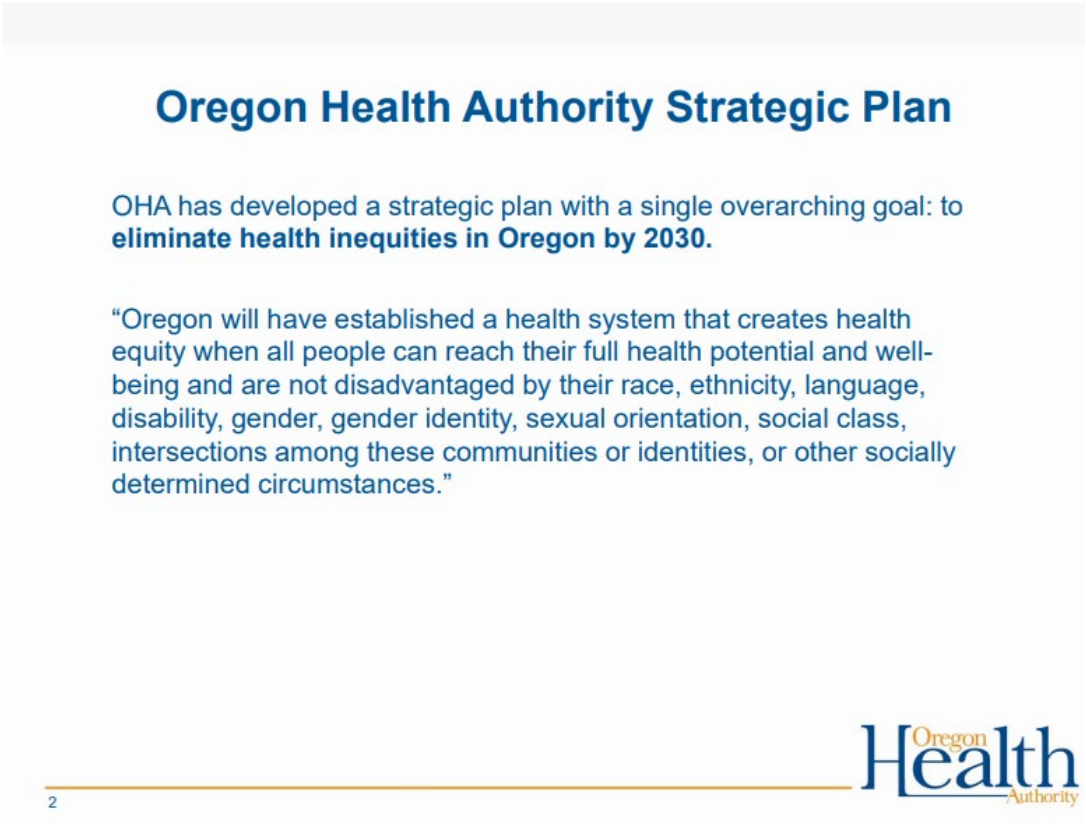
## Timeline

| Task/Deliverable | Date |
|---|---|
| Workplan development, background research, and preparation for Psilocybin Stakeholder Group kickoff meeting<br>Support HCA efforts to secure Stakeholder Group members | April – May 2022 |
| Psilocybin Stakeholder Group Kickoff Meeting<br>• Review legislation and workplan<br>• Oregon update<br>  ○ M109 overview<br>  ○ Psilocybin Advisory Board<br>Administrative Rules (approved and drafted) | June 2022 |
| Analysis of Oregon rules | July 2022 |
| Psilocybin Stakeholder Group Meeting #2<br>• Oregon update<br>• Overview from state agency:<br>  ○ Washington Liquor & Cannabis Board | August 4, 2022 |
| Begin drafting Preliminary Brief Legislative Report | September 2022 |
| Psilocybin Stakeholder Group Meeting #3<br>• Oregon update<br>• Discussion on patient safety considerations (panel of national experts)<br>• Agency update/feedback as needed:<br>  ○ Washington Liquor & Cannabis Board<br>  ○ Washington Department of Health<br>  ○ Washington Department of Agriculture<br>Review draft Preliminary Brief Legislative Report | October 31, 2022 |
| Final edits to Preliminary Legislative Report Due | November 2022 |
| Preliminary Brief Legislative Report Due | December 2022 |
| Psilocybin Stakeholder Group Meeting #4<br>• Overview from state agency:<br>  ○ Washington Department of Health | December 2, 2022 |
| Work with HCA staff to identify what issues need further research and stakeholder input for Final Legislative Report | January 2023 – June 2023 |
| Psilocybin Stakeholder Group Meeting #5<br>Oregon update | February 2023 |
| Psilocybin Stakeholder Group Meeting #6<br>Review initial Final Draft of Legislative Report | April 2023 |
| Complete Final Draft of Legislative Report | June 2023 |

| | |
|---|---|
| Final Legislative Report Due | December 2023 |

# Appendix D: Oregon Presentations



## State Health Improvement Plan: *Healthier Together Oregon*, 2020-2024

In early 2019, the PartnerSHIP identified five priorities:

- **Institutional bias**
- **Adversity, trauma and toxic stress**
- **Economic drivers of health**
- **Access to equitable preventive health care**
- **Behavioral health**

OPS is committed to health equity and working toward the agency's strategic plan goal of eliminating health inequities by 2030, as well as connecting our work to the goals outlined in Healthier Together Oregon, Oregon's State Health Improvement Plan (SHIP) for 2020-24.



## Oregon Psilocybin Services Section

Oregon Psilocybin Services is a new section housed within the Oregon Health Authority Public Health Division's Center for Health Protection.

The OPS team has been designed around three program areas:

- **Policy and Engagement**
- **Licensing**
- **Compliance**

Each program will center on health equity, including outreach to partners and communities and working to ensure access to services.

# Oregon Psilocybin Advisory Board

**The Oregon Psilocybin Advisory Board:**

- Advises OHA on available scientific studies and research on the safety and efficacy of psilocybin in treating mental health conditions, and make recommendations on the requirement, specifications, and guidelines for providing psilocybin services in Oregon
- Develops a long-term strategic plan for ensuring that psilocybin services will remain a safe, accessible, and affordable option for persons 21 years of age and older
- Monitors and study federal laws, regulations, and policies regarding psilocybin

Current OPAB subcommittees include **Equity, Training, Research, Products, and Licensing Subcommittees.**



# Ballot Measure 109: The Oregon Psilocybin Services Act

In November of 2020, Ballot Measure 109, the Oregon Psilocybin Services Act was passed by voters in Oregon.

**M109:**

Creates a license and regulatory framework for production of psilocybin and facilitation of psilocybin services for adults 21 years of age and older

**M109 does not:**

- Create a consumer market for psilocybin
- Allow for export or import of psilocybin
- Allow licensees to interact with unregulated markets

# Licensure Types

**Manufacturer License**

- Greater than 50% ownership group are Oregon residents
- An individual may not hold an interest in multiple manufacturers
- Must demonstrate that property owner has consented to production of psilocybin
- Cannot cultivate outdoors
- Premise must have defined boundaries
- Cannot exceed production quantities established in rule



# Licensure Types

**Testing Lab License**

- All psilocybin products must be tested by a licensed laboratory prior to transfer to Service Center
- Laboratories must be accredited by the Oregon Environmental Laboratory Accreditation Program
- Testing results must be entered in the product tracking system

# Licensure Types

**Facilitator License**

- Must complete **OHA approved training program** before applying for licensure
- Must have been an Oregon resident for two years (expires January 2025)
- Must pass exam approved or administered by OHA
- Cannot transfer psilocybin products to clients



# Licensure Types

**Service Center License**

- Greater than 50% of ownership group are Oregon residents
- An individual may not hold an interest in more than five service
- centers
- Cannot be located within 1000 feet of a school
- Must have defined boundaries
- Transfers psylocibin products to client for use during administration
- session
- Only license authorized to transfer psylocibin products to clients
- Most employees will be required to hold a **worker permit** issued by OHA

## Psilocybin Services

**Psilocybin will only be administered to persons 21 years or older in licensed service center settings under the supervision of trained and licensed facilitators.**

**Psilocybin Services may include:**

- Preparation Session
- Administration Session
- Integration Session (optional)



## Product Tracking

**Product tracking system required to track manufacturing, sale and transfer of psilocybin products to:**

- Prevent diversion
- Prevent tampering
- Ensure accurate accounting
- Ensure accurate reporting of lab testing results

**OHA shall:**

- Develop and maintain tracking system, or
- Contract with Oregon Liquor and Cannabis Commission (OLCC) to use cannabis tracking system vendor

# Local Government Issues

**Local Government Opt-Out:**

- Local governments (cities and counties) may adopt ordinances that prohibit Manufacturers and Service Centers
- Ordinances must be referred to voters at the next general election

**Local Government Time Place and Manner Regulations**

- Local governments may adopt reasonable regulations on hours, location, and operation of licenses
- Local taxes and fees are prohibited

**Land Use Compatibility Statements (LUCS)**

- Applicants for Service Center and Manufacturer licenses are required to request a LUCS from their local government before submitting a license application



# License and Application Fees, Taxes

**License and Application Fees**

- OHA shall adopt rules designating application, license, and renewal fees for all license types
- Fees must be reasonably calculated not to exceed the cost of administration
- Oregon Psilocybin Services will be a fee-based program and fees must cover the costs associated with the agency's work

**Taxes**

- Service Centers collect a 15% tax on the sale of psylocibin products payable to Oregon Department of Revenue
- Tax revenues help fund administrative costs for Department of Revenue and Oregon Psilocybin Services

# M109 Statutory Requirements

- Development Period: **January 1, 2021 to December 31, 2022**
- OHA published the Rapid Evidence Review: **July 31, 2021**
- Oregon Psilocybin Advisory Board will submit findings and recommendations: **June 30, 2022**
- OHA shall adopt rules: **December 31, 2022**
- OHA will begin receiving applications for licensure: **January 2, 2023**



# Accomplishments

- **Oregon Psilocybin Advisory Board** meetings and recommendations
- **Scientific Literature Review** published on July 30, 2021, translated into Spanish in September 2021
- **Oregon Psilocybin Services Website** rebuilt in September 2021
- **Oregon Psilocybin Services Public Listening Sessions** held December 13-15, 2021, and will be scheduled for July 2022 with Spanish, American Sign Language Interpretation, and CART captioning
- **Oregon Psilocybin Services Community Interest Survey** administered January 7, 2022, translated into Spanish, Russian, Vietnamese, Simple Chinese/Mandarin, and Somali, and Survey Findings Report published February 2022
- **Oregon Psilocybin Services Rulemaking Advisory Committees** held in February for Training Programs, Products, and Testing (rules adopted on May 20, 2022), and more RACs will be scheduled for September 2022 for remainder of rules
- **Oregon Psilocybin Services** accepting applications from training programs for curriculum approval on June 6, 2022
- **Oregon Psilocybin Advisory Board** to make recommendations to OHA by June 30, 2022 for remainder of rules

# OHA Key Dates

- **November 24, 2021:** Recommendations for Training/Products
- **December 2021:** Public Listening Sessions
- **January 1, 2022:** Community Interest Survey
- **February 14-25, 2022:** RAC for Training/Products
- **April 1-21, 2022:** Public Comment for Training/Products
- **May 13, 2022:** Effective Date for Training/Products
- **June 1, 2022:** OHA begins accepting applications for training programs
- **June 30, 2022:** Recommendations for Remaining Rules
- **July 2022:** Public Listening Sessions
- **September 2022:** RAC for Remaining Rules
- **November 1-21, 2022:** Public Comment for Remaining Rules
- **December 30, 2022:** Effective Date for Remaining Rules
- **January 2, 2023:** OHA begins accepting applications for licensure



# OHA Engagement

- Oregon's 9 Federally Recognized Tribes
- Psilocybin Partners
- Academic Institutions
- Professional Associations
- Advocacy Organizations
- Internal Agency Partners
- External State Agency Partners
- Professional Boards
- Local Governments
- Local Public Health Authorities
- Law Enforcement
- Members of the public

# Opportunities for Public/Partner Engagement

- Open seats for Oregon Psilocybin Advisory Board
- Participation in Rulemaking Advisory Committees (2/22 and 9/22)
- Public comment period in response to draft rules (4/22 and 11/22)
- OHA Public Listening Sessions (12/2021 and 7/2022)
- Oregon Psilocybin Services Community Interest Survey (1/22)
- Opportunities to listen to advisory board and subcommittee meetings (public meetings) and make public comments during public comment period
- Sign up on Oregon Psilocybin Services website for distribution list
- Job recruitment for Oregon Psilocybin Services team



# Thank You!

## Please visit our website:

## https://www.Oregon.gov/psilocybin

Healing Advocacy Fund

# Measure 109

Program Overview for
Psilocybin Therapy in Oregon

## Our Mission:

The Healing Advocacy Fund is a nonprofit organization dedicated to supporting the thoughtful and effective development, implementation, and education of the nation's first regulated psilocybin therapy program, which Oregon voters passed through Measure 109 in November 2020.

Healing Advocacy Fund

# Measure 109 Recap

## Oregonians Are Suffering Now, More Than ever

1. According to a recent survey conducted by CDC's National Center for Health Statistics and the Census Bureau: At the start of quarantine, 1 in 5 Americans were experiencing symptoms of clinical anxiety or depression, but **now over a third of Americans say they are experiencing symptoms amid the country's coronavirus pandemic**.
2. Here in Oregon, the mental health crisis is even more acute. According to Mental Health America, **Oregon's mental health crisis is the most severe in the country, and that was before the pandemic hit.**

# Psilocybin Research

- Rigorous studies at the leading medical research institutions such as Johns Hopkins, UCLA, University of Alabama and NYU show that psilocybin works. It is uniquely effective in treating depression, end-of-life anxiety, and addiction.
- It shows so much promise the FDA recently granted it a "breakthrough therapy" designation - meaning that it may demonstrate substantial improvement above and beyond what is currently available.


# The Measure

# M 109: A measured approach

**GOAL:** Create licensing and regulatory framework to serve those who seek Psilocybin Therapy and could safely benefit from it.

## What Measure 109 Does

- Establishes a **regulatory framework** within the Oregon Health Authority (OHA) that will allow trained practitioners to administer psilocybin services at specially licensed centers
- Establishes the **Oregon Psilocybin Advisory Board,** appointed by the Governor
- Imposes a **two-year development period** before initial licenses are granted
- Requires the establishment of a **training and licensure** system for psilocybin facilitators, psilocybin manufacturers, and testing labs
- Requires the establishment of a **tracking system** for psilocybin products

## M 109 does NOT allow:

- Retail sales
- Off-site consumption or possession
- Branding or advertising
- Unregulated or untracked psilocybin production, delivery, or inventory
- Service centers in residential neighborhoods or near a school
- Access for minors

# Psilocybin Services

## A Four Step Process


# Implementation

# Overview

- Measure 109 establishes an initial **two-year development period**.
- During that period, the Oregon Health Authority, **with the guidance of an Advisory Board**, will study psilocybin research and science and develop a regulatory program, including **rules, training requirements, and licensing requirements**.
- In January 2023, at the completion of the two-year study period, OHA will begin accepting applications and issuing licenses to:
  - **Facilitate** psilocybin service administration sessions,
  - **manufacture** psilocybin products,
  - **operate** psilocybin service centers, and
  - **facilitate** psilocybin therapy services.

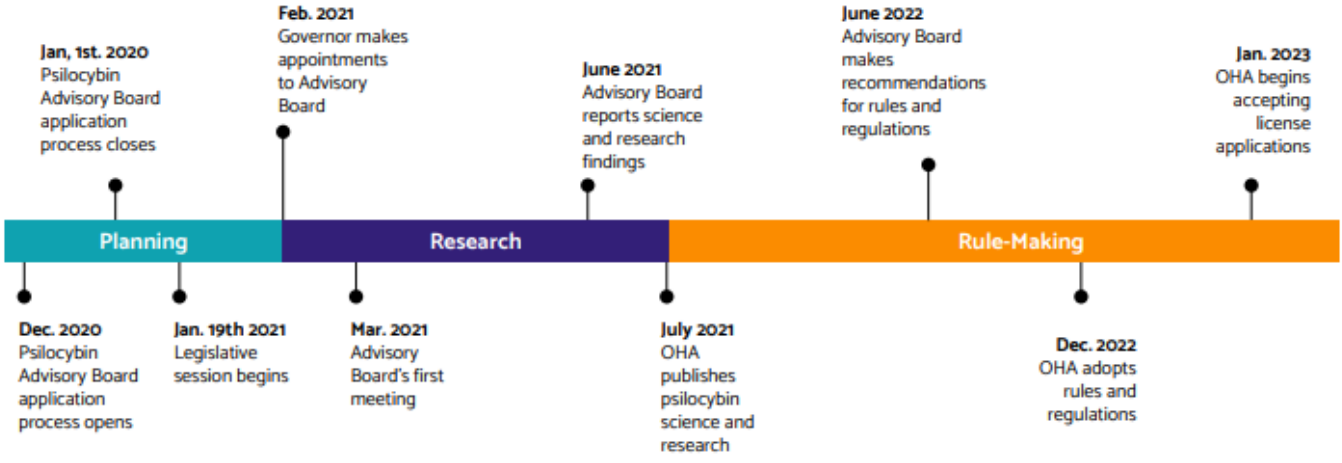
## Psilocybin Advisory Board

- Governor appoints 14-16 members
- Duties of the board:
  - Collect existing studies
  - Recommend guidelines for serving clients and licensing facilitators, service centers, etc.
  - Establish public safety standards
  - Establish professional conduct, certification, and training requirements
  - Develop a long-term strategic plan for ensuring that psilocybin services will be accessible and affordable therapeutic option
  - Monitor and study federal law, attempt to work with federal gov
  - Can establish subcommittees

# Psilocybin Advisory Board Members

- **Public Health Director Designee:** Andre Ourso, OHA
- **State Health Officer Designee:** Dr. Tom Jeanne, OHA
- **Oregon Health Policy Board Designee:** Barb Hansen
- **State Employee w/ Public Health Expertise:** Ali Hamade, OHA
- **Local Health Officer:** Dr. Sarah Present, Clackamas County
- **Addictions Medicine Specialist:** Kevin Fitts, Portland
- **Licensed Psychologist:** Dr. Kimberly Golletz, Corvallis
- **Licensed Physician:** Dr. Todd Korthuis, OHSU
- **Tribal Representative:** Angie Butler
- **Academic Researcher:** Dr. Chris Stauffer, Portland
- **Mycologist:** Dr. Jessie Uehling, Oregon State University
- **Hard Reduction Specialist:** Dr. Angela Carter, Portland
- **Psychopharmacological Specialist:** Dr. Atheir Abbas, OHSU
- **OLCC:** Nathan Rix
- **Oregon DOJ:** David Hart
- **Member of the Public:** Steph Barrs, Bend
- **Member of the Public:** Dr. Rachel Knox, Portland

# Implementation Timeline



# Local Control

## Overview

What powers does Measure 109 provide for local governments?

1. **Opt-in** by adopting reasonable time, place, and manner (TPM) regulations
2. **Take no action** and default to state regulations
3. **Opt-out** by sending the question to residents at the next general election

## Questions?

Sam Chapman
Executive Director
Sam@healingadvocacyfund.org

## Thank You

# Appendix E: Summary of Stakeholder Survey #1

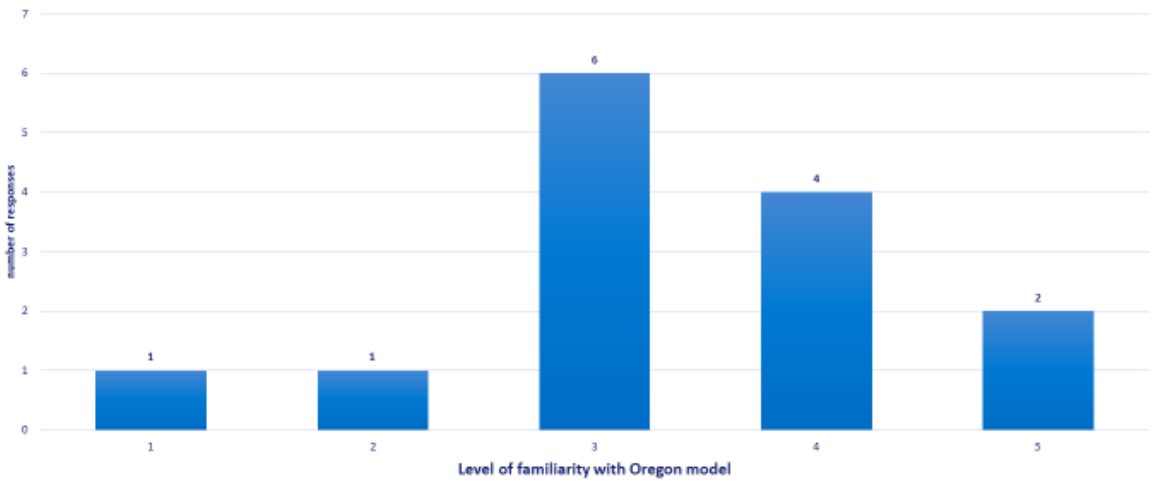
All stakeholder feedback in this section was not edited or corrected for grammar and is reported exactly as submitted.

## Survey 1
14 respondents

1

Washington State Health Care Authority

On a scale of 1-5 (with 5 being very familiar), please rate your level of familiarity with Oregon's model.



## From what you currently know about Oregon's psilocybin program, what elements should Washington **look to duplicate**?

- A 2-year period to organize and develop the needed infrastructure and that providers don't need to be licensed
- Promote access by those in end-of-life care
- Generally duplicate, but improve, Oregon's program
- Specially licensed centers to start
- What Oregon did was pass Measure 110 at the same time it passed 109
  - Unauthorized possession of fewer than 12 grams: penalty reduced from a Class A misdemeanor to a Class E violation
  - Possession of 12 or more grams: penalty reduced from a Class B felony to a Class A misdemeanor

3

Washington State Health Care Authority

## From what you currently know about Oregon's psilocybin program, what elements should Washington **look to duplicate**? (cont.)

- Educate the people about the safety and efficacy of psilocybin in treating mental health conditions
- Continue the robust training and practitioner programs that OR has suggested, while also allowing those with only a high-school diploma to take classes and training to ensure accessibility to all demographics, generally duplicate, but improve, Oregon's program
- Limiting psilocybin mushroom cultivation to P. cubensis
- Specially licensed centers to start
- Facilitator training to be universal

4

Washington State Health Care Authority

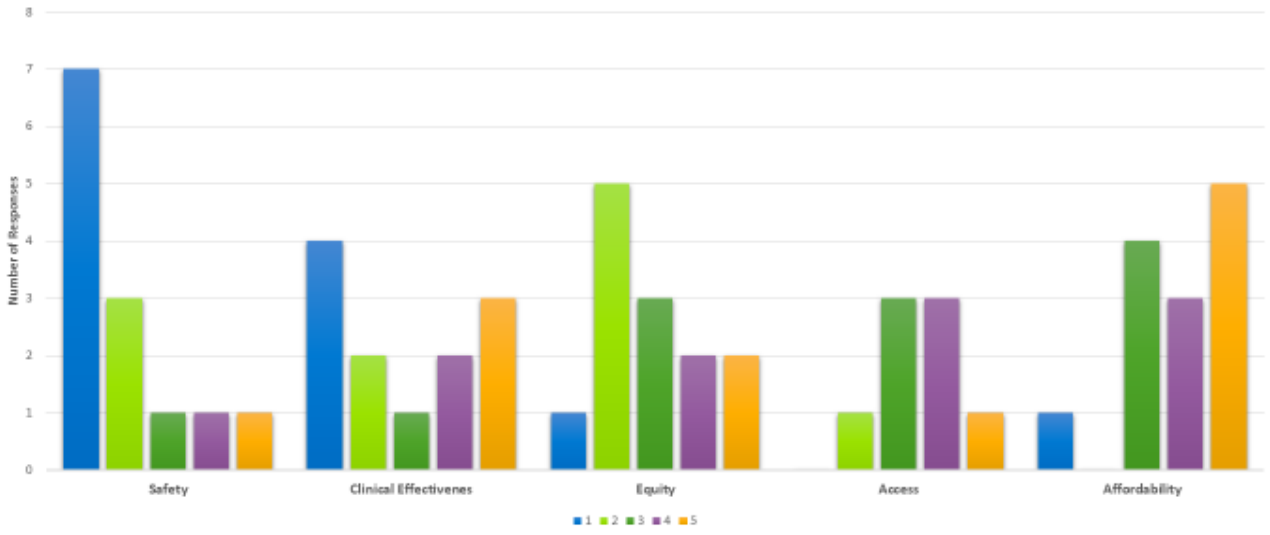
## From what you currently know about Oregon's psilocybin program, what elements should Washington **look to avoid or modify**?

- Enable micro dosing outside of service centers / permit online sessions
- Standardized method of tracking outcomes, similar to a REMS program - or a Risk Evaluation and Mitigation Strategy so we had some centralized way to track outcomes
- Allow for at-home administration for people with mobility access issues
- Give much more protections for equitable accessibility
- Incorporate cost-analysis to ensure that psilocybin sessions remain affordable for the average consumer

5

Washington State Health Care Authority

## Please prioritize the categories below based on their level of importance in shaping a future psilocybin program in Washington. (1 = most important, 5 = least important)




7

## Are there any other categories you would like to see prioritized? Please describe

- Advancing research - there are many gaps in the research literature that need to be addressed; e.g., differences between natural and synthetic psilocybin. Currently the research environment is very difficult
- Not interfering with pre-existing indigenous practices
- Equity, Access and Affordability should probably either be the same category, or there should be a way to ensure that those three categories have shared priorities because they are all so closely related. Same with Safety and Clinical Effectiveness
- Laws need to be flexible enough to allow for new innovations in the field

8

Washington State Health Care Authority

## What do you see as the **biggest opportunities** to Washington developing the regulatory framework and administrative capacity to legally administer psilocybin services?

- Huge unmet need of psychiatric conditions
- Potential to drastically improve the mental health and well-being of thousands of Washington resident
- Reduction of crime, prevention of mental illness
- Serving as a thought leader for other states by improving Oregon's template
- Simplifying and clarifying the regulatory pipeline to pursue research and other activities under this framework

9

Washington State Health Care Authority

## What do you see as the **biggest challenges and concerns** to Washington developing the regulatory framework and administrative capacity to legally administer psilocybin services?

- Department of Health doesn't have a framework to approve controlled substance registration applications for psychedelics
- Intersection with behavioral health license boards, accessibility due to cost, diversity of practitioners to meet population needs
- Standing up a regulatory framework for growth/manufacturing, safety assurance, and administration of schedule 1 substances
- Important not to underestimate the complexities of developing a regulatory framework for this industry
- Simplifying and clarifying the regulatory pipeline to pursue research and other activities under this framework

10

Washington State Health Care Authority

## What do you see as the **biggest challenges and concerns** to Washington developing the regulatory framework and administrative capacity to legally administer psilocybin services?

- Monopolization, corporatization, loss of sacred, loss of traditional medicine and practice
- Promoting access by, and investments in, the industry by historically disadvantaged communities / ensuring the industry doesn't become dominated by non-local investors
- Ensuring the safety of the individual and community
- Obtaining DEA/FDA legal permissions for continued research for ways psilocybin can be investigated for use

11

Washington State Health Care Authority

# Appendix F: Summary of Stakeholder Survey #2

All stakeholder feedback in this section was not edited or corrected for grammar and is reported exactly as submitted.

## Survey #2
13 respondents

1

Washington State Health Care Authority

## Level of Support for Micro-dosing Recommendation

| | Strong | | Medium | | Low | |
|---|---|---|---|---|---|---|
| | 5 | 4 | 3 | 2 | 1 | **Weighted Avg** |
| How strongly would you support including a recommendation for consideration of **micro-dosing** procedures and policies: | 9 | 1 | 3 | 0 | 0 | **4.0** |

Washington State Health Care Authority

## What, if any, additional feedback and recommendations do you have for the workgroup on how a **micro-dosing policy framework** could work?

- Reduce the waiting period from ~5 hours or eliminate the waiting period entirely. Promote access by those in end-of-life care
- Look at how people in Washington are doing microdosing or even non-microdosing and essentially putting some helpful and not onerous health and safety policies in place. Specially licensed centers to start
- Micro-doses to be obtained only through qualified providers (much like cannabis stores).

3

Washington State Health Care Authority

## What, if any, additional feedback and recommendations do you have for the workgroup on how a **micro-dosing policy framework** could work? *(cont.)*

- Recommend following and completing further state sponsored study on the Stamets stack for micro-dosing. Additionally, recommend allowance for businesses to create microdosing level products to deliver medicine, whether in pill form or liquid form.
- I think we lack any good evidence that micro-dosing has any clinical effects at this point.

4

Washington State Health Care Authority

# Level of Support for Clinical and Wellness Models

| | Strong | | Medium | | Low | |
|---|---|---|---|---|---|---|
| | 5 | 4 | 3 | 2 | 1 | Weighted Avg |
| How strongly would you support recommending a **clinical model** for psilocybin: | 2 | 1 | 4 | 2 | 4 | **2.61** |
| How strongly would you support recommending a **wellness model** for psilocybin: | 8 | 3 | 0 | 1 | 1 | **4.2** |

Washington State Health Care Authority

# What, if any, feedback do you have for the workgroup to consider around **clinical vs. wellness models**?

- Why not both? Wellness model for 3 grams or less, clinical model for anything over 3 grams, including option for higher dose choices, like those over 10 grams.
- Clinical model will create equity issues (similar, I suspect, to Ketamine- even with regulated facilitators, this has become a for-profit business, for those that are inclined.
- The wellness model seems concerning, as it seems to follow a "consumer" model. This worries me as I think we don't have enough understanding to ensure safety at this stage.
- The more safe, structured access that is offered, the less people will seek illicit sources.

6

Washington State Health Care Authority

## What, if any, feedback do you have for the workgroup to consider around **clinical vs. wellness models**? *(cont.)*

- Clinical model would be an improvement over the status quo, ideally psilocybin services should be made accessible to anyone who needs it. Psilocybin is safe enough in PK/PD metrics for most people to consume it without complications.
- There can be facilitators in the wellness model who have additional credentials, so that option can be there for those who need it.
- There should be provisions for facilitation to happen in people's homes or retreat centers.
- I'm in favor of the clinical model if it's the only foreseeable way to get this bill passed, otherwise the wellness model is more equitable, affordable, and accessible.

7

Washington State Health Care Authority

## What, if any, feedback do you have for the workgroup to consider around **clinical vs. wellness models**? *(cont.)*

- Adopting a clinical model would substantially impair this bill by significantly raising costs and other unnecessary barriers to access by low-income and marginalized populations. There can be facilitators in the wellness model who have additional credentials, so that option can be there for those who need it.
- Strongly recommend going with a wellness model due to the equity and access concerns. Many people who do not fit a mental health diagnosis can benefit from psilocybin services, and many people who are not licensed medical professionals can be and are competent psilocybin service facilitators.
- In wellness model, recommend age 21 years and older

8

Washington State Health Care Authority

# Level of Support for Tiered Training Structure

| | Strong | | Medium | | Low | |
|---|---|---|---|---|---|---|
| | 5 | 4 | 3 | 2 | 1 | **Weighted Avg** |
| How strongly would you support recommending a **tiered training structure** designed for different populations (i.e., general wellness, spiritual experience, dual diagnoses, mental health): | 2 | 7 | 2 | 1 | 1 | **3.61** |

Washington State Health Care Authority

# What, if any, feedback do you have for the workgroup to consider around creating **population-based training designs**?

- I'd like our state to have the forethought of an apprenticeship training model, with 300-2,000 training hours before certification.
- Don't reinvent the wheel, don 't make this another profitable venture, and don't rely on colleges (who have too much bureaucracy and will take too long and cost too much)
- Conceptually support this approach, but it could be much more complicated to implement, communicate, and regulate (who decides what is spiritual?)

10

Washington State Health Care Authority

## What, if any, feedback do you have for the workgroup to consider around creating **population-based training designs**? *(cont.)*

- We are not licensing clinicians here, so we shouldn't use that as a template. All the topics mentioned should be included in all facilitator's training.
- There is no research support for tiered training. Rather, there is considerable research to support an emphasis on experiential training for all facilitators / service providers working with all populations.
- I'm wary of too narrowly limiting this to certain medical professionals, Oregon's offering of training to anyone with the high-school diploma is a positive aspect.



Washington State Health Care Authority

## Level of Support for Insurance Coverage

| | Strong | | Medium | | Low | |
|---|---|---|---|---|---|---|
| | 5 | 4 | 3 | 2 | 1 | **Weighted Avg** |
| How strongly would you support including a recommendation for all psilocybin sessions be **covered by private insurance**: | 8 | 2 | 3 | 0 | 0 | **4.38** |
| How strongly would you support including a recommendation that **Medicaid explore legal and financial policies** for covering psilocybin sessions with state funding: | 8 | 4 | 1 | 0 | 0 | **4.54** |

Washington State Health Care Authority

## What, if any, feedback do you have for the workgroup to consider around **insurance coverage**?

- Insurance coverage is critical in order for psilocybin to be equitable.
- Strongly support subsidizing access to those with a mental health diagnosis who wouldn't otherwise be able to afford psilocybin services.
- Make insurance companies do what we want them too! They should follow our laws. (Why is acupuncture, for example, not covered?)
- Insurance and Medicaid coverage will be very important for ensuring access for low-income and marginalized populations.
- This is medicine and insurance should cover it. As a consumer, I'm willing to pay extra tax that would help fund low income and non-insured, including refugees to help cover or defray costs

13

Washington State Health Care Authority

## What, if any, feedback do you have for the workgroup to consider around **insurance coverage**? *(cont.)*

- I can see this from both sides.. 1) equity concerns, if the cost ends up being prohibitive and 2) more expensive for all due to insurance / 3rd party payer involvement. If one gets a rx for Tylenol, it costs about $24 a bottle, vs $1 at the dollar store.
- There should be parity between expectations of Medicaid and private insurance for equity and access reasons.

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# Level of Support for Oregon's Model

| | Strong | | Medium | | Low | |
|---|---|---|---|---|---|---|
| | 5 | 4 | 3 | 2 | 1 | **Weighted Avg** |
| How strongly would you support a **2-year implementation period** | 5 | 5 | 2 | 0 | 1 | **4.0** |
| How strongly would you support **passing decriminalization policy** concurrently | 10 | 3 | 0 | 0 | 0 | **4.77** |
| How strongly would you support **limiting psilocybin species to P.cubensis only** | 0 | 1 | 3 | 1 | 8 | **1.77** |
| How strongly would you support requiring **only a high school diploma** for facilitators | 6 | 2 | 2 | 0 | 3 | **3.62** |

Washington State Health Care Authority

# Level of Support for Oregon's Model (cont.)

| | Strong | | Medium | | Low | |
|---|---|---|---|---|---|---|
| | 5 | 4 | 3 | 2 | 1 | **Weighted Avg** |
| How strongly would you support **limiting consumption to on-site service centers** only. | 1 | 2 | 4 | 2 | 4 | **2.54** |
| How strongly would you support recommending that Washington's policy similarly **not include exemptions** for personal, religious, or indigenous use? | 1 | 1 | 2 | 1 | 8 | **1.92** |
| How strongly would you support recommending that Washington's policy **not specifically target populations** with addiction, PTSD, and end-of-life diagnoses? | 2 | 4 | 3 | 2 | 2 | **3.15** |

Washington State Health Care Authority

## What, if any, feedback do you have on Oregon's model or **implementation of Measure 109?**

- Strongly support the implementation of home-administration by service providers and allow entheogenic use for religious leaders and clergy members. I believe the clinical research supports the use of psilocybin for specific populations, but also there may be people who find psilocybin beneficial for other use cases outside of these target populations. I wouldn't want it strictly limited to specific diagnoses.
- Exemptions should be granted to anyone who wants one on personal, religious, spiritual or philosophical grounds. There should be no "testing" of the sincerity of those claims.

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Washington State Health Care Authority

## What, if any, feedback do you have on Oregon's model or **implementation of Measure 109?** *(cont.)*

- WA's policy should specifically target populations with addiction, PTSD, and end-of-life diagnoses and should include exemptions for personal, religious, or indigenous use.
- Measure 109 should have explicitly stated that Training Programs do *not* need to get approval from the HECC (the Oregon version of WSAC). Getting HECC approval is costing training programs many thousands of dollars and not adding any quality to the services they are providing, as HECC does not understand psilocybin training. SB5660 should explicitly exclude the need for WSAC approval.

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Washington State Health Care Authority

## What, if any, feedback do you have on Oregon's model or **implementation of Measure 109?** *(cont.)*

- Given the early state of research, I have concerns about using these compounds for any indication. Seems there has to be some narrowing in use until we can better understand its mechanisms and effectiveness.
- High school diploma okay, with the additional training (where a college degree is NOT a prerequisite) -- End of life, addiction PTSD are a good target population.
- 2y implementation: Oregon said it wasn't enough, so we go 3 years?
  - Limiting species- I think species should be expanded beyond one single strain.
  - Apprenticeship model for training, even if applicant is only high school or GED grad.
  - Treatment centers, estimate and amount a hospice centers.
  - Personal, religious, indigenous- this would be acceptable following wellness model of less than 3 grams
  - Addiction, PTSD, end of life - this would be acceptable following clinical model, allowing dose greater than 3 grams.
  - Both wellness and clinical models can work side by side

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Washington State Health Care Authority

## Any additional feedback you wish to provide?

- We should develop policy that recognizes the human geography of entheogens like psilocybin fungi which people have been naturally forming spiritual/meaningful relationships with for millennia. We should keep the system as open as possible to recognize, honor, and respect traditional practitioners and facilitators. The state's job should should be to provide unbiased education and some mild health and safety regulation.
- Please include questions/focus on excluding the need to WSAC approval for SB5660 training programs. It costs many thousands of dollars and takes 2+ years to obtain.
- Language for both wellness and clinical models that provides for integration assistance and this be covered by insurance also. Additionally recommend rapid veteran focused use retreats asap.

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Washington State Health Care Authority

# Appendix G: State Legislative Activity Analysis

## State Legislation and Ballot Activity Regarding Psychedelic Drugs

## Executive Summary

Since 2019, 21 bills and ballot initiatives have been introduced into state legislatures across the country attempting to legalize, research, and decriminalize psychedelic drugs. Eight bills have passed and are now law, among them 4 advisory workgroup bills, 2 research bills, 1 decriminalization bill, and 1 ballot initiative focused on facilitated psychedelic-assisted therapy (PAT). Five bills are active in committee and have either passed in one legislative chamber or are pending a state ballot. Of the remaining 8 bills, 3 received substantive legislative support and were pushed to the next session for further review.

Oregon's Ballot Measure 109 to authorize facilitated PAT was the first to pass in November of 2020, followed by New Jersey's decriminalization bill in December 2020. Texas' research bill and Connecticut's study group bill passed in 2021, and bills in Maryland, Oklahoma, Utah, and Washington in 2022. Despite the surge of state action in recent years, few of these 21 bills and ballot initiatives use similar language, with the following exceptions: New York, Maine, and Washington's bills have some similarity to Oregon's Measure 109. Florida's bill is a near copy of the 2021 bill passed in Texas.

Notably, much of the psychedelic legislation introduced to date has bipartisan co-sponsors and support from both parties. Legislation in Connecticut, Georgia, Maryland, Missouri, New Hampshire, Oklahoma, Pennsylvania, Texas, and Utah received bipartisan support while bills in Florida, Rhode Island, and Maine were met with Republican opposition. The bipartisan support for psychedelic legislation, paired with the speed with which these bills have been introduced into state legislatures, suggests that additional states are likely to introduce their own legislation.

This analysis covers the existing 21 state bills and ballot initiatives introduced as of July 2022, and summarizes themes in the following 7 areas:

- Psychedelic Substances Considered for Approval
- Research Directive
- Public Availability and Target Diagnosis
- Bill Model and Goal
- Equity Approach
- Decriminalization Directives
- Funding Approach

The analysis does not examine the available evidence on psychedelic therapy but focuses only on state legislative and ballot activity. Appendix A provides detail about each state's bill or ballot initiative including citations and a link to the original bill or ballot initiative.

## Psychedelic Substances Under Consideration

There was significant variation among states regarding which psychedelic substances were included in the bill or ballot initiative. Psilocybin or its equivalent, psilocyn, was the sole therapeutic drug up for approval in 12 bills focused on therapeutic use, decriminalization, or research. Other states took a broader approach to inclusion of psychedelic drugs (Table 1)—these can be separated into 3 general categories with slight variations from state to state:

- Natural Medicines—N-dimethyltryptamine (DMT), ibogaine, mescaline, psilocybin, psilocyn. Most states using the term natural medicine acknowledge peyote's vulnerable status, and its importance to certain First Nation traditions, but peyote is generally banned from production or consumption in these bills.
- Therapeutic Medicines— 3,4-methylenedioxy-methamphetamine (MDMA), psilocybin, ketamine. These three drugs have some research supporting therapeutic efficacy and are farthest along in the FDA approval process.
- Psychedelic Medicines—psilocybin, DMT, ibogaine, mescaline, lysergic acid diethylamide (LSD), MDMA. This category is the most inclusive of the three and does not exclude notable psychedelics. In some cases, bill wording leaves opportunity for other substances to be added if approved by research institutions, an advisory board, or a state agency.

Notable variations in substance approval include Rhode Island's bill that proposes to allow possession of buprenorphine (a pharmacotherapeutic for heroin and methadone dependence) and psilocybin, and Utah's bill that makes no mention of any psychedelic substance, leaving the decision of substance approval to its advisory board. Notably, none of the 21 state bills and ballot initiatives analyzed include any mention of a microdosing facilitation or research plan. Psychedelic microdosing is repeated use of small sub-therapeutic doses, such as 10–20 mcg of LSD or less than 1-3 mg of psilocybin.[1]

## Research Directive

Sixteen state bills include some form of research directive with 11 of those states proposing establishment of an advisory board or workgroup. Advisory boards and workgroups are generally given a specified window of time to complete their review and issue a report to the governor or legislature, with Utah having the nearest advisory report due date of October 31, 2022. These advisory groups have some common membership composition requirements across states, often specifying individuals with experience in therapy, medicine, public health, drug regulation, and substance abuse treatment as members. Another 6 membership categories were common among states, including:

- Indigenous rights—California, Colorado, Maine, Oregon, Washington
- Equity—Colorado, Maine, New York, Oregon, Washington
- Law enforcement, first responders—California, Colorado
- Harm reduction—California, Colorado, Maine, New York, Oregon, Utah, Washington
- Veterans—Colorado, New York, Washington
- Agriculture—Colorado, Maine, Oregon, Washington

Three states included notable advisory board membership category requirements outside the listed criteria above:

- Oregon—includes a member experienced in the legalization of cannabis

- California—includes a member experienced in youth drug use control and education
- Washington—includes several additional member requirements:
    - a member experienced in end of life and palliative care
    - a member experienced in the cannabis legalization process
    - members with the lived experience of using psychedelics
    - a LBQTQIA advocate
    - disability rights advocate

Connecticut, Georgia, and Pennsylvania's bills do not include the same type of required memberships categories. Rather, Connecticut's bill states that 9 members are to be appointed by various government officials, without reference to specific qualifications or areas of expertise. Georgia's bill proposes an advisory group composed of 6 members, 3 of them veterans, 2 House of Representatives members, and 1 Department of Health member. Finally, Pennsylvania proposed to employ an existing committee, the Health Research Advisory Committee (HRAC), to advise on psychedelic implementation.

Many of the bills leave psychedelic research oversight to a specific branch of government, usually the state's Department of Health (DoH), but some states selected other agencies or organizations:

- Connecticut—Department of Mental Health and Addiction Services
- Georgia—House Committee on Defense and Veterans Affairs
- Missouri—Department of Health and Senior Services
- Texas—Texas Medical Board

States not employing an advisory board model typically partner with outside research institutions. Texas, for example, names the Baylor College of Medicine as its research partner, and Maryland names Johns Hopkins and the citizen advocacy nonprofit, Brainfutures, in its legislation. Other states offer licenses to research institutions for the production, synthesis, and testing of psychedelics, with bills in Oklahoma, New York, and Missouri proposing to allow eligible institutions to produce certain psychedelic drugs in-state for research purposes.

## Public Availability and Target Diagnosis

Many state bills and ballot measures contain eligibility requirements for individuals seeking PAT, such as age, type of employment, diagnosis, but the requirements vary greatly from state to state. This section will focus on legislation that contains a proposed psychedelic facilitation plan; this can be described as any proposal that allows an individual to take a psychedelic drug under supervision in a licensed facility.

Age is one of the threshold criteria. Nearly all state proposals require a minimum age of 21 years, Oklahoma is the notable exception with a minimum age of 18 years. Of the states with a facilitation plan proposal, 6 allow for all individuals above 21 to be treated without a diagnosis or doctors approval. These state bills and ballot measures are oriented towards a wellness model where psychedelic therapy would be offered outside a traditional medical structure.

Veterans and their associated diagnoses are another focus area for eligibility. Georgia and Maryland limit psychedelic treatment to veterans while Connecticut limits treatment to veterans, first responders, and healthcare workers. Georgia allows for veterans with PTSD, major depressive disorder, and substance use disorder to be treated, while Maryland limits treatment to veterans with PTSD and traumatic brain injuries.

Even though Connecticut limits treatment to veterans, first responders, and healthcare workers, the state legislation does not require a medical diagnosis.

Another 7 state proposals pursue a medical or research model and list a variety of diagnoses in bill or ballot measure language. These states include depression as a diagnosis eligible for treatment, and most include anxiety and PTSD. From this point there is variation among the states as substance use disorder, traumatic brain injury, bipolar disorder, end-of-life treatment, migraines, and chronic pain are scattered among different bills, depending on the focus of each piece of legislation. Oklahoma makes the distinction of "treatment-resistant" status for anxiety and depression, which would exclude a greater population from treatment.

Despite finite lists of diagnoses seen in many state bills and ballot initiatives, Missouri, New York, and Pennsylvania all have clauses allowing for petition or further determinations by the state DoH or advisory boards to consider other conditions. Washington and Utah do not specify any diagnosis, and leave the decision of public availability to the workgroup or future legislative action.

## Equity Approach

Eleven states mention equity in proposed legislation but vary in the degree of practical implementation guidance for facilitating accessible and affordable therapy. Decriminalization bills, which are generally oriented towards improving equity, are not included in this section; see Decriminalization Directives below for more information.

California, Colorado, Connecticut, New York, Pennsylvania, and Washington include the most detail and direction in their bill or ballot measure language calling for an advisory board to investigate the accessibility and affordability of the proposed psychedelic therapy facilitation plan. The equity section of these state bills and ballot initiatives is short, outlining equity as a priority, but making no further mention of equity, insurance coverage, cost-reimbursement, minority ownership, etc. Only Colorado, Washington, and New York have designated members on the advisory board specifically focused on and experienced in equitable health policy.

The remaining states have a more limited or unique approach to equity. Hawaii and Maine call for the program to be "safe, accessible, and affordable", but outline no process or directive to achieve this goal. Maryland has a "$1 million, non-lapsing fund" that would cover the treatment of all eligible veterans in the state if implemented. Missouri explicitly outlines that health care insurers and the Department of Corrections cannot be required to cover psychotherapy drug treatment, but does explicitly state that associated treatment or therapy can covered by insurance.

A subcommittee in Oregon has been formed by the Measure 109 advisory board specifically to address equity. More recently, Oregon SB 1580 has been pushed to next session; if passed in 2023, a 15-member task force "The Task Force on Psilocybin Health Equity" would be created to study health equity as it relates to psilocybin facilitation.

Lastly, in Washington's 2021-22 SB 5660, which did not pass, the state introduced the Social Opportunity Program (SOP). Despite the bill not passing, the SOP is now being studied by the Washington State advisory workgroup for its applicability to the state's emerging psilocybin program. As outlined in Section 115 of SB 5660, the primary goal of the program is to identify distressed areas and offer assistance to individuals and entities within distressed areas who qualify by including reduced psilocybin therapy center

license fees and enhanced scoring for licensing applications. The bill outlines criteria for distressed areas and SOP applicants, which is summarized below.

- A distressed area is categorized as such by the Washington State Department of Labor and/or where:
    - 50% of children participate in free lunch
    - 20% of households are under federal supplemental nutrition assistance program
- A SOP applicant is:
    - an entity where at least 51% of ownership is with individuals that have lived in a distressed area for 5 of the last 10 years
    - an entity where more than half of its employees reside in a distressed area
- The SOP remains open-ended to allow for other criteria and benefits to be added as seen fit by the department

Washington's proposed SOP is the most detailed of the existing equity proposals. If new legislation in Washington passes with the SOP included, states should observe its implementation to determine the impact on creating equitable health policy.

## Decriminalization Directives

State-level decriminalization is an essential step for psychedelic therapy. It is critical to note, however, that aside from ketamine, all other psychedelic drugs mentioned in this analysis remain illegal at the federal level. Federal fines and criminal action can still be applied even if a state decriminalizes a psychedelic drug. Interaction of state and federal law is complicated, and it is often left to the current President's administration to determine the degree to which federal law will be pursued when in conflict with state law. Nonetheless, federal illegality of psychedelic drugs has serious impacts for PAT business viability as it relates to tax breaks, loans, and other legal and financial considerations. Therefore, decriminalization remains a top priority for many states looking to move forward with psychedelic therapy.

Three distinct decriminalization categories can be identified from existing legislation, which are outlined below. Of the existing legislation, 7 have possession bills, 2 have reclassification bills, and 3 have broad decriminalization bills.

Possession bills are the most common approach to decriminalization. Requirements for jail time and felony charges for low levels of possession of an illegal psychedelic drug are removed, with a small fine being left as a punitive measure. Possession bills seek to decriminalize the drug in most cases of small possession, which limits the degree to which law enforcement can make arrests, though sale and distribution of psychedelic substances remains illegal. There is variation in how low-level possession is defined from state to state, from 4 grams of psilocybin in Missouri to 28 grams in New Jersey to 1.5 ounces in Oklahoma.

Reclassification involves a change in regulatory or statutory language to recategorize a drug within the state, effectively removing it from the state's schedule 1 drug categorization. Hawaii and New York have bills introducing this strategy. As stated above, interactions with federal law are complex—but, in this case as with all others, the drug would remain illegal on a federal level even if reclassified at a state level.

Lastly, broad decriminalization efforts, separate from existing PAT legislation, are being pursued in a handful of states. Maine and Oregon have bills that propose to decriminalize illegal drug possession, and

Washington's recent state supreme court decision paves the way for legislators to decriminalize illegal drug possession. Though federal restrictions still apply, these last two approaches have implications for the viability of psychedelic drug facilitation, production, training, and testing centers in each state.

## Funding Approach

Funding for psychedelic therapy in many cases has not been thoroughly addressed, as much of the existing PAT legislation has years before implementation. Despite this, funding sources are important to consider in the case of legislative success. In instances where funding is included, bills or ballot initiatives designate funding from the state DoH or establish a fund for the implementation of PAT. The legislation with funding plans is mentioned below:

- Connecticut and Maryland have established funds with allocations of $1.5 million and $1 million respectively
- Texas and Hawaii are to receive funds directly from the state DoH
- Oklahoma and Missouri will use outside research institutions for research and funding
- Georgia's funding will be allocated from the House of Representatives' budget
- Decriminalization bills such as Virginia and New Hampshire take funds earned from illegal drug possession fees and put them towards addiction treatment services in the state

## Bill Model and Goal

The categories above break down the functions of existing psychedelic drug bills and ballot initiatives. Building on these categories and functions, it is possible to identify model definitions that describe the goal being pursued in a bill or ballot initiative. The definitions below are flexible and broad as each state bill or ballot initiative varies greatly from the next. What the model definitions below aim to achieve is a shared terminology to better describe the range of options being pursued at the state level.

- Medical Model—The individual seeking therapy must have a diagnosis from a doctor that is included in the specific diagnoses eligible for treatment by the state for PAT.
    - Under this model, a state agency such as the Department of Health may be involved in oversight.
    - Facilitators for psychedelic therapy may include those with clinical training or state licenses.
- Wellbeing Model—Available to all above the age requirement, psychedelic therapy facilitators are not necessarily clinical professionals, and no diagnosis or doctor's recommendation is needed.
    - Without a direct connection to a medical diagnosis, reimbursement by health insurance seems unlikely.
- Possess & Share Model—Low level possession is legal at state level, individuals are allowed to cultivate, possess, and use certain psychedelics, as long as there is no sale of the drug and possession stays below state-set legal limits.
    - This plan likely involves little to no government regulation.
    - Possession limits vary.
- Research Model—Psychedelics are only used in a research setting; research institutions may cultivate and administer psychedelics to certain populations for research purposes with goal of developing a recommendation for a facilitated PAT model in the state.
    - Not all states allow for cultivation in-state.

    - Research on the efficacy of treating select diagnoses or conditions is encouraged.
- Prescription Model—Psychedelics are available to obtain by prescription for use outside a licensed facility.
- Decriminalization Model—Bill does not propose any research or facilitation plan, but removes penalties on certain levels of psychedelic drug possession, or decriminalizes or reclassifies the drug(s) within the state.
    - Revenue from fines levied for low level possession are often directed towards research or addiction treatment programs.
- Advisory Board Recommendation Model—The state will consider future legislation or form an implementation plan based on the recommendations of an advisory board.
    - In some cases, the advisory board is given directives by bill language to implement or recommend a certain model, often a Medical Model.
    - In other cases, the advisory board is given less direction and more say in the scope of recommendations.

# Conclusion

The pace of psychedelic drug legislation is rapidly increasing. Within the last two years, 19 pieces of legislation have been introduced attempting to decriminalize, research, or facilitate the use of psychedelics. The bills and ballot measures introduced contain a remarkable degree of variation, indicating that there are still opportunities for states to exchange lessons learned on program design. The identified models—Medical, Wellbeing, Possess & Share, Research, Prescription, Decriminalization, Advisory Board Recommendation—give policymakers options to consider, along with a sense of the proposed landscape of activity. This analysis is intended to compile those options and create a shared language to define them as models.

PAT faces legitimate barriers to success, foremost of which being therapeutic psychedelics' classification as a federal schedule 1 drug. Federal illegality presents legitimate challenges to facilitative therapy, legal production, and insurance coverage, among other challenges. Systematic inequalities, when placed alongside the potential cost of a facilitation session, pose a serious challenge to affordable and accessible access to psychedelic therapy.

Future legislation, advisory board recommendations, and other forms of governmental action relating to PAT should scrutinize the facilitative models currently being passed in states to ensure equitable access to care. By continuing to support research related to PAT, and sharing research findings and implementation strategies, state policy makers can slowly begin to form consensus on harm reduction strategies, training, evidence for treatment, and supportive facilitation models. Through collaborative policy development, PAT has a chance to be implemented in a manner to ensure safety and equitable access for individuals.

Table 1. Psychedelic Drugs

| Drug Name/Common Name | Research Supported Indications | Controlled Substance Status |
|---|---|---|
| psilocybin | • SUD<br>• MDD<br>• Anxiety<br>• Cancer<br>• PTSD | • Schedule I |
| psilocin | • Responsible for "high" in 'shrooms<br>• MDD<br>• TRD | • Schedule I |
| 3,4-methylenedioxy-methamphetamine (MDMA) | • PTSD<br>• Anxiety | • Schedule I |
| lysergic acid diethylamide (LSD) | • SUD<br>• Depression<br>• PTSD<br>• Anxiety | • Schedule I |
| N-dimethyltryptamine (DMT) | • SUD<br>• Depression<br>• PTSD<br>• Anxiety | • Schedule I |
| ketamine | • Anesthetic<br>• MDD<br>• Anxiety | • Schedule III |
| ibogaine | • SUD<br>• Reduce opioid withdrawal symptoms and reduce cravings | • Schedule I |
| peyote | • Rheumatism<br>• Burn wounds<br>• Tuberculosis<br>• Pneumonia<br>• Scarlet fever<br>• Intestinal issues<br>• Diabetes | • Schedule I |

# Appendix: State Legislation and Ballot Detail

| | California[1] | Colorado[2] | Connecticut[3,4] |
|---|---|---|---|
| Date of Introduction/Bill Number | August 2021<br>SB 519 | January 2022<br>Initiative 58 | HB 5396<br>Budget Bill, March 2022<br>SB 1083, June 2021 |
| Bill Status/Potential Implementation Date | • Bill passed the Senate in 2021, was made into a two-year bill to be revisited in 2022 | • Approved for circulation, petition due in August 2022<br>• To be on the ballot in November 2022 | • Bill stalled in Senate, but the recent budget proposal nearly mirrors bill, which was signed by the governor<br>• Funding to be distributed by March 2023<br>• SB-1083 was signed in June of 2021 creating a study group with similar guidelines to the group proposed by HB-5396 |
| Sponsor/Political Party | Sen. Scott Weiner (D) | Initiative filed by psilocybin advocate Kevin Matthews and entrepreneur Veronica Perez[5] | • Rep. Steinberg (D)<br>• Bipartisan support for budget bill<br>• Rep. Mitch Bolinsky (R) |
| Substances up for Approval | Psilocybin, psilocyn, DMT, ibogaine, mescaline, LSD, and MDMA | • DMT, ibogaine, mescaline, psilocybin, or psilocyn<br>• Excludes the growth and use of Peyote | MDMA, psilocybin, other psychedelics to be reviewed by the advisory board |
| Research Directive | • Research Advisory Panel created to study projects concerning cannabis or hallucinogenic drugs<br>• Department of Public Health to create a work group to make recommendations to the legislature on the regulation and use of these substances | • Natural Medicine Advisory Board approves psilocybin, and will look into other substances (ibogaine, mescaline, DMT) and make recommendations in the 2022 report to the governor and legislature<br>• Natural Medicine Advisory Board will only approve Psilocybin and Psilocin until 2026 | • Mental Health and Addiction Services (DMHAS) to establish pilot program to broader audience<br>• Connecticut Psychedelic Treatment Advisory Board established in 2021 by DMHAS to investigate the mental health benefits of psilocybin |
| Availability/Target Diagnosis | Individuals 21 years and over, no diagnosis needed | Individuals 21 years and over, no diagnosis needed | • First responders, veterans, health care workers<br>• Separate failed bill was more inclusive, included "underserved communities" |

| | California[1] | Colorado[2] | Connecticut[3,4] |
|---|---|---|---|
| Bill Model/Goal | Possess & Share Model<br>• "allows for the possession, obtaining, and giving away of psychedelics"<br>• Allows for the production, cultivation, and growth of psychedelics, as long as this production does not involve profit | Wellbeing Model/Possess & Share Model<br>• Natural medicine services provided by a facilitator, licenses to be given to non-medical institutions and individual practitioners<br>• individuals do not need a diagnosis to receive treatment<br>• Natural medicine can be grown on private property, can be shared and used, but not for profit | To be determined by advisory board<br>• Once study group reports its findings, group will advise on medical model for veterans |
| Equity Approach | • Work group focusing on education, harm reduction, end of life care, etc.,<br>• charged with finding regulatory systems that would promote "safe and equitable access" | • Review sustainability, and the impact on indigenous cultures<br>• For "disproportionately harmed" communities, reduce fees for licensing, reduced prices for low income individuals<br>• Bill calls for effectiveness of equity policies to be reviewed annually | • Advisory Board advises DMHAS on equity, cost and insurance reimbursement standards |
| Decriminalization Directives | • 4 grams of psilocybin mushrooms are legal<br>• $70 fine for greater possession | • Decriminalization of the possession, cultivation, growing, and using of natural medicines<br>• Section 170 makes possession, cultivation, etc. "not an offense" | No decriminalization plan |
| Funding for Bill | No Funding Plan | Regulated natural medicine access program fund established through the Colorado State Treasury | Qualified Patients for Approved Treatment Sites Fund, "PAT Fund", administered by DMHAS, $1.5 million set aside for supporting trial runs of facilitation centers |
| Links to Bill | https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB519 | https://leg.colorado.gov/sites/default/files/initiatives/2021-2022%2520%252358.pdf | https://www.cga.ct.gov/2022/TOB/H/PDF/2022HB-05396-R00-HB.PDF |

| | Florida[6] | Georgia[7] | Hawaii[8,9] |
|---|---|---|---|
| Date of Introduction/Bill Number | January 2022<br>HB 193 | March 2022<br>LC 48 (substitute to HR 896) | March 2022<br>HB 2400<br>SB 738 |
| Bill Status/Potential Implementation Date | • Bill died in committee | • Bill yet to be scheduled for a hearing<br>• Committee to be dissolved in December 2022 | • Passed in Senate, pending in House<br>• Workgroup to be dissolved in June 2023 |
| Sponsor/Political Party | Rep. Michael Grieco (D) | Rep. Bill Hitchens (R), bipartisan support with no Democrat proposals | Sen. Chang (D), Sen. Acasio (D),<br>Democratic support |
| Substances up for Approval | MDMA, psilocybin, and ketamine | Psilocybin | Psilocybin |
| Research Directive | • The Department of Health, along with the Florida Board of Medicine, will research the effectiveness of the psychotherapy drugs on the conditions listed | • House Committee on Defense and Veterans Affairs creates "study committee on alternate PTSD treatment resources for veterans"<br>• Committee membership includes with six members, three veterans, two House members, and one public health official | • Workgroup to examine effects of Psilocybin and develop a long-term plan for implementation<br>• Report due to the Legislature in 2023 |
| Availability/Target Diagnosis | Depression, anxiety, PTSD, bipolar disorder, migraines, chronic pain | Veterans with PTSD, major depressive disorder, and substance abuse issues | • Anxiety, depression, end of life treatment<br>• Individuals 21 years and older |
| Bill Model/Goal | Research model<br>• no plan or wording in the bill about implementation to the broader public<br>• bill is a near copy of Texas bill | To be determined by advisory board<br>• Once study group reports its findings, group will advise on medical model for veterans | To be determined by advisory board<br>• Bill states treatment is necessary for a "shortage in mental health professionals"<br>• Bill wording encourages a medical model |
| Equity Approach | No equity plan mentioned | No equity plan mentioned, program specifically for veterans | Bill calls for program to be "safe, accessible, and affordable for adults |

| | Florida[6] | Georgia[7] | Hawaii[8,9] |
|---|---|---|---|
| | | | twenty—one years of age or older" |
| Decriminalization Directives | No decriminalization plan | No decriminalization plan | • SB 738 proposes removing psilocybin and psilocyn from the list of schedule 1 substances, effectively decriminalizing the substances<br>• Bill was tabled until next session |
| Funding for Bill | No funding plan | Funds built into the Georgia state budget | No funding plan |
| Links to Bill | https://www.flsenate.gov/Session/Bill/2022/193/BillText/Filed/PDF | https://www.legis.ga.gov/legislation/62532 | http://kslegislature.org/li/b2021_22/measures/hb2465/ |

| | Kansas[10] | Maryland[11] | Maine[12,13] |
|---|---|---|---|
| Date of Introduction/Bill Number | January 2022<br>HB 2456 | February 2022<br>SB 709 | April 2021<br>SP 496 |
| Bill Status/Potential Implementation Date | • Bill died in committee | • Bill passed<br>• Workgroup to report findings at the beginning of 2024 | • Bill passed in the Senate<br>• Did not pass in the House |
| Sponsor/Political Party | Rep. Aaron Coleman (D) | Sen. Sarah Elfreth (D), Rep. Seth Howard (R),<br>Bipartisan unanimous support | Sen. Bailey (D), met with Republican opposition |
| Substances up for Approval | Psilocybin, psilocyn | Psilocybin, MDMA, ketamine | Psilocybin |
| Research Directive | No research plan | • Research process organized by the Maryland Dept. of Health<br>• DoH to consult with Johns Hopkins, | • Maine Psilocybin Advisory Board set up by the Department of Health and Human Services<br>• Advisory board to do research on available data |

| | Kansas[10] | Maryland[11] | Maine[12,13] |
|---|---|---|---|
| | | Brainfutures, and other research institutions | and make recommendations |
| Availability/Target Diagnosis | Individuals 21 years and over, no diagnosis needed | Veterans with PTSD and traumatic brain injuries | Individuals 21 years and over, no diagnosis needed |
| Bill Model/Goal | Possess & Share Model/Wellbeing Model<br>• Would not be a violation to grow/cultivate/use/ possess psilocybin | To be determined by advisory board<br>• Maryland Dept of Health to consult various research institutions, submit action plan by end of 2022<br>• Will likely be a medical model treating veterans with existing conditions | Wellbeing Model<br>• similar to Oregon, there is no medical diagnosis needed, primary care doctors to help recommend dosages |
| Equity Approach | No equity, accessibility, or affordability plan | Treatment is cost free, to be funded by the state | Bill calls for program to "become and remain a safe, accessible and affordable therapeutic option<br>for all persons who are years of age or older and for whom psilocybin services may be appropriate;" |
| Decriminalization Directives | • Fine to not exceed $250 if quantity less than 100 grams<br>• decriminalizes higher possession, making it a class B nonperson misdemeanor for possession over 100g | No decriminalization plan | Two other bills, one sponsored by Anne Perry (D), decriminalizes psilocybin among other drugs |
| Funding for Bill | No funding plan, workgroup to be run and supported by DoH | • PTSD and Traumatic Brain Injury Alternative Therapies Fund established<br>• Funding set at $1mil, non-lapsing fund | No funding plan |
| Links to Bill | https://www.capitol.hawaii.gov/session2022/bills/SB3160_SD2_.pdf | https://mgaleg.maryland.gov/mgawebsite/Legislation | https://legislature.maine.gov/bills/getPDF.asp?pap |

| | Kansas[10] | Maryland[11] | Maine[12,13] |
|---|---|---|---|
| | https://www.capitol.hawaii.gov/session2021/bills/SB738_.pdf | /Details/SB0709?ys=2022rs | er=SP0496&item=1&snum=130 |

| | Missouri[14] | New Hampshire[15] | New Jersey[16] |
|---|---|---|---|
| Date of Introduction/Bill Number | March 2022<br>HB 2850 | January 2022<br>HB 1349 | December 2020<br>A 5084 |
| Bill Status/Potential Implementation Date | • First hearing for the bill occurred in March 2022<br>• Next hearing not scheduled | • Bill passed in the Senate<br>• Did not pass in the House | • Bill Passed |
| Sponsor/Political Party | Rep. Tony Lovasco (R) | Rep. Tony Labranche (D)<br>Bipartisan co-sponsors | Sen. Scutari (D) |
| Substances up for Approval | • Psilocybin, psilocyn, DMT, ibogaine, mescaline<br>• Excludes peyote | Psilocybin | Psilocybin |
| Research Directive | • Facilitation of the bill done by the Department of Health and Senior Services<br>• Research institutions allowed to produce in-state<br>• No research specifically called for, individuals may petition to the Department to get treated for conditions not listed | No research program in bill | No Research program in bill |
| Availability/Target Diagnosis | PTSD, depression, terminal illness, or any illness that has been shown to be positively | No Treatment Plan | No treatment plan |

| | Missouri[14] | New Hampshire[15] | New Jersey[16] |
|---|---|---|---|
| | associated with treatment | | |
| Bill Model/Goal | Medical Model<br>• An eligible patient needs a doctor's prescription to access "Natural medicine" | Decriminalization Bill | Decriminalization bill |
| Equity Approach | • Bill explicitly mentions that health care insurers and the department of corrections cannot be required to cover psychotherapy drug treatment<br>• Bill does allow for associated treatment or therapy to be covered by insurance | No equity, accessibility, or affordability plan | No equity, accessibility, or affordability plan |
| Decriminalization Directives | Up to 4 grams decriminalized, max $500 fine no jail time | 12 grams less than $100 fine | • Possession is no longer a third-degree crime<br>• Is reclassified as a disorderly persons offense for possession under an ounce (28 grams)<br>• Jail time limited to 6 months, max fine $1,000 |
| Funding for Bill | No funding plan mentioned, initial production and trials to be funded by research institutions | Funds collected from fees to go to drug abuse fund | No funding plan |
| Links to Bill | https://house.mo.gov/Bill.aspx?bill=HB2850&year=2022&code=R | https://www.gencourt.state.nh.us/bill_status/legacy/bs2016/bill_status.aspx?lsr=2618&sy=2022&sortoption=&txtsessionyear=2022&txttitle=psilocybin | https://pub.njleg.gov/bills/2020/S3500/3256_I1.PDF |

| | New York[17] | Oklahoma[18] | Oregon[19-21] |
|---|---|---|---|
| Date of Introduction/Bill Number | December 2021<br>A08569<br>A06065 | February 2022<br>HB 3414 | November 2022 (Measure 109)<br>March 2022 (SB 1580) |
| Bill Status/Potential Implementation Date | • No hearing scheduled for any of the proposed legislation | • Passed in the House, just shy of emergency clause to make legislation effective immediately<br>• Committee to release findings no later than December 2025 | • Measure 109 passed in Nov 2020<br>• SB 1580 is in Senate committee |
| Sponsor/Political Party | Rep. Linda Rosenthal (D) sponsored both the research and decriminalization bills | Rep. Daniel Pae (R), Rep. Logan Phillips (R) | Thomas and Sheri Eckert are the founders of the Oregon Psilocybin Society (OPS) |
| Substances up for Approval | Psilocybin | Psilocybin, psilocyn | Psilocybin |
| Research Directive | • Advisory board to be created through the DoH, to make recommendations every two years<br>• DoH can consult with outside institutions for research, though it will conduct independent research as well<br>• Production is allowed in the state through a licensing process | • Research institutions obtain a license from the DoH<br>• Research is explicitly encouraged to study the science of cultivation, synthesis, extraction and processing | • The Oregon Health Authority (OHA) encouraged to "examine, publish and distribute research relating to health and efficacy" primarily for public education |
| Availability/Target Diagnosis | PTSD, addiction, depression, end-of-life anxiety, allows petition for other issues | • PTSD, treatment-resistant and refractory depression, anxiety, obsessive compulsive disorder, traumatic brain injury, dementia, palliative care, end of life care, opioid use, chronic pain | • Program aims to "Reduce the prevalence of mental illness"<br>• Individuals 21 years and over |

| | New York[17] | Oklahoma[18] | Oregon[19-21] |
|---|---|---|---|
| | | • Individuals 18 years and over | |
| Bill Model/Goal | To be determined by advisory board<br>• will have treatment centers, likely be a wellbeing model with no limits on who can receive care | Research Model<br>• primarily a research and decriminalization bill, not yet calling for implementation. Clinical trials could occur at research institutions | Wellbeing Model<br>• Available to all individuals, no doctor's note is required<br>• First legal model, psilocybin is facilitated in centers with trained facilitators, testers, and producers |
| Equity Approach | • Marijuana Regulation & Taxation Act set a standard for an equity focused approach that will be used in these bills, not in language of the bill[22]<br>• Equity is mentioned as a priority for advisory board, no specific language used<br>• A member with knowledge of care in underserved communities will be on the advisory board | No equity, accessibility, or affordability plan | "Task Force on Psilocybin Health Equity" created, 15 members, to study how to make psilocybin more accessible to certain disenfranchised communities (SB 1580) |
| Decriminalization Directives | • A06065 reclassifies psilocybin out of State Schedule 1 classification<br>• Psilocybin and Psilocyn is removed from list of Schedule 1 drugs in this bill | • Decriminalizes 1.5 ounces, or approx. 42 grams<br>• Fine limited to $400 or less | • M109 permits persons licensed to manufacture and distribute psilocybin services.<br>• M110 decriminalizes/reduces penalties for all illegal drug possession<br>• The revenue saved goes to a state funded addiction treatment program |

| | New York[17] | Oklahoma[18] | Oregon[19-21] |
|---|---|---|---|
| Funding for Bill | Psilocybin Services Grant Program fund established | Research institutions granted licenses to conduct trials and produce, funds will come from private research institution budgets | Psilocybin Control and Regulation Fund established |
| Links to Bill | https://nyassembly.gov/leg/?default_fld=%0D%0A&leg_video=&bn=A08569&term=2021 Summary=Y&Actions=Y&Memo=Y&Text=Y | http://webserver1.lsb.state.ok.us/cf_pdf/2021-22%20int/hb/HB3414%20int.pdf | https://sos.oregon.gov/admin/Documents/irr/2020/034text.pdf |

| | Pennsylvania[23,24] | Rhode Island[25] | Texas[26] |
|---|---|---|---|
| Date of Introduction/Bill Number | March 2022<br>HB 2421 | March 2022<br>H 7715 | March 2021<br>HB 1802 |
| Bill Status/ Potential Implementation Date | • Bill is currently in House<br>• Met with strong opposition from Rep. Rapp, House Health Committee Chair<br>• Final report due 2025 | • Measure held for further study | Bill filed without Governor's signature and is effective immediately, report due December 2022 |
| Sponsor/Political Party | Rep. Tracy Pennycuick (R) with bipartisan support, strong opposition | Rep. Brandon Potter (D), primarily Democratic support for bill | Sen. Donna Cambell (R), bipartisan cosponsors |
| Substances up for Approval | Psilocybin | Psilocybin, buprenorphine | MDMA, psilocybin, ketamine |
| Research Directive | • The Health Research Advisory Committee established by the DoH would submit a report every 180 days, final report by 2025 | No research program in bill | • The Department of State Health Services, in conjunction with The Texas Medical Board, will study the benefits of psilocybin, MDMA, ketamine |

| | Pennsylvania[23,24] | Rhode Island[25] | Texas[26] |
|---|---|---|---|
| | • At least one research institution will work with the advisory committee to collect data and study the effects of psilocybin-assisted therapy | | • The Texas Medical Board will consult with Baylor College of Medicine and prepare a report by December 1st, 2022 |
| Availability/ Target Diagnosis | • PTSD, depression, anxiety, suicidal ideation, eating disorders, bipolar disorders, chronic pain, migraines, substance use disorders, traumatic brain injury<br>• Other conditions to be reviewed by the department, advisory board, or research institution | No list of conditions on bill, practitioners are allowed to use good faith. | Depression, anxiety, PTSD, bipolar disorder, migraines, chronic pain |
| Bill Model/Goal | To be determined by advisory board<br>• Primarily a research bill<br>• Bill language promotes pursuing a medical model | Prescription Model/Decriminalization bill<br>• a practitioner acting in "good faith" can dispense/prescribe as a therapeutic | Research model<br>• no plan or wording in the bill about implementation to the broader public |
| Equity Approach | Bill calls for research into "methods to reduce cost and increase scalability of treatment" | No equity, accessibility, or affordability plan | No equity, accessibility, or affordability plan |
| Decriminalization Directives | • No decriminalization plan<br>• HB 1959 was more liberal, allowed for cultivation in-state | • Would decriminalize psilocybin, marijuana and buprenorphine, possession limits, maximum fees and punishments are not listed | No decriminalization plan |
| Funding for Bill | No funding plan | No funding plan | Funding from Department of State Health Services |

| | Pennsylvania[23,24] | Rhode Island[25] | Texas[26] |
|---|---|---|---|
| Links to Bill | https://www.legis.state.pa.us/cfdocs/billinfo/billinfo.cfm?syear=2021&sind=0&body=H&type=B&bn=2421 | http://webserver.rilin.state.ri.us/BillText/BillText22/HouseText22/H7715.pdf | https://capitol.texas.gov/tlodocs/87R/billtext/pdf/HB01802I.pdf#navpanes=0 |

| | Utah[27] | Virginia[28] | Washington[29,30] |
|---|---|---|---|
| Date of Introduction/Bill Number | January 2022<br>HB 167 | January 2022<br>SB 262<br>HB 898 | March 2022<br>Budget Bill<br>SB 5660 |
| Bill Status/Potential Implementation Date | The bill has passed, report due October 31, 2022 | Bill voted down in Senate, other bill pushed until next session | Budget bill approved, creating a workgroup, which will determine all specifications for facilitation program, issuing a final report to the Governor due December 2023<br>Bill 5660 died in committee in the Senate |
| Sponsor/Political Party | Rep. Brady Brammer (R)<br>Nearly unanimous support | Sen. Ghazala F. Hashmi (D), Rep. Dawn Adams (D) | Rep. Salomon (D) et al., all sponsors are Democrats |
| Substances up for Approval | Mentions no drugs specifically, the committee will decide which drugs to be studied | Psilocybin, psilocyn | Psilocybin |
| Research Directive | • The Department of Health and Human Services to establish the Mental Illness Psychotherapy Drug Task Force<br>• The advising committee to do research when needed, directives are very open ended | No research program in bill | • Workgroup created for an 18-month period to evaluate the social opportunity program proposed in HB 5660, the Oregon psilocybin program, various licensing processes for behavioral professionals, and liquor and cannabis board policies/regulations |

| | Utah[27] | Virginia[28] | Washington[29,30] |
|---|---|---|---|
| Availability/Target Diagnosis | The conditions treated will be determined by the advisory board | No treatment plan | 5660 called for treatment of (but not limited to) addiction, depression, anxiety, end of life, trauma, psychological distress, enhance physical and mental wellness |
| Bill Model/Goal | To be determined by advising board<br>• the bill leaves the implementation of psychotherapy to the advisory board | Decriminalization bill | To be determined by advisory board<br>• 5660 called for a model similar to Oregon, but with greater emphasis on equity<br>• workgroup is instructed to refer to the Social Opportunity Program of 5660. |
| Equity Approach | No equity, accessibility, or affordability plan | No equity, accessibility, or affordability plan | • 5660 introduced a Social Opportunity Program to identify distressed areas and develop other criteria for qualifications<br>• Provide reduced license fees to organizations and individuals. |
| Decriminalization Directives | No decriminalization plan | • Made possession of unnamed amount of psilocybin subject to a maximum fine of $100<br>• Was formerly a Class 5 felony | • The Washington State Supreme Court ruled the seizure of controlled substances for possession to be illegal<br>• The legislature now has the ability to decriminalize drugs in the state |
| Funding for Bill | No funding plan | Funds collected from the newly imposed fine would go to the state's Drug Offender Assessment and Treatment Fund, which supports substance | • 5660 proposed a Psilocybin Regulation and Control account<br>• Budget bill allots $200,000 to the workgroup for the research of psilocybin |

| | Utah[27] | Virginia[28] | Washington[29,30] |
|---|---|---|---|
| | | misuse treatment programs | |
| Links to Bill | https://le.utah.gov/~2022/bills/static/HB0167.html | https://lis.virginia.gov/cgi-bin/legp604.exe?221+sum+SB262 | https://app.leg.wa.gov/billsummary?BillNumber=5660&Initiative=false&Year=2021<br><br>https://www.hca.wa.gov/hca-seeks-members-psilocybin-workgroup |

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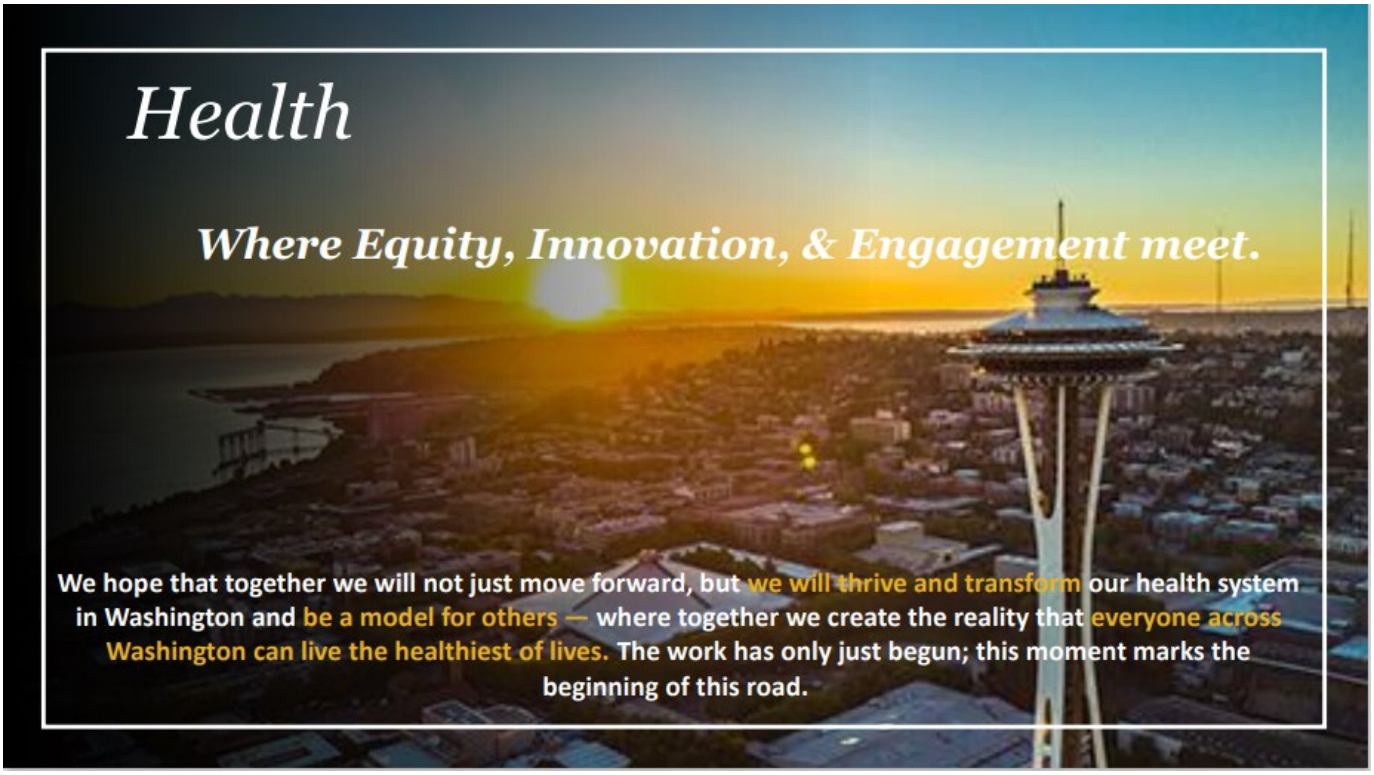
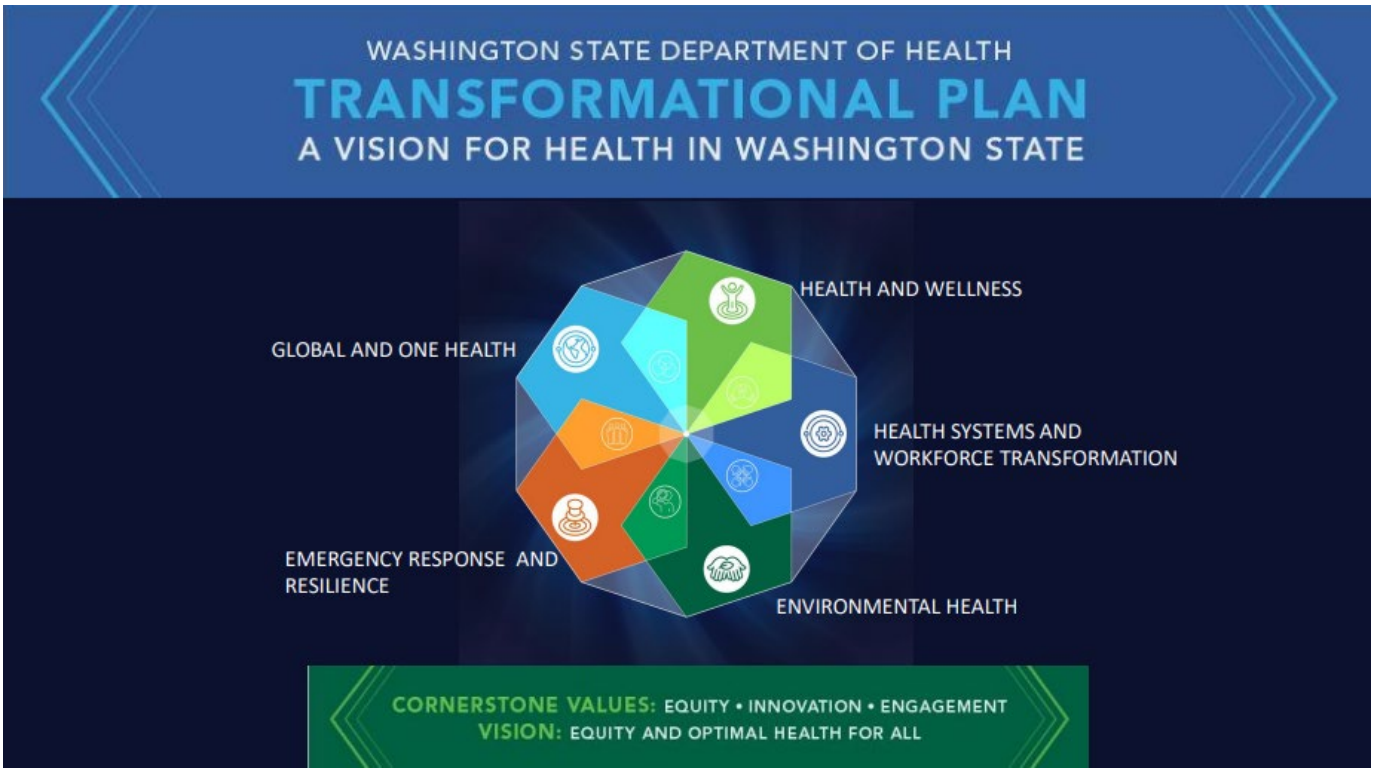
# Appendix H: Department of Health Presentation

Washington State Department of Health

PSILOCYBIN WORKGROUP MEETING

December 2, 2022




WASHINGTON STATE DEPARTMENT OF HEALTH
TRANSFORMATIONAL PLAN
A VISION FOR HEALTH IN WASHINGTON STATE
HEALTH AND WELLNESS
GLOBAL AND ONE HEALTH
HEALTH SYSTEMS AND WORKFORCE TRANSFORMATION
EMERGENCY RESPONSE AND RESILIENCE
ENVIRONMENTAL HEALTH
CORNERSTONE VALUES: EQUITY • INNOVATION • ENGAGEMENT
VISION: EQUITY AND OPTIMAL HEALTH FOR ALL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TRANSFORMATIONAL PLAN
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# Existing Regulatory Framework for Health Care in Washington and DOH's Role

## When Should a Health Profession Be Regulated?

- Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public,
- The potential for harm is easily recognizable and not remote,
- The public will benefit from an assurance of professional ability, and
- There is no other, more cost-effective means of protecting the public.

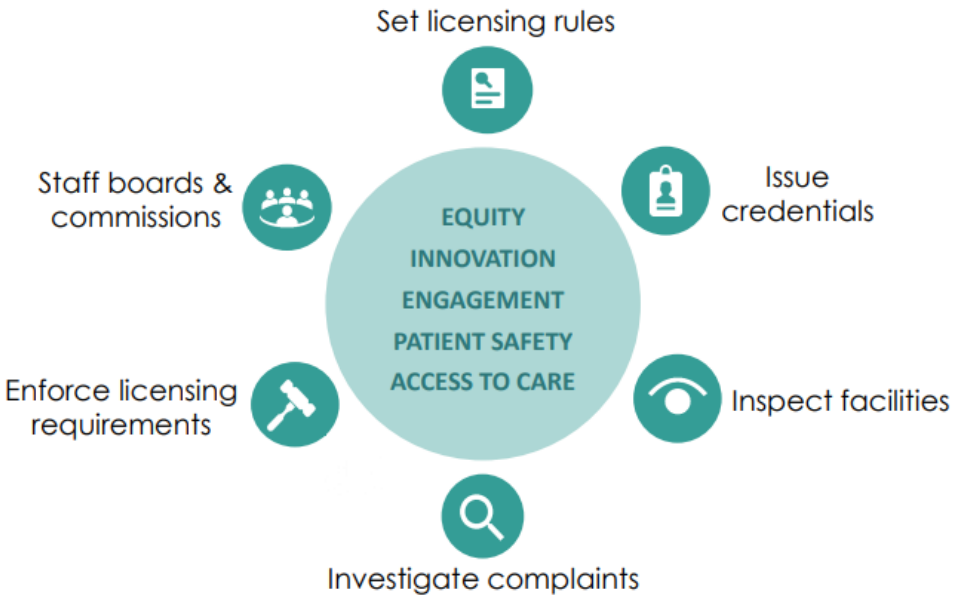
# Title 18 RCW – Businesses and Professions

| Legislature | DOH, Boards, Commissions |
|---|---|
| • Establishes the regulatory authority for the profession (the body that sets rules and can take disciplinary action on a license)<br>• Sets the scope of practice (broadly, what licensees are allowed to do)<br>• Creates general requirements for licensure | • Set additional, more specific licensure requirements in rule:<br>  • Education and training<br>  • Testing<br>  • Supervised experience<br>  • Continuing education<br>  • Health and safety standards<br>  • Policies and procedures |

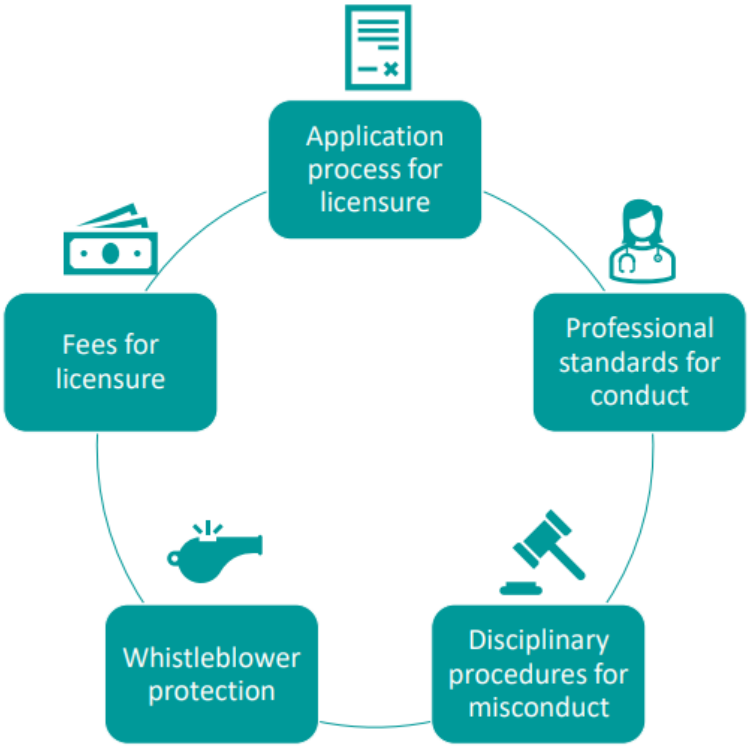
# Health Care Regulators

| DOH | Boards and Commissions |
|---|---|
| Emergency medical technicians<br>Home care aides<br>Mental health counselors<br>Social workers<br>Substance use disorder professionals | Dentists<br>Nurses<br>Physical therapists<br>Physicians (MD, DO, ND)<br>Psychologists<br>Pharmacists |
| Hospitals<br>Ambulatory Surgery Centers<br>Behavioral Health Agencies<br>Residential Treatment<br>Medical Test Sites<br>Home Care and Hospice | Pharmacies |

# Health Care Regulation in DOH




All health care professionals regulated under Title 18 are subject to a **common set of laws** in addition to profession-specific practice acts.



# The Uniform Disciplinary Act (UDA)
## Chapter 18.130 RCW

- Provides a common set of professional standards for practice
- Provides standardized procedures for licensing and disciplining all health professionals in Washington
- Applies to all health professions under Title 18, regardless of whether the regulatory authority is DOH or a board or commission
- Legislative intent: UDA should cover all health and health-related professions newly regulated by the state

# UDA – Authority of DOH, Boards, Commissions

- Grant or deny license applications
- Restrict or place conditions on a license of new licensees
- Investigate complaints of unprofessional conduct; review and audit records
- Hold hearings, issue subpoenas, take depositions, compel attendance at hearings
- Impose sanctions, issue citations, assess fines, revoke a license
- Order summary suspension or restriction of a license when there is an immediate threat to public health and safety

# UDA – Application Review

- Does the applicant have a criminal history that would pose risk to patients?
  - State (WSP) and federal (FBI) background checks
  - No disqualifying crimes list
  - Each application assessed individually, taking into consideration the applicant's past crimes and the type of license they are applying for
- Can the applicant practice with reasonable skill and safety?
  - Self-reported health conditions
  - Voluntary substance use monitoring programs

# UDA – Examples of Professional Misconduct

- Violating any state or federal law regulating the profession
- Engaging in dishonest acts, corruption, fraud, misrepresentation
- Obtaining a license through false or misleading statements
- Aiding or abetting unlicensed practice
- Providing neglectful or poor-quality care that results in injury or unreasonable risk of harm
- Failing to cooperate or comply with an order
- Practicing beyond the allowed scope

# UDA – Examples of Professional Misconduct

- Failing to adequately supervise staff
- Being convicted of a gross misdemeanor or felony related to practice of the profession
- Possessing, using, or prescribing drugs other than for legitimate purposes or violating any drug law
- Allowing drugs to be unlawfully removed from a facility or shared, or prescribing for oneself
- Current misuse of alcohol, controlled substances, legend drugs
- Abusing or engaging in sexual contact with a patient or client

# Whistleblower Protection

- RCW 43.70.075
  - Protects confidentiality of whistleblowers who make complaints to DOH against health care professionals and facilities
  - Provides a right to civil action to whistleblowers who are subjected to retaliatory action
- Chapter 49.60 RCW (Human Rights Commission)
  - Provides remedies for employees who are subjected to retaliatory action for complaining against their employer

# Fees for Health Professions and Facilities

- State law requires the regulation of health professions and facilities to be supported by fees paid by licensees (RCW 43.70.250)
- Fees from one profession may not be applied to regulating any other profession
- In very limited cases, the legislature has chosen to provide funding to offset licensing costs (e.g., midwives, emergency medical professionals)

# Fees for Health Professions and Facilities

- DOH is obligated to charge fees that allow us to recover the costs associated with regulating each profession
- What is cost recovery?
  - Off-set expenditures for rulemaking, licensure, complaint investigation, discipline
  - Maintain a sufficient financial reserve to cover fluctuations in expenditures (e.g., a very expensive disciplinary case)

# Role of the Pharmacy Quality Assurance Commission in Drug Regulation

## Pharmacy Quality Assurance Commission Role

- The commission regulates the practice of pharmacy and the dispensing, distribution, wholesaling, and manufacturing of all controlled and non-controlled substances, including psilocybin (exception is cannabis)
- Controlled substances are listed in drug schedules in chapter 69.50 RCW, chapter 246-945 WAC (commission's rules), and in the DEA's drug schedules (21 CFR §1308)
  - Pharmacy commission licensees must follow WA state law, the commission's rules, and the DEA's rules
  - Controlled substances necessitate registration with both the DEA and PQAC, unless an exemption is otherwise met

# Pharmacy Commission Role, continued

- "Manufacture" in RCW 18.64.011(21) includes the "production, preparation, propagation, compounding, or processing of a drug or other substance or device..."
  - Manufacturing in WA requires a manufacturer's license from PQAC (RCW 18.64.045)
  - All manufacturers in WA must adhere to the FDA's Current Good Manufacturing Practice (CGMP) (WAC 246-945-550)
- Other activities that require registration with PQAC
  - Research with controlled substances, analytical labs, animal related drug control

# DOH Responsibilities Under SB 5660 and Ability to Implement

# SB 5660 – DOH Responsibilities

- Establish a psilocybin advisory board with >20 appointed members to advise DOH
- Conduct rulemaking, license, and regulate:
  - Psilocybin manufacturers, service centers, and facilitators
  - Employees of manufacturers and service centers
  - Laboratories that test psilocybin products
- Create a social opportunity program for the psilocybin industry to aid people from distressed areas through reductions in fees
- Develop and maintain a system for tracking transfer of products or use LCB's
- Publish research and information on safety and efficacy of psilocybin
- Develop a hotline/website to answer questions about licensed premises

# DOH Expertise and Capacity to Implement

- Standing up psilocybin services involves novel work for DOH such as a social opportunity program for fees and regulation of a cultivated product
- The proposed regulatory structure is highly complex
- The proposed regulatory structure has some similarities to existing laws for other health professions (e.g., Uniform Disciplinary Act), but it is distinct and will require extensive rule-making, procedure development, and IT system changes
- Can DOH implement SB 5660? **Yes**, if appropriately resourced and with more time

# Timeframe to Implement

- Two to three years
- Why?
  - Staff must be hired (approximately 30 FTE)
  - Advisory board needs to be established
  - Many complex rules need to be developed by on new concepts and in an equitable manner that allows broad community engagement
  - Social Opportunity Program must be developed – method for identifying distressed communities, fiscal analysis of tiered fees
  - Psilocybin tracking system must be acquired and implemented

# Additional Considerations

- Social opportunity program
  - Intriguing concept for addressing equity in a regulatory structure
  - Reduced fees for licensees from distressed communities means higher fees for licensees from non-distressed communities
  - DOH must recover the full cost of the psilocybin regulatory program unless the legislature chooses to offset the cost
- System for tracking transfer of psilocybin product
  - Acquiring a new system for this purpose would be expensive and take several years
  - Adapting an existing system (e.g., LCB's) is the more cost-effective approach

# Additional Considerations

- Psilocybin Advisory Board
  - DOH has authority for rules and enforcement; Advisory Board is advisory even though it has requirements similar to a Class 1 board
  - DOH must follow the Administrative Procedures Act when rule-making which requires seeking broad public input and engagement beyond the Advisory Board
- Regulation of health care providers that participate
  - Regulatory authorities (DOH, board, commissions) have a duty to consider disciplinary action when they become aware that a licensee is engaging in illegal activity on any level – local, state, or federal
  - As long as psilocybin remains federally illegal, boards and commissions will be challenged to fulfill their duty regardless of state law

# Recommendation

- Consider using the regulatory framework for health care in Washington (e.g., Uniform Disciplinary Act) to minimize implementation timeframe

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