Washington State Health Care Authority

Washington Psilocybin Task Force

Final Report

Second Substitute Senate Bill 5263; Section 6; Chapter 364; Laws of 2023

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Clinical Quality & Care Transformation
P.O. Box 45520
Olympia, WA 98504
Phone: (360) 725-1915
hca.wa.gov

Center for Evidence-based Policy
3030 S Moody Ave., Suite 250
Portland, OR 97201
Phone: (503) 494-2182
centerforevidencebasedpolicy.org

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Executive Summary

In its 2023 session, the Washington State Legislature passed Second Substitute Senate Bill 5263 that directed the Health Care Authority (HCA) to establish a psilocybin Task Force and provide a report on psilocybin services. The legislative language can be found in Appendix A. The psilocybin Task Force was directed to provide a final report detailing its work that includes:

1. Reviewing the available clinical information around specific clinical indications for use of psilocybin, including what co-occurring diagnoses or medical and family histories may exclude a person from use of psilocybin;
2. Reviewing and discussing regulatory structures for clinical use of psilocybin in Washington and other jurisdictions nationally and globally. This should include discussing how various regulatory structures do or do not address concerns around public health and safety the Task Force has identified.

The Legislature specified that the Task Force be chaired by the Director of HCA or her designee and specified certain other membership details. Task Force membership can be found in Appendix B. HCA contracted with the Center for Evidence-based Policy ("the Center") to provide technical assistance, manage and facilitate the Task Force, and draft the final report summarizing the Task Force's deliberations to be submitted to the Legislature by HCA.

This report and body of work is the second to be requested by the Washington State Legislature. In 2022, SB 5693 directed the Health Care Authority (HCA) to provide a report on psilocybin services and opportunities in consultation with a group of specified stakeholders. A specific deliverable of the first report was to provide feedback on a proposed Social Opportunity Program meant to promote equitable access to a potential legal psilocybin industry.

Discussions about equity and the need to be thoughtful and deliberate in addressing issues and concerns were common in both legislatively directed groups.

- In the first report, emphasis was placed on the need to not replicate with any future psilocybin model, the current cannabis model where outside venture capital interests were put in a more favorable position to succeed.
- In addition, the workgroup cautioned against creating training or licensing models that would lead to high fees for participation, potentially eliminating the ability of many to participate.
- Appendix I of this report provides recommendations meant to assure equity considerations remain a foundational part of any future work done in Washington addressing legal access to psilocybin.

Summary of Task Force Duties

This report summarizes the work completed by the psilocybin Task Force to address the two key tasks of the legislation. The Task Force held three meetings between June 2023 and October 2023. The meetings were organized around the two key tasks from the Task Force legislation. Work began by designing and conducting the clinical evidence review update and then the Task Force moved to evaluating regulatory structures after meeting #2. The process was flexible and iterative and informed by both the members and policy research conducted. The table below summarizes the process used by the Task Force to address the two key tasks.

Key Responsibilities

Assigned Duties	Task Force Actions	Date
Task Force Responsibility #1: Clinical evidence review focused on specific clinical indications for use of psilocybin, including what co-occurring diagnoses or medical and family histories may exclude a person from use of psilocybin. Any review of clinical information should: • Discuss populations excluded from existing clinical trials; • Discuss factors considered when approval of a medical intervention is approved; • Consider the diversity of participants in clinical trials and the limitations of each study when applying learnings to the population at large; • Identify gaps in the clinical research for the purpose of identifying opportunities for investment by the state for the University of Washington, Washington State University, or both to consider studying.	A proposed approach to conducting the rapid evidence review was presented and approved by the Task Force at Meeting #1. The rapid evidence review was completed in August 2023. Results from the review were presented at Task Force meeting #2. At Task Force meeting #3, members were asked to rank the identified gaps and areas for future research as well as identify an additional gaps.	Information from the rapid evidence review was first presented to the Task Force on August 28th, 2023. Task Force members received an update at Meeting #3 on October 5th, 2023.
Task Force Responsibility #2: Review and discuss regulatory structures for clinical use of psilocybin	Task Force members were asked to respond to a regulatory-focused survey documenting their support or	The regulatory survey was administered from September 12 – 25th, 2023.

in Washington and other jurisdictions nationally and globally. This should include: • Discussion of how various regulatory structures do or do not address concerns around public health and safety the task force has identified.	opposition to various categories included in existing psilocybin regulatory structures. Members were asked to identify areas of concern and offer improvements or additions to be considered for any future Washington regulation.	Results were shared at Meeting #3 on October 5th, 2023 and polling was conducted at the meeting to determine group support for key survey results.

Task Force Responsibility #1

Review the available clinical information around specific clinical indications for use of psilocybin, including what cooccurring diagnoses or medical and family histories may exclude a person from use of psilocybin.

Action Taken

Researchers from the Center for Evidence-based Policy (Center) conducted and updated review of Oregon Psilocybin Advisory Board Rapid Evidence Review and Recommendations (published on July 30, 2021)[1] that synthesized relevant studies published since the literature search for the Oregon review. The update synthesized publications from four randomized controlled trials (RCTs), two double-blind placebo-controlled crossover studies, two observational cohort studies, four systematic reviews, and additional studies to answer questions about the potential risks and benefits of supervised and unsupervised psilocybin. Highlights from the clinical evidence review are included in this section and full results can be found in Appendix C, including a summary of findings from the Oregon Psilocybin Advisory Board Rapid Evidence Review and Recommendations report.

Key Questions

The key questions in this clinical evidence review are the key questions developed for the Oregon Psilocybin Advisory Board Rapid Evidence Review.

KQ1. What are the potential benefits and risks (e.g., interpersonal, medical, and psychological) of psilocybin in controlled settings in persons seeking services for improving condition-specific symptoms and quality of life in the following categories?

a. Depression
b. Anxiety disorders and OCD
c. Trauma-related disorders, including racial trauma
d. Substance use disorders
e. Palliative care
f. Spirituality
g. Other conditions

KQ2. What are the potential benefits and risks of unsupervised psilocybin use for the categories above?

a. How do the potential benefits and risks of psilocybin differ by population subgroups, including but not limited to dosage, psilocybin source, age, setting, co-ingestion, or personal characteristics?

KQ3. What are provider or patient risk assessment tools that can identify persons likely to benefit or be harmed by psilocybin-assisted therapy?

KQ4. What are the relative potential benefits and risks of different sources of psilocybin?

Key Findings

Depression: Significant Reduction in Severity During Short-Term Follow-Ups

- Results from 2 new RCTs with low and moderate risk of bias added more evidence that psilocybin may be effective at rapidly reducing depression severity, although significant improvement in depression may only last weeks to months.[2-4] In contrast, a crossover study with a moderate risk of bias reported no effect of psilocybin microdoses on depression and anxiety.[5]

Dosing Estimate for Depression: May Only Be Relevant for Populations Similar to Study Samples

- A meta-analysis of dosing in studies with participants with depression concluded that a dose of 30 to 35 mgs per 70 kilograms of participant weight may optimize the therapeutic effect for participants with primary or secondary depression.[6] However, this recommendation may only be applicable to individuals similar to the participants in the 5 clinical trials analyzed (e.g., White cisgender individuals in middle adulthood).

Cluster Headache: Preliminary Results Suggest No Significant Effect

- A single small RCT with a moderate risk of bias did not find significant improvement after psilocybin use for participants with cluster headache.[7]

Migraine Suppression: Preliminary Results Suggest Short-Term Reduction in Migraine Days

- A single crossover study with a high risk of bias suggested that psilocybin dosing may be associated with a reduction in migraine days during the 2 weeks following the dose.[8]

Frequent Headaches, Nausea, Anxiety, but Rare Worsening Depression and Suicidal State

- Most participants across identified studies of supervised and unsupervised psilocybin use experienced temporary adverse effects such as headache, nausea, and anxiety.
- A small minority of study participants reported worsening depression or suicidal state, and a few participants experienced paranoia during dosing sessions.

Low-Quality Evidence: Unsupervised Psilocybin Use

- The Center did not identify high-quality studies of unsupervised psilocybin use, and the 1 crossover trial[5] and 2 observational studies[9,10] we identified on this topic had moderate to high risk of bias. Participants self-reported generally positive experiences and similar adverse events to participants in the supervised studies (i.e., typically mild, transient adverse effects and a few serious adverse events).

No New Evidence Identified for a Few Chronic Conditions and for Efficacy by Subgroups

- The Center did not identify new studies of psilocybin for anxiety disorders, obsessive-compulsive disorder (OCD), trauma-related disorders, substance use disorders, palliative care, or spirituality.
- There were no publications that addressed efficacy by subgroup (e.g., psilocybin source, age, setting, co-ingestion, or personal characteristics of the user).

Patient or Provider Risk Assessment Tools

- The Center did not identify validated risk assessment tools designed for providers or patients to predict risk and benefit for individuals who may use psilocybin.

Comparative Risks and Benefits for Different Sources of Psilocybin

- The Center did not identify new information about the relative benefits and risks of different sources of psilocybin.

Relevant Ongoing RCTs

- The Center identified 30 ongoing RCTs with protocols relevant to key questions of risk and benefit of psilocybin use. Nine of these studies have primary completion dates by the end of 2023.

Discuss Populations Excluded From Existing Clinical Trials

Controlled studies included in the rapid review excluded participants with comorbid medical and psychiatric conditions, which may limit the generalizability of findings beyond these populations. For example, results around dosing estimates for depression may only be applicable to individuals similar to the participants in the 5 clinical trials analyzed (e.g., White cisgender individuals in middle adulthood). In some studies, potential participants with the most serious depressive conditions were excluded, and in all studies individuals with serious comorbid conditions were excluded (e.g., suicidal ideation with intent, history of psychosis).

Additional populations were identified for future research efforts and are listed in their entireties beginning on page 10 but major population groups missing from existing clinical trials include:

- People with disabilities
- People of all races, ages, income levels, and gender identification
- Indigenous populations
- People with comorbid psychiatric conditions
- General population (e.g., with no psychiatric diagnosis)
- People receiving end-of-life care
- LGBTQ+ populations
- People for whom English is not their first language
- Justice-involved populations

Discuss Factors Considered When Approval of a Medical Intervention is Approved

The Oregon rapid review did not identify any validated risk assessment tools for evaluating the likelihood of individual benefit or risk for potential psilocybin use. The rapid evidence review searched for provider or patient risk assessment tools that can identify people who are likely to benefit or be harmed by psilocybin-assisted therapy, but researchers did not find any validated risk assessment tools intended to indicate who may be an ideal candidate for the use of psilocybin. There is, however, a recent systematic review of psychometric assessments used in psychedelic research.[11] The review identified 3 measures related to assessing risk before and after use of psychoactive drugs, but none were validated in clinical populations or participants using or considering using psilocybin and only 1 measure was developed specifically for psilocybin use.[11] The 3 measures are summarized below and more information can be found in Appendix C.

- The Wave test, developed in Spain, has 30 items intended to assess risk of developing psychotic disorder and risk of developing bipolar disorder due to use of psychoactive drugs.[12] This tool was

administered in populations of university students, and has not been validated in clinical populations.[11,12] It is not clear whether this tool is available only in Spanish.

- The Psychotomimetic States Inventory (PSI), was developed to assess delusory thinking, perceptual disorientation, cognitive disorientation, anhedonia, mania, and paranoia during and after use of psychoactive substances.[11,13]
- The Challenging Experience Questionnaire (CEQ) has 26 items based on selections from 3 other instruments intended to evaluate psychedelic experience.[11] This questionnaire evaluates experience of grief, fear, death, insanity, isolation, physical distress, and paranoia after use of psilocybin.[14] This tool is intended to assess acute psychological adverse reactions to psilocybin use, not to predict whether an individual is at risk for experiencing those adverse reactions.[14]

Consider the Diversity of Participants in Clinical Trials and the Limitations of Each Study When Applying Findings to the Population at Large

Failure to recruit diverse samples was a major limitation of included studies. This lack of diversity may impact the relevance of all results. The population mix for Washington state as a whole more closely resembles the participant mix in the clinical trials, with 77% of people self-reporting as White in 2022.[15] However, results may not be applicable to the more diverse Apple Health population since, as of August 2023, 43% of Medicaid enrollees in Washington state were not White.[16]

In addition to a lack of diversity among study participants, small sample sizes make effect identification difficult and subgroup analysis impossible (i.e., understanding for whom psilocybin may be effective), and limited follow-up duration, and exclusion of potential participants with comorbid conditions also complicate applicability of the findings. Each of these considerations limit the generalizability of the study results to a broader population. All of the publications noted that larger, more diverse, placebo-controlled trials with longer follow-up are needed to understand the efficacy and safety of psilocybin as a treatment for mental health conditions.

Identify Gaps in the Clinical Research for the Purpose of Identifying Opportunities for Investment by the State for the University of Washington, Washington State University, or Both to Consider Studying.

To identify gaps in the research, the Center structured the categories in the PICOS research model (**P**opulation, **I**ntervention, **C**omparator, **O**utcomes, and **S**etting). Identified gaps were presented to the Task Force on October 5th, 2023 and members were asked to rank gaps within each category according to their importance of being considered in future research efforts. Task Force members were also asked to identify any additional gaps. Key results from that exercise are presented in this section. The questions are organized under the PICOS structure; with the ranking results first and additional gaps identified from the Task Force listed after. Unedited responses to the gap identification exercise can be found in Appendix D.

Ranking of Population Gaps

Racial diversity	1st
Including people with comorbid conditions in trials focused on psychiatric conditions	2nd
Larger sample sizes	3rd
Inclusion of general population in multi-arm trials	4th
Income	5th
Age diversity	6th
Gender identification	7th
Use among people with prior experience with psilocybin or other psychedelics	8th
Education	9th

Additional Population Gaps Identified by Task Force

Category	Task Force Identified Gaps
Population	People with disabilities
	People with pain-related disabilities
	End of life care
	Elderly population
	LGBTQ+
	People for whom English may not be their first language
	Spiritual and religious affiliations
	Justice-involved individuals
	Rural populations
	Indigenous populations

	People with bipolar disorder and schizophrenia
	Veterans

Ranking of Intervention Gaps

Whole mushroom (synthetic version is used in most studies)	1st
Optimal number of psychotherapy sessions	2nd
Number of dosing sessions	3rd
Dosing variety	4th
Other types of co-occurring psychological support (e.g., not a psychotherapist)	5th
Use of psilocybin for general wellbeing	6th
Co-ingestion	7th
Spacing of serial dosing	8th

Additional Intervention Gaps Identified by Task Force

Category	Additional Gaps Identified by Task Force
Intervention	More psilocybin species or types (e.g., "Stamet's Stack" (psilocybin, Lion's Mane, and Niacin))
	"Entourage effect" or secondary compounds
	Group dosing
	Number of integration sessions
	Type of integration session
	Comparing different types of therapeutic modalities (e.g., CBT vs. ACT vs. supportive)
	Optimal post-treatment psychotherapy sessions
	Comparison to Baeocystin mushroom
	Effect of different methods of cultivation, dehydration, storage, and expiration for use

Ranking of Comparator Gaps

Lack of comparison to optimal treatment	1st
Lack of comparison to general wellness outcomes	2nd

Additional Comparator Gaps Identified by Task Force

Category	Additional Gaps Identified by Task Force
Comparators	Comparison to bipolar disorder, schizophrenia, and brain injuries
	Comparison to a spiritual model
	Mental health of ancient indigenous communities
	Whole psilocybin baseline

Ranking of Outcomes Gaps

More outcomes for substance use disorder	1st
More outcomes for PTSD	2nd
General wellbeing	3rd
More outcomes for alcohol use disorder	4th
More outcomes for anxiety	5th
Chronic pain (beyond low back)	6th
Palliative care	7th
More outcomes for migraines and cluster headaches	8th

More outcomes for anorexia nervosa	9th

Additional Outcomes Gaps Identified by Task Force

Category	Additional Gaps Identified by Task Force
Outcomes	Longitudinal traumatic brain injury treatment Effects on treatment-resistant depression
	Impact on families
	Chronic pain (other than low-back)
	Feelings of connectedness
	Reduced isolation
	Measures of infant or child loss grief
	Measures of family system dynamics
	Outcomes for Black, Indigenous, and People of Color with Post-Traumatic Stress Disorder
	Spiritual and religious health outcomes
	Societal trauma
	Bipolar Disorder Type 1 versus Bipolar Disorder Type 2

Ranking of Settings Gaps

Use in non-research community-based settings	1st
Unsupervised use	2nd

Additional Settings Gaps Identified by Task Force

Category	Additional Gaps Identified by Task Force
Settings	Group versus individual settings
	Settings with experienced, non-licensed professional
	Sessions with couples
	Outdoor settings
	Rural tribal reservation setting
	Spiritual setting
	Impact of setting combined with other indigenous practice (i.e., sweat lodge)

Task Force Responsibility #2

Review and discuss regulatory structures for clinical use of psilocybin in Washington and other jurisdictions nationally and globally.

Action Taken

Center researchers reviewed regulatory structures from national and international examples and determined the best way for Task Force members assess public health and safety concerns would be to focus on the recently established regulations for Oregon's Psilocybin Services Program. Oregon's regulations were chosen as a model because they were informed by a clinical and safety evaluation performed by the Center for Evidence-based Policy. Updating, to make current the work previously done by the Center for Evidence-based Policy, also providing support to the Health Care Authority for this work, was chosen as a fiscally responsible approach. Members were asked to record their support for various Oregon regulations via an online survey that was administered from September 12-25th, 2023. The full survey can be found in Appendix E.

Sixteen of the 18 Task Force members responded to the survey. The survey was built around 11 categories that encapsulated most of Oregon's current psilocybin services regulations: facilitator training, facilitator conduct, service centers, preparation sessions, administration sessions, integration sessions, group sessions, social equity, safety, licensing, and manufacturing and distribution. Full survey responses are reported in Appendix F. Key responses from the survey and the subsequent discussion of results from the October 5th Task Force meeting are summarized in this section.

Discussion of How Various Regulatory Structures Do or Do Not Address Concerns Around Public Health and Safety the Task Force has Identified.

This section summarizes the 2 parts of the discussion of regulatory structures beginning with presenting key findings from the online survey Task Force members responded to in September 2023. Following receipt of those survey responses, Center staff developed discussion questions to document the group's support for key ideas in the survey responses. Task force members responded to the follow-up questions via a PollEverywhere exercise at the 3rd Task Force meeting on October 5th, 2023. This section begins with key findings from the survey and ends with a summary of results from the meeting discussion polls.

Survey Key Findings

Key findings from the survey are summarized in this section, both from the written feedback and choice response sections of the survey. Discrete data points are not presented with each response as respondents could respond as supporting, opposing, neutral or needing more information for each question. To get a sense of the directionality for the response, each category noted above was assigned a numerical response and a total score calculated and listed in the appendix. Because all respondents did not answer all of the questions, making comparisons between questions difficult, numeric findings are not listed below. Full, unedited responses to the survey can be found in Appendix E.

Introduction and Background

- Overall, members agreed with the organization of subcommittees within Oregon's Psilocybin Advisory Board (equity, licensing, products and research, and strategic planning) but there was less support for the board not having any regulatory authority

Facilitator Training

- Strongest support for all facilitators being required to complete 40 practicum hours
- Members opposed allowing training programs to set their own criteria for accelerated training
- Some opposition to requiring a high school diploma for facilitators
    - Elders, healers, and immigrants may not have a high school diploma
- Members were split in their support of Oregon's $500 non-refundable application fee for training programs
- Members were split on issues around accelerated training hours and training exemptions for prior experience
- Some support for more frequent renewal of education via training programs

Facilitator Conduct

- Overall strong support for Oregon's regulations in this section
- Almost unanimous support for providing interpretation services at all facilitation centers
    - Comment made that facilitators who speak a second language should be compensated more
- Strong support for disallowing romantic or sexual relationships between clients and facilitators (or family members) for one year after services, requiring disclosure of mandatory reporter status, allowing for supportive touch (limited in definition) during the session when written consent is received, and prohibiting financial interactions between facilitators and clients
    - Comment made that in small tight knit communities, facilitators who are very involved may have difficulty avoiding certain relationships with clients

Service Centers

- Strong opposition to allowing local governments to adopt ordinances to prohibit centers and manufacturing licenses
- Some opposition to service centers not being within 1000 ft of a school
    - Comment made that the two-year requirement for state residency should be increased to five years
- Strong support for service centers annually renewing their license

Preparation Sessions

- Overall strong support for Oregon's regulations in this section
- Unanimous support for requiring client to meet and approve facilitator in private session
- Support for requirements around preparation session occurring 24 hours to 90 days before administration session
    - Comments made that the window should be made smaller; the time between preparation and administration sessions should be less than 90 days and more than 24 hours

- Strong support for requiring a safety plan (including transportation and support) and requiring written consent on various elements (e.g., supportive touch, participating in practicum session, recording, data sharing, etc.), and allowing preparation session to be in-person or virtual
- Support for allowing a preparation session to be skipped if a facilitator is performing service with a repeat client at the same service center
    - Recommendation that if two sessions are particularly far apart in time, a preparation session must be performed, even if the participant has done a session at the same center before
- Some opposition to preparation sessions conducted virtually

Administration Sessions

- Very strong support for allowing outdoor sessions
- Task Force members were mixed on Oregon's regulations around length of session per dose (e.g., 1 hour for 2.5mg or less, 2 hours for 5-10mg, etc.)
    - Support for not requiring an administration session for a dose of 2.5mg psilocybin analyte or less
- Most members support requiring facilitators to always be present during an administration session and requiring an additional licensee at the site to be backup in case of emergency

Integration Sessions

- Unanimous support for requiring follow-up contact with clients within 72 hours of administration session and offering an optional integration session
- Strong support, with a minority opposition, of requiring facilitators to use a non-directive facilitation approach for the integration session
- Members commented that referrals to therapist should be offered if warranted as well as offering psychospiritual care when appropriate

Group Sessions

- When compared to other sections in the survey, more members requested additional information on group session regulations
- Members were mixed in their support, with many needing more information, on allowing a maximum of 25 people per session and on client to facilitator ratio regulations (e.g., facilitator to client ratio is 1:25 if dose is between 5 and 10 mg, etc.)
- There was a comment that 5mg of psilocybin analyte or less should not require supervision
- There was almost unanimous support for requiring facilitators to separate a disruptive client from the group
- Members supported prohibiting participant from touching each other unless consent is given by both parties for supportive touch

Social Equity

- Very strong support for requiring social equity plans from all facilitation centers
- There were mixed reactions to Oregon's 15% sales tax
    - A recommendation was made that the tax should be between 7 and 10% instead of 15%
- There was very strong opposition to prohibiting mobile service centers

    - Members commented that this is an accessibility issue and that mobile centers would help with equity and access as long as all matters of safety be accommodated
- There was strong support for offering a 50% reduction in licensing fee if an entity meets certain requirements
    - A comment was made that the 50% reduction program would need either additional funding or would have to find a different legal pathway
    - One member commented that there should be a no-cost path for religious and non-profit tracks
- Members commented that Oregon's approach to the social equity plan does not address systematic inequity because it does not allow for religious freedoms and creates a commercial system with tax revenue.
- Members suggested adding a sliding scale fee to the social equity program and creating sample equity plans or structured templates for licensees to use.
- Additional suggestions for social equity programs:
    - A permanent equity sub committee
    - Creation of no cost religious and non-profit paths
    - Social equity should be part of the facilitator training curriculum
    - An equity task force should be running concurrently with this Task Force while creating reports to inform the legislature

Safety

- Questions on safety were open-ended and the unedited responses are presented in Appendix F
- Comments were mixed on safety with some members suggesting more screening regulations and mandated therapy referrals and other members suggesting looser regulations

Licensing

- There was strong support for not limiting the number of licenses distributed and for pricing the annual license at $150
- There was some concern over the $10,000 annual license fee for manufacturers and service centers
- Members showed mixed support for requiring the state's Department of Health to reimburse 100% of costs of operation

Manufacturing and Distribution

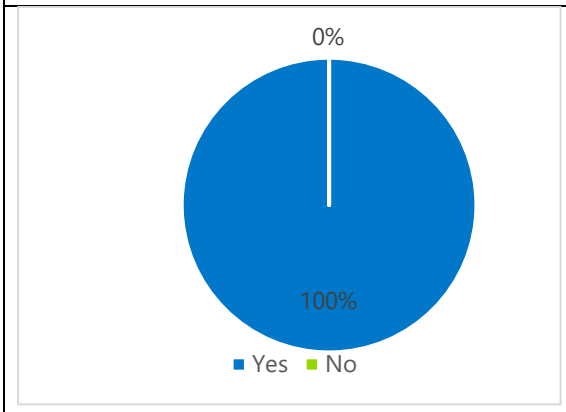
- The majority of members opposed limiting the species to psilocybe cubensis only (as is the law in Oregon)
- There was also mixed support for regulations around how much psilocybin analyte manufacturers and service centers are allowed to carry (200 grams and 100 grams respectively)
    - One member commented that these entities should be allowed to stock different medicines for various applications
- Strong support for advertising restrictions to prevent false advertising, to discourage illegal activity, and to avoid advertising to minors

Results from Task Force Meeting #3 Poll Exercise

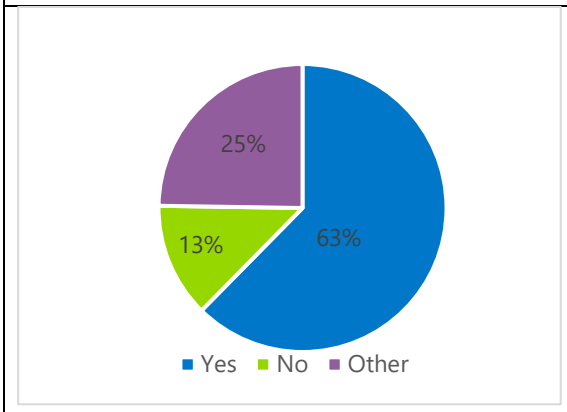
Following the survey results, Center staff developed a series of discussion questions to further gauge Task Force support for various key findings of the online survey. These questions were asked via PollEverywhere during meeting #3 as summary results from the survey were presented. Below are graphics of a small selection of recommendations, along with a summary of the recommendations that received majority support. Full, unedited responses can be found in Appendix F.

Question: The Oregon Psilocybin Services (OPS) advisory board has no regulatory power. Should the advisory board to the Department of Health have regulatory power? If so, what points would this board regulate?	**Key Responses** • No, advisory board should not have regulatory authority • Protection of safety • Grandfathering indigenous elders to facilitate • Regulations to allow homegrown fungi • Yes, advisory board should have regulatory authority • The board should have regulatory power and speak for first peoples, indigenous, religious and Entheogenic users • Should regulatory for ethical considerations, use cases, and licensing

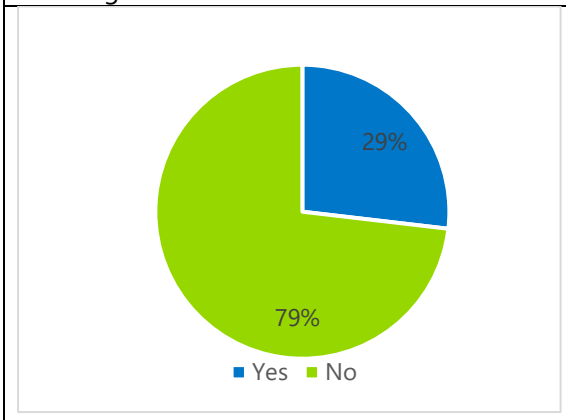
Question: OPS rulemaking allows training programs to set their own qualification guidelines to bypass certain facilitator training sections. Should standard statewide criteria be developed for determining whether a facilitator can bypass certain training modules?



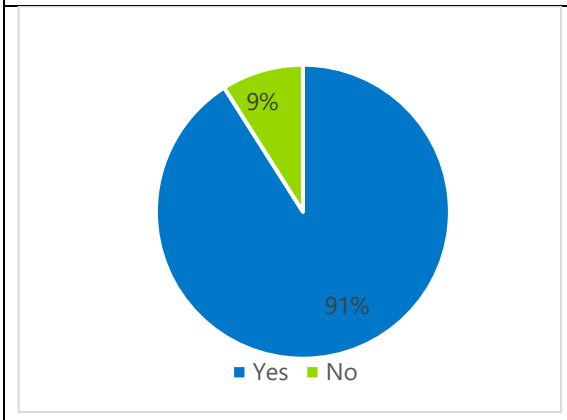
Question: OPS allows local governments to adopt ordinances prohibiting service or manufacturing centers in their county. Should Washington State not allow local governments to adopt ordinances prohibiting service and manufacturing centers?



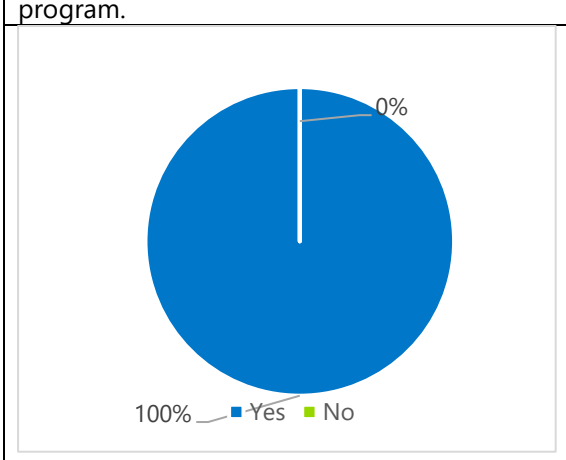
Question: OPS allows the preparation session to be bypassed if an individual has done a session at the same center before. Should more sessions be completed for the preparation session to be bypassed in Washington?



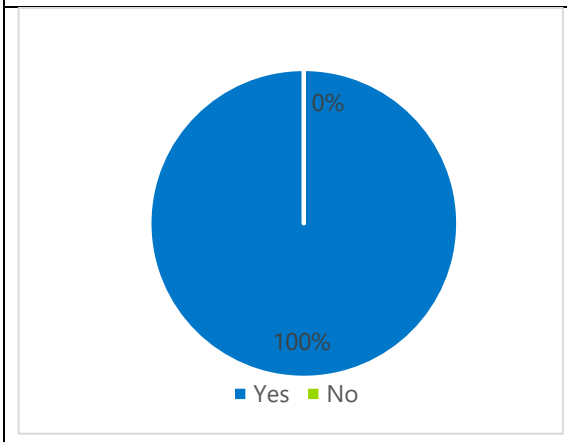
Question: OPS prohibits mobile service centers. Should mobile service centers be permitted in Washington if safety regulations can be properly maintained?



Question: First people, indigenous and religious users need either exemptions or should be allowed to operate fully independently from a Washington psilocybin program.



Question: Should a future Washington psilocybin program recommend the use of a sliding scale fee in service centers?



Question: What dosage bracket (ex. 2.5 mg psilocybin or less) should have a reduced (from 30 mins) administration session associated with it?	**Key Responses** • Less than 0.5 grams should not require facilitation • Anything less than 7.5 mg • Needs more research • 2mg should have reduced administration session

Task Force Recommendations

This section summarizes key recommendations from the Task Force on important regulatory structures for any future psilocybin program in Washington state based on results from the online survey, regulatory polling, and Task Force discussions.

Unanimous Recommendations

If the Washington State legislature were to enact legislation in the future that would allow for legal use of psilocybin, the Washington State Taskforce gave unanimous support for the following recommendations:

- A permanent equity subcommittee should be established as part of any ongoing committee or workgroup established to address the legalization or use of psilocybin in Washington State
- Washington Psilocybin Services should recommend the usage of a sliding scale model for service centers in rulemaking language
- First people, Indigenous users, and religious users need either full exemptions from Washington training and licensing fees, or need to be able to operate fully outside of the Washington regulatory structure
- Washington Psilocybin Services should allow a greater range of genus and species of psilocybin mushrooms to be used in services
- Washington Psilocybin Services should develop standard statewide evaluation criteria to determine if a facilitator-in-training is qualified to bypass certain sections of training
- Washington Psilocybin Services should establish a low dosage bracket (approx. .5g psilocybin analyte or less) that does not require a facilitation session

Majority Support Recommendations

- Washington Psilocybin Services should make integration sessions mandatory.
    - All 14 respondents in the survey indicated integration sessions should occur within 72 hours of the administration session.
- Washington Psilocybin Services should allow directive facilitation to be used by facilitators if agreed upon in the preparation session.
    - 92% of respondents thought directive facilitation was appropriate if agreed upon in the preparation session.
- Washington Psilocybin Services should allow for mobile services centers, as long as safety standards can be maintained.
    - 91% of respondents felt mobile services centers should be allowed if safety regulations could be properly maintained.
- Washington State should not allow local governments to adopt ordinances prohibiting the creation of service and manufacturing centers.
    - 63% of respondents did not think Washington State should allow local governments to adopt ordinances prohibiting the creation of service and manufacturing centers.

Conclusion

This final report outlines the Task Force's process for collaborating with stakeholders to provide information on psilocybin services and complete the 2 assigned responsibilities of the Task Force: an updated clinical evidence review and regulatory structure analysis.

The rapid evidence review outlined in this report echo previous conclusions that psilocybin combined with psychotherapeutic support in a supervised setting may be effective for a rapid reduction of depression severity for at least a few weeks after dosing. Depression, anxiety, and substance use disorders are the most common indications for psilocybin use that have been studied, and continue to be studied, in controlled clinical trials. High-quality studies of psilocybin use in unsupervised settings are challenging to find, and the information from low-quality studies of unsupervised use suggests adverse effects are similar in both settings.

The Center did not identify validated risk assessment tools designed for providers or patients to predict risk and benefit for individuals who may use psilocybin. Limitations of studies included small sample sizes, lack of diversity in study samples, limited follow-up duration, and exclusion of participants with multiple comorbid conditions.

Task Force members assessed Oregon's psilocybin program regulations and documented suggested changes for a future psilocybin program in Washington State. Major recommendations focused on improving access and equity to psilocybin and received majority support from poll voters during meeting #3 of the Task Force:

- Allowing for multiple species of psilocybin (unlike Oregon's program that is restricted to psilocybe cubensis only)
- Allowing for mobile service centers
- Allowing for unsupervised facilitation for certain low doses
- Establishing a permanent equity subcommittee
- Recommending a sliding scale fee in any future service centers
- Allowing first people, indigenous and religious users exemptions to operate fully independent from a Washington psilocybin program

As with other key public health topics, activity at the state and national level are continually evolving. There is active legislation in almost half of states and the 30 ongoing RCTs demonstrate the fast pace at which research on psilocybin for various chronic conditions is emerging.

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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: Task Force Members

Task Force Members	
Dr. Charissa Fotinos (Chair), Health Care Authority	Ryan Mielcarek, Military Veteran
Dr. Sunil Aggarwal, AIM Institute	Dr. Lisa Price, Institute of Naturopathic Medicine
Gary Bahr, Department of Agriculture	Dr. John Roll, Washington State University
Alison Bradywood, Nursing Care Quality Assurance Commission	Dr. Tony Rousmaniere, Clinical Psychologist
Ric Escobedo, Licensed Clinical Social Worker	Dr. Caitlein Ryan, The Cannabis Alliance
Lacy Fehrenbach, Department of Health	Dr. Nathan Sackett, University of Washington
Kate Foster, RN, Bellingham Patient Navigator	Dr. Tana Silvas, Tavasi Labs
Kathy Hoffman, RN; Bellingham Patient Navigator	Dr. Darron Smith, University of Washington
Bryan Janssen, Religious Practitioner	Paul Stamets, Fungi Perfecti
Dr. Jae Kennedy, Washington State University	Ben Tobias, Religious Practitioner
Emma Knighton, American Psychedelic Practitioners Association	Todd Youngs, Religious Practitioner
Seth Maier, Military Veteran	Kody Zalewski, Psychedelic Medicine Alliance of Washington
Dr. Alvina Marris, Clinical Psychologist; Colville Tribal Member	

Appendix C: Clinical Evidence Review

Potential Benefits and Risks of Psilocybin: Update of Rapid Evidence Review

Prepared for the Washington Psilocybin Task Force

August 2023

Center for Evidence-based Policy
Oregon Health & Science University
3030 S Moody, Suite 250
Portland, OR 97201
Phone: 503-494-2182
Fax: 503-494-3807
http://centerforevidencebasedpolicy.org/

Overview

In its 2023 session, the Washington State Legislature enacted Senate Bill 5263 "[c]oncerning access to psilocybin services by individuals 21 years of age and older" (p. 1).[1] Senate Bill (SB) 5263 directs the Health Care Authority (HCA) to form a Psilocybin Task Force to review the available clinical information around specific clinical indications for use of psilocybin, including what co-occurring diagnoses or medical and family histories may exclude a person from use of psilocybin.[1]

The HCA requested an update to the Oregon Psilocybin Advisory Board Rapid Evidence Review and Recommendations, published on July 30, 2021, that synthesizes relevant studies published since the literature search for the Oregon review.[2] This update synthesizes publications from 4 randomized controlled trials (RCTs),[3-7] 2 double-blind placebo-controlled crossover studies,[8,9] 2 observational cohort studies,[10,11] 4 systematic reviews,[12-15] and additional studies to answer questions about potential risks and benefits of supervised and unsupervised psilocybin use.

Key Findings

Depression: Significant Reduction in Severity During Short-Term Follow-Ups

- Results from 2 new RCTs with low and moderate risk of bias added more evidence that psilocybin may be effective at rapidly reducing depression severity, although significant improvement in depression may only last weeks to months.3,5,6 In contrast, a crossover study with a moderate risk of bias reported no effect of psilocybin microdoses on depression and anxiety.16

Dosing Estimate for Depression: May Only Be Relevant for Populations Similar to Study Samples

- A meta-analysis of dosing in studies with participants with depression concluded that a dose of 30 to 35 mgs per 70 kilograms of participant weight may optimize the therapeutic effect for participants with primary or secondary depression.15 However, this recommendation may only be applicable to individuals similar to the participants in the 5 clinical trials analyzed (e.g., White cisgender individuals in middle adulthood).

Cluster Headache: Preliminary Results Suggest No Significant Effect

- A single small RCT with a moderate risk of bias did not find significant improvement after psilocybin use for participants with cluster headache.8

Migraine Suppression: Preliminary Results Suggest Short-Term Reduction in Migraine Days

- A single crossover study with a high risk of bias suggested that psilocybin dosing may be associated with a reduction in migraine days during the 2 weeks following the dose.9

Frequent Headaches, Nausea, Anxiety, but Rare Worsening Depression and Suicidal State

- Most participants across identified studies of supervised and unsupervised psilocybin use experienced temporary adverse effects such as headache, nausea, and anxiety.

- A small minority of study participants reported worsening depression or suicidal state, and a few participants experienced paranoia during dosing sessions.

Low-Quality Evidence: Unsupervised Psilocybin Use

- We did not identify high-quality studies of unsupervised psilocybin use, and the 1 crossover trial16 and 2 observational studies10,11 we identified on this topic had moderate to high risk of bias. Participants self-reported generally positive experiences and similar adverse events to participants in the supervised studies (i.e., typically mild, transient adverse effects and a few serious adverse events).

No New Evidence Identified for a Few Chronic Conditions and for Efficacy by Subgroups

- We did not identify new studies of psilocybin for anxiety disorders, obsessive-compulsive disorder (OCD), trauma-related disorders, substance use disorders, palliative care, or spirituality.
- There were no publications that addressed efficacy by subgroup (e.g., psilocybin source, age, setting, co-ingestion, or personal characteristics of the user).

Patient or Provider Risk Assessment Tools

- We did not identify validated risk assessment tools designed for providers or patients to predict risk and benefit for individuals who may use psilocybin.

Comparative Risks and Benefits for Different Sources of Psilocybin

- We did not identify new information about the relative benefits and risks of different sources of psilocybin.

Relevant Ongoing RCTs

- We identified 30 ongoing RCTs with protocols relevant to key questions of risk and benefit of psilocybin use. Nine of these studies have primary completion dates by the end of 2023.

Policy Context

In its 2022 and 2023 sessions, the Washington Legislature passed 2 bills, SB 5693 and SB 5263, respectively, that directed the HCA to report on psilocybin services and evidence in consultation with a group of specified stakeholders. For SB 5693, HCA convened a psilocybin stakeholder work group that met 6 times between June 2022 and April 2023. The work group meetings were organized around 5 key tasks specified in SB 5693:

- Review the Oregon Health Authority's proposed rules for the regulation of psilocybin
- Review systems and procedures established by the Washington State Liquor and Cannabis Board to monitor manufacturing, testing, and tracking of cannabis
- Review a social opportunity program approached to promote equitable access and assess current capacity of the Washington State Department of Health to oversee aspects of psilocybin use; and
- Discuss options to integrate licensed behavioral health professionals into the practice of psilocybin therapy

The HCA will submit its final report for SB 5693 to the Legislature in the fall of 2023.

In June 2023, the HCA convened the Psilocybin Task Force required by the legislation. To meet the requirements of SB 5263, the HCA invited the work group members to join the new Psilocybin Task Force and added new members.

This rapid evidence review seeks to address the Task Force's charge to "review the available clinical information around specific clinical indications for use of psilocybin, including what co-occurring diagnoses or medical and family histories may exclude a person from use of psilocybin."

Clinical Research Background

Psilocybin and psilocin are psychoactive alkaloids found in 200 species of mushrooms that have chemical structures similar to serotonin, and thought to bind to and activate serotonin receptors.[17-19] The number of studies related to the use of psilocybin and psilocin to treat mental health conditions has increased substantially in recent years, perhaps due to the Federal Drug Administration granting breakthrough status in 2018 to a synthetic psilocybin for the treatment of depression.[17] A number of RCTs and other study designs have included participants with depression, anxiety, substance use disorders, OCD, PTSD, and other chronic conditions.[18,20-25]

In July of 2021, the Oregon Psilocybin Evidence Review Writing Group published the Oregon Psilocybin Advisory Board Rapid Evidence Review and Recommendations, which synthesized results from high-quality, peer-reviewed studies addressing the risks and benefits of psilocybin use.[2] The authors synthesized information from:

- 4 clinical trials with individuals with depression
- 1 trial for individuals with OCD
- 3 trials with individuals with end-stage cancer and depression
- 2 trials with patients with substance use disorder

- 1 trial with individuals with migraine headaches
- 1 systematic review with 10 RCTs that evaluated long-term changes in spirituality after psilocybin use.

The conclusions of the review were[2]:

- Psilocybin is effective for reducing depression and anxiety, including individuals with end-stage cancer. All participants in these trials had co-occurring psychotherapy in the weeks before and after psilocybin dosing.
- Preliminary results suggest psilocybin may be effective in reducing problematic use of alcohol and tobacco.
- Psilocybin increased average spiritual well-being among study participants when spiritual well-being was measured.
- Study participants typically reported positive experiences, and many rated their experiences with psilocybin as meaningful.
- Psilocybin use was associated with the following short-term adverse effects:
    - Nausea
    - Vomiting
    - Headache
    - Increases in heart rate
    - Increases in blood pressure
    - Grief
    - Anxiety
    - Fear
    - Feelings of isolation
    - Preoccupation with death
    - Transient thought disorder
    - Transient paranoia

The effects may be dependent on dose.

Rare and severe adverse effects reported in the studies included sustained worsening depression and anxiety, but the authors were not certain these effects were caused by psilocybin.

The Oregon review noted that although there are well-established screening practices to exclude individuals who may have high risk of adverse effects, it did not identify any psilocybin-specific tools for providers or patients to estimate individual risk or benefit.[2]

Neither the Oregon rapid review nor the present update of clinical evidence were scoped to search for or summarize knowledge and experiences outside of published scientific literature. The perspectives and experiences of indigenous communities and other non-Western communities and institutions typically are not represented in published scientific literature.

Key Questions

The key questions in this clinical evidence review are the key questions developed for the Oregon Psilocybin Advisory Board Rapid Evidence Review[2]:

KQ1. What are the potential benefits and risks (e.g., interpersonal, medical, and psychological) of psilocybin in controlled settings in persons seeking services for improving condition-specific symptoms and quality of life in the following categories?

   a. Depression
   b. Anxiety disorders and OCD
   c. Trauma-related disorders, including racial trauma
   d. Substance use disorders
   e. Palliative care
   f. Spirituality
   g. Other conditions

KQ2. What are the potential benefits and risks of unsupervised psilocybin use for the categories above?

   a. How do the potential benefits and risks of psilocybin differ by population subgroups, including but not limited to dosage, psilocybin source, age, setting, co-ingestion, or personal characteristics?

KQ3. What are provider or patient risk assessment tools that can identify persons likely to benefit or be harmed by psilocybin-assisted therapy?

KQ4. What are the relative potential benefits and risks of different sources of psilocybin?

Methods

Researchers from the Center of Evidence-based Policy searched Ovid Medline, PsycINFO, and the Cochrane library for publications from RCTs, systematic reviews with any component study type (i.e., KQ1), and publications with risk assessment tools (i.e., KQ3). For key questions that had no eligible RCTs or systematic reviews to report, cohort and observational studies were identified (i.e., KQ2). These searches used the strategies and search terms from the Oregon rapid evidence review,[2] and limited the search to studies published in January 2021 to May 2023. We also hand-searched the following top journals in psychedelic and psychoactive research: The Journal of Psychedelic Psychiatry, Psychedelic Medicine, Journal of Psychoactive Drugs, and Journal of Psychedelic Drugs. At the recommendation of a task force member, we searched the Porta Sophia database for relevant publications of studies of psilocybin use. Appendix C.1 includes search terms, strategies, and more details on methods.

The updated searches for Ovid Medline, PsycINFO, and Cochrane library identified 246 publications since January 2021 that were potentially relevant. The journal hand-search identified 39 potentially relevant publications, and the Porta Sophia database search did not

identify any relevant publications beyond those that were identified in the other databases and hand-search. Two researchers reviewed the abstract for each of the 285 results and 68 publications were advanced to full text review. Two researchers used the full text of each publication to assess relevance to the key questions and identified publications from 4 RCTs, 2 double-blind placebo-controlled crossover studies, 2 observational cohort studies, and 4 systematic reviews with additional studies for inclusion. These publications are described in the Findings section. We evaluated the risk of bias for each included study before abstracting and summarizing information pertaining to the key questions. Appendix C.2 lists systematic reviews of studies included in the Oregon rapid evidence review; overlapping systematic reviews were excluded.

We used published research protocols and clinical trial registries to search for relevant ongoing studies.

Findings

This section synthesizes new findings published since the literature search from the Oregon report.

KQ1: Risks and Benefits of Supervised Psilocybin Use

We identified publications from 4 RCTs[3-6,8] completed since the publication of the Oregon rapid review, 1 publication that presented a re-analysis of data from a previously reported RCT,[7] and 1 placebo-controlled crossover study[9] related to the use of psilocybin in supervised settings. The primary efficacy results are summarized by condition (i.e., depression and cluster headache), then by a description of a meta-analysis to provide optimal dosing of psilocybin for depression, and finally a synthesis of adverse events.

We did not identify any new eligible publications reporting on safety and efficacy of psilocybin for anxiety disorders, OCD, trauma-related disorders, substance use disorders, palliative care, or spirituality. There were no publications that addressed efficacy by subgroup (e.g., psilocybin source, age, setting, co-ingestion, or personal characteristics).

Depression: Significant Reduction in Severity During Short-Term Follow-Ups

We identified 2 recent systematic reviews[12,13] that included the studies from the Oregon rapid review plus the studies described below. Both reviews, which we assessed as having a low risk of bias, concluded that studies of psilocybin as a treatment for depression demonstrated at least short-term improvement compared with placebo for some participants.[12,13] The exclusion criteria for all included studies remained a limitation (i.e., exclusion of participants with severe features of depression), as did failure to recruit diverse samples (i.e., participants were predominantly White) and the short follow-up periods.[12,13]

The first 2 RCTs, reported in 3 publications[3,5,6] described below were not reported in the Oregon rapid review, followed by 2 other publications[4,7] that presented additional results from 2 RCTs whose primary results were discussed in the Oregon rapid review.

We identified 1 RCT by von Rotz et al.[6] (NCT03715127) with 52 participants with major depressive disorder who were randomized to receive psychotherapy plus either a single dose of psilocybin based on participant weight (0.215 mg/kg body weight) or a placebo. We assessed this RCT as having a low risk of bias, although the study sample was not diverse and the follow-up period was brief. Compared with the placebo group, the group that received psilocybin had a statistically significant greater decrease in depression scores. About half of the participants in the psilocybin group (54%; 14 participants) had low enough depression scores to be considered in remission at the 14-day follow-up.[6] The authors noted that larger RCTs with longer-term follow-ups are needed to better understand the efficacy of psilocybin as a treatment for depression.[6]

Two publications from an RCT (NCT03775200) with 233 participants with a treatment-resistant episode of major depression reported results from outcomes measured 3 weeks and 12 weeks after administration of a single dose of psilocybin (high dose group: 25 mg; low dose group: 10 mg; control group: 1 mg).[3,5] We assessed this RCT as having a moderate risk of bias because the summary estimate may have overestimated the relationship between the psilocybin and outcomes (i.e., type of statistical analysis used), and the COMP360 manufacturer funded the study.[3,5] Goodwin et al. reported a significant decrease in depression severity and anxiety for the 25-mg dose group compared with the control group 3 weeks after administration of psilocybin, but this statistically significant improvement was not sustained through the 12-week follow-up.[3,5] Out of the 79 participants in the 25-mg dose group: 37% were treatment responders (i.e., had a 50% decrease in depression scores), 29% were considered to be in remission (i.e., very low depression score), and 20% had a sustained response through week 12.[3] In contrast, there were fewer treatment responders in the 10 mg and 1 mg groups (19% and 18% respectively), fewer participants in remission (9% and 8% respectively), and fewer participants whose response was sustained at 12 weeks (5% and 10% respectively).[3] The authors noted studies with longer follow-up, larger sample sizes, more diverse participants, and possibly a series of doses are important for further understanding the efficacy and safety of psilocybin for treatment-resistant depression.[5]

We identified a 12-month follow-up[4] for an RCT described in the Oregon rapid review with 24 participants with major depressive disorder that reported significantly lower depression severity for the group given psilocybin compared with a wait-listed group (Davis et al.[26]; NCT03181529). We assessed this follow-up as having a high risk of bias because the 2 groups were collapsed for analysis, potential participants with the most serious depression were excluded, and there was unclear influence of funding sources. Guskayan et al.[4] reported 75% of the immediate and delayed treatment groups had a 50% decrease in depression symptoms at the 12-month follow-up, and 58% of participants were considered to have attained remission.[4,26] The 2 doses administered to participants were weight-dependent (session 1: 20mg/70 kg; session 2: 30 mg/70 kg) and were accompanied by supportive psychotherapy.[26] The authors noted the need for larger samples, recruitment of more diverse participants, and maintenance of longer comparisons between intervention and control groups for future studies of psilocybin as a treatment for depression.

Nayak et al.[7] re-analyzed data from the trial reported in the Carhart-Harris et al.[27] publication (NCT03429075) described in the Oregon rapid review. The study enrolled 59 participants with

major depressive disorder.[7] We assessed the RCT as having a moderate risk of bias because of conflicts of interests among the study investigators. After applying a different analytic approach to data that compared participants with major depression randomized to receive either psilocybin or escitalopram, Nayak et al.[7] concluded that psilocybin was non-inferior to escitalopram, but the difference between the 2 groups' reduction in depression did not represent a clinically meaningful difference. Escitalopram (brand names include Lexapro and Cipralex) is a selective serotonin reuptake inhibitor used to treat depression and generalized anxiety.

Dosing for Treatment of Depression

We identified a systematic review with a meta-analysis that evaluated the dosage of psilocybin across 7 RCTs and open-label prospective studies with 136 participants who were administered psilocybin as a treatment for depression.[15] We assessed this systematic review as having a low risk of bias, and the systematic review authors reported that component studies had high quality. The authors concluded that data from 5 similar clinical trials indicate that a dose of 30 to 35 mgs per 70 kgs of participant weight may optimize the therapeutic effect for participants with depression.[15] The included trials enrolled participants with major depression (i.e., primary depression) and secondary depression related to a cancer diagnosis.[15] The dosing recommendation may only be applicable to individuals similar to the participants in the 5 clinical trials analyzed (e.g., White cisgender individuals in middle adulthood).

Migraine Suppression: Preliminary Results Suggest Short-Term Reduction in Migraine Days

Schindler et al.[9] reported results from an exploratory double-blind, placebo-controlled, crossover study (NCT03341689) with 10 participants who had 2 or more migraine attacks per week and were not diagnosed with serious medical or psychiatric disease. We assessed this study as having a high risk of bias due to study design limitations (e.g., no randomization), small sample, short follow-up periods, and a lack of information about conflicts of interest and funding. There was a statistically significant decrease in migraine days (psilocybin mean, −1.65; psilocybin 95% confidence intervals, −2.53 to −0.77; placebo mean, − 0.15; placebo 95% confidence interval, −1.13 to 0.83; P = .003; effect size, −1.15).[9] A similar reduction was found in migraine attack frequency per week after psilocybin use (effect size, −1.22; P = .004), and decreased use of migraine abortive medication (effect size, -0.86; P = .014).[9] All participants noted either a headache or a migraine the day after dosing sessions.[9] Authors emphasized the importance of larger scale replication with dosing ranges and longer follow-ups before clinical application.[9]

Cluster Headache: Preliminary Results Suggest No Significant Effect

Schindler et al.[8] (NCT02981173) reported that psilocybin did not reduce cluster headache frequency, pain intensity, or duration in the 8 intervention group participants compared with the 6 placebo group participants over an 8-week follow-up period. We assessed this study as having a moderate risk of bias, due to the funding sources, decision to drop 2 placebo group members from the analysis, and small sample size with participants who were all Caucasian and mostly male. The intervention group took 3 serial doses each about 5 days apart and were followed intensively for 8 weeks, with an additional follow-up after 6 months.[8] The researchers noted the small number of participants in the trial may have made it difficult to find a significant effect of

psilocybin on cluster headaches, and future studies should include a more representative sample, larger number of participants, and plan to test for difference in response between individuals with chronic versus episodic cluster headaches.[8]

Adverse Events: Frequent Headaches, Nausea and Anxiety, and Rare Worsening Depression

We identified a systematic review assessed as having a low risk of bias that reported adverse events from 20 articles with 257 participants who received psilocybin.[14] The authors noted most studies relied on participants to spontaneously report adverse events rather than using a scale or standard forms to regularly request information about adverse events from participants.[14] Overall, the authors concluded psilocybin was well-tolerated by participants, although there were frequent reports of moderate to severe nausea, headache, dizziness, anxiety, and infrequent reports of paranoia that resolved with staff therapeutic support during the dosing session.[14]

In addition to the adverse events compiled by the systematic review above, we pulled out adverse event information reported by the studies summarized in this section that were not included in the systematic review. Schindler et al.[8] reported 1 of the 8 participants administered psilocybin had paranoia that required staff intervention, and this participant did not receive a final dose. Many other participants reported experiencing nausea, headache, and fatigue.[9] In a sample of participants with treatment-resistant depression, Goodwin et al. reported about three-fourths of participants experienced headache, nausea, dizziness, or fatigue (179 out of 233 participants), but some participants had more serious adverse events.[3] Thirty-one participants had worsening suicidal state 3 weeks after baseline, 3 participants had suicidal behavior, 1 had adjustment disorder with anxiety and depressed mood, and 1 had intentional self-injury.[3] The 3 participants with suicidal behavior had no treatment response at week 3, and had reported that they had a history of suicidal behavior at baseline before the trial.[3]

KQ2: Risks and Benefits of Unsupervised Psilocybin Use

We identified 1 placebo-controlled crossover study[16] and 2 observational cohort studies[10,11] related to the use of psilocybin in unsupervised settings.

We did not identify any new information about the risks and benefits of psilocybin in unsupervised settings for participants with anxiety disorders, OCD, trauma-related disorders, substance use disorders, palliative care, or spirituality. There were no publications that addressed efficacy by subgroup (e.g., dosage, psilocybin source, age, setting, co-ingestion, or personal characteristics).

Microdosing for Participants with Depression or Anxiety: No Significant Effect

In a controlled crossover study of the effect of 7 self-administered microdoses of psilocybin on depression and anxiety that analyzed data from 58 participants, Marschall et al.[16] reported there was not a significant change in symptoms of anxiety or depression between participants taking placebo or psilocybin. We assessed this study as having a moderate risk of bias, primarily due to high attrition, unclear methods to support randomization process, and participants' awareness of taking a placebo or psilocybin.[16] The microdoses were about a tenth of a medium-high dose, with

0.7 grams of dried psilocybin-containing Galindoi truffles.[16] The authors suggest the small sample and possibility that the self-selected participants may not have been naïve to psilocybin and may have contributed to the lack of power to find an effect, if there was an effect.[16]

Unsupervised Use for Self-Treatment of Mental Health Conditions

Kopra et al.[10] reported findings from the Global Drug Survey 2020, which compiled information from 3,364 individuals who used psilocybin or lysergic acid diethylamide (LSD) in unsupervised settings. We assessed this study as having a high risk of bias. A majority of the participants were young adults, 72% identified as male, 80% identified as White, and 56% had been diagnosed with a mental health condition at some point in their life.[10] About 60% of respondents noted using at least 1 of these psychoactive drugs to self-treat depression or anxiety.[10] Out of this larger sample, 1,368 reported using psilocybin, and on average reported higher improvements in a scale intended to assess well-being, psychiatric symptoms, social-emotional skills, and health behaviors.[10] The authors concluded respondents reported mild to moderate improvements for an average of 3 weeks after psilocybin or LSD use, but some respondents reported adverse events. Most respondents noted mild adverse effects that diminished within a day or a week (e.g., confusion, feelings disconnected, worry, poor mood), but 183 respondents reported severe adverse effects lasting up to 4 weeks (e.g., irrational fear, memory problems, inability to regulate emotions).[10]

Glynos et al.[11] reported information gathered from 1,435 anonymous survey participants who answered questions about clinical diagnoses, psychoactive drug use, perceived outcomes including use patterns, motivations to use, and effects on well-being and health. We assessed this study as having a high risk of bias. Most participants (88.8%) identified as White, 52% identified as men, the mean age was 35 (±12.5 years), 78.1% lived in the US, and 92.1% had used psilocybin.[11] All of those who noted psilocybin use had used mushrooms and 10% had also used a synthetic psilocybin.[11] About half of the participants reported they had used psychoactive drugs to self-treat depression, anxiety, or PTSD.[11] Only 4% had ever used psilocybin in a clinical setting with the support of a therapist or health care professional, but 71.4% of those individuals reported that the presence of the professional was very helpful.[11] Most respondents (93.2%) indicated they perceived improvement in overall psychological, emotional, mental, or physical well-being after use of psychoactive drugs, including respondents who had been diagnosed with depression, anxiety, or PTSD.[11] Fewer than 5% of respondents reported worsened symptoms for the latter conditions, but 9% reported worsened symptoms of bipolar depression and sleep disorders.[11] About a third of respondents reported using alcohol, tobacco, and prescription opioids less frequently after using psychoactive drugs, but about 4% of respondents reported increased use of those substances.[11] Other adverse effects were not collected by the survey.[11] Overall, the authors concluded that although most respondents had predominantly positive self-reported experiences, more clinical training and support of health care professionals may help address adverse effects and give therapeutic support to improve efficacy.[11]

KQ3: Provider and Patient Risk Assessment Tools

We did not identify any validated risk assessment tools intended to indicate whether a patient may benefit from or experience risk or harm from the use of psilocybin. However, we identified a recent systematic review of psychometric assessments used in research related to the use of psychedelics.[28] Three of the measures described in the systematic review were related to assessing risk before and after use of psychoactive drugs, but none were validated in clinical populations of participants using or considering using psilocybin and only 1 measure was developed specifically for psilocybin use.[28] The 3 measures are summarized below.

- The Wave test, developed in Spain, has 30 items intended to assess risk of developing psychotic disorder and risk of developing bipolar disorder due to use of psychoactive drugs.[29] This tool was administered in populations of university students, and has not been validated in clinical populations.[28,29] It is not clear whether this tool is available only in Spanish.
- The Psychotomimetic States Inventory (PSI), was developed to assess delusory thinking, perceptual disorientation, cognitive disorientation, anhedonia, mania, and paranoia during and after use of psychoactive substances.[28,30]
- The Challenging Experience Questionnaire (CEQ) has 26 items based on selections from 3 other instruments intended to evaluate psychedelic experience.[28,31] This questionnaire evaluates experience of grief, fear, death, insanity, isolation, physical distress, and paranoia after use of psilocybin.[31] This tool is intended to assess acute psychological adverse reactions to psilocybin use, not to predict whether an individual is at risk for experiencing those adverse reactions.[31]

Among the 3 instruments listed above, only a single instrument was intended to predict risk of adverse experiences before use of psychoactive drugs, but it was not validated in populations relevant to the scope of this report. The other 2 instruments may be useful as ongoing assessments of adverse experiences after psilocybin use, but we did not identify publications where the instruments were used or tested as periodic assessment tools. The CEQ was listed in Appendix 3 of the Oregon rapid evidence review under a section for research tools for tracking changes, but the PSI and Wave test were not included in the screening instruments list.[2]

Appendix 2 of the Oregon rapid evidence review presented considerations for screening individuals considered to have high risk for adverse experiences or events, and we did not identify additional populations to add to that list during the evidence review for this update.[2]

KQ4: Relative Potential Risks of Different Sources of Psilocybin

We did not identify any publications with additional information to what the Oregon rapid evidence review summarized.[2]

Ongoing RCTs With Psilocybin for Included Conditions

Table 1 summarizes 30 relevant ongoing RCTs identified while searching trial registries for RCTs relevant to the key questions in this review. Twenty-five of the protocols listed co-occurring psychotherapy with the psilocybin use. Follow-up ranged from 2 weeks to a year across protocols. Seventeen studies recruited participants with psychiatric conditions, with 13 focused

on major depressive disorder. Twelve studies recruited participants with substance use disorders, and 7 of these studies focused on alcohol use disorder. Some of the protocols lacked precise dosing information, but 12 study protocols noted used of a 25 mg or 30 mg dose.

The primary completion dates listed on the trial registry entries ranged from January 2020 to November 2027, with 9 RCTs listing a primary completion date before the end of 2023. This may be an indication that published results relevant to the key questions in this report may be forthcoming.

Table 1. Identified Ongoing RCTs Relevant to Key Questions

Number of Studies Number of Participants Population of Focus	Intervention(s) Length of Follow-up	Trial Identifier
Substance Use Disorders		
7 RCTs with 548 individuals diagnosed with alcohol use disorder	Single doses of psilocybin: 5 RCTs with 25 mg dose and 1 RCT with 30 mg dose 1 RCT with 2 doses of psilocybin (unspecified amount) 6 RCTs include co-occurring psychotherapy Follow-up for 8 weeks to 52 weeks	NCT05416229 NCT05421065 NCT04141501 NCT04620759 NCT05398484 NCT05646303 2021-006200-33 (EU Clinical Trials Register)
2 RCTs with 161 individuals who used tobacco	1 RCT with a single 30 mg dose plus psychotherapy 1 RCT with a 30 mg dose followed by a 30 to 40 mg dose 1 week later, plus psychotherapy Follow-up for 52 weeks	NCT01943994 NCT05452772
1 RCT with 92 individuals who used an opioid agonist	Single 40 mg dose plus methadone maintenance Follow-up for 12 weeks	NCT05242029
1 RCT with 40 participants who used cocaine	Single 0.36 mg per kg of body weight dose plus psychotherapy Follow-up for 24 weeks	NCT02037126
1 RCT with 30 participants who used methamphetamine	A 25 mg dose followed by a 30 mg dose 2 weeks later plus psychotherapy Follow-up for 32 weeks	NCT04982796

Number of Studies Number of Participants Population of Focus	Intervention(s) Length of Follow-up	Trial Identifier
Psychiatric Conditions		
13 RCTs with 1,652 participants diagnosed with major depressive disorder	3 RCTs with single 25 mg dose of psilocybin plus psychotherapy 10 RCT protocols did not specify the number of doses or amount of psilocybin, plus psychotherapy Follow-up for 24 hours to 6 months, with 6 RCTS planning follow-up for 4 to 6 weeks	NCT03866174 NCT05385783 NCT05675800 NCT05259943 NCT04630964 NCT03380442 NCT04959253 NCT05383313 NCT05029466 NCT05624268 NCT05711940 NCT04670081 NCT05710237
1 RCT with 60 participants diagnosed with anorexia nervosa	Unspecified dose of psilocybin Follow-up for 4 weeks	NCT05481736
2 RCTs for existential distress in 400 participants with advanced stage cancer	Single 25 mg dose of psilocybin plus psychotherapy 1 RCT compares psilocybin with ketamine Follow-up for 2 to 8 weeks	NCT05398484 NCT05403086
1 RCT with 30 participants with professional caregiver burnout, PTSD, or moral injury	Unspecified dose of psilocybin plus psychotherapy Follow-up for 4 weeks	NCT05163496
Other Conditions		
1 RCT with 30 participants with chronic low back pain	Unspecified single dose of psilocybin Follow-up for 4 weeks	NCT05351541

Abbreviations. kg: kilogram; mg: milligram; PTSD: post-traumatic stress disorder; RCT: randomized controlled trial.

Discussion

This update to the Oregon rapid review about the potential risks and benefits of psilocybin use in supervised and unsupervised settings synthesized information from studies published after the Oregon rapid review literature search. When considered with the body of evidence presented in the Oregon rapid review, the results summarized here echo the conclusion that psilocybin combined with psychotherapeutic support in a supervised setting may be effective for a rapid reduction of depression severity for at least a few weeks after dosing. A meta-analysis reviewed in this update suggested a dose of 30 to 35 mgs per 70 kgs of participant weight may optimize the therapeutic effect for participants with depression, and several ongoing studies testing psilocybin have doses close to that range. However, this recommendation may only be applicable to individuals similar to the participants in the 5 clinical trials analyzed (e.g., White cisgender individuals in middle adulthood). Although most study participants reported mild to moderate

transient adverse events (e.g., headache, nausea, anxiety), a minority of participants reported worsening depression or suicidality.

Since the searches were conducted in May 2023, we were alerted to the publication of an additional RCT with 104 participants with major depressive disorder randomized to receive a single 25-mg dose or an active placebo of 100-mg niacin.[32] Both groups received psychological support and identical facilitation of sessions for preparation, dosing, and integration (i.e., debrief discussion of experience during dosing session).[32] Individuals with serious comorbid conditions were excluded (e.g., suicidal ideation with intent, history of psychosis), and 89% of the participants identified as White.[32] Overall, the results of this study supported the findings in this report: the psilocybin group had a significantly greater decrease in depression scores at 8, 15, 29, and 43 days after dosing compared to the niacin group.[32] The publication reported similar types and frequencies of adverse events as the RCTs previously described in this review, although 3 additional serious adverse events occurred: nephrolithiasis, obstructive incisional hernia, and appendicitis.[32] Due to limitations on staff time, we were unable to conduct a full bridge search in all databases for newly published studies between May 1, 2023 and September 1, 2023.

The synthesized studies related to cluster headache and microdosing for depression indicated there was not statistically significant improvement in conditions for the participants.

High quality information about psilocybin use in unsupervised settings was challenging to find, and the only data we identified to answer questions about unsupervised use came from a crossover study with moderate risk of bias and 2 observational studies with high risk of bias. Adverse events from these studies were similar to those found in the controlled studies of supervised psilocybin use. Similarly, most participants perceived improvement in well-being after use while a minority reported worsening conditions.

We did not identify validated risk assessment tools designed for providers or patients to predict risk and benefit for individuals who may use psilocybin.

We did not identify new information about the relative benefits and risks of different sources of psilocybin.

Limitations of Included Studies and Considerations for Future Reviews

Limitations of included studies include a lack of diversity among study participants, small sample size that make effect identification difficult and subgroup analysis impossible (i.e., understanding for whom psilocybin may be effective), limited follow-up duration, and exclusion of potential participants with comorbid conditions. Each of these considerations limit the generalizability of the study results to a broader population. All of the publications noted that larger, more diverse, placebo-controlled trials with longer follow-up are needed to understand the efficacy and safety of psilocybin as a treatment for mental health conditions.

The 30 ongoing RCTs described in a prior section of this report demonstrate the fast pace at which research on psilocybin for various chronic conditions is emerging. Results from the multiple ongoing trials with individuals with depression or with substance use disorders may add

important depth of information about the role of psilocybin in treating those conditions. Publications from these trials may reasonably be anticipated within the next 2 to 5 years.

The studies synthesized in this rapid clinical evidence review did not explicitly include knowledge and experiences outside of published scientific literature, including perspectives and experiences of indigenous communities and other non-Western communities and institutions.

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Appendix C.1 Clinical Evidence Methods

Search Strategy

We searched clinical evidence sources to identify systematic reviews (with and without meta-analyses), technology assessments, and randomized controlled trials (RCTs) including the terms *psilocybin*, *psilocin*, and *mushroom*. We used the search strategies developed by the authors of the Oregon rapid evidence review,[1] and limited searches of sources to citations published after December 2020.

1. We searched the following evidence sources:

- Agency for Healthcare Research and Quality (AHRQ)
    - Evidence-based Practice Centers (EPC) Reports
    - Effective Health Care (EHC) Program
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Cochrane Library (Wiley Interscience)
- National Institute for Health and Care Excellence (NICE), Evidence
- Ovid MEDLINE including In-Process & Other Non-Indexed Citations and Epub Ahead of Print
- Veterans Administration Evidence-based Synthesis Program (ESP)

The Journal of Psychedelic Psychiatry
Psychedelic Medicine
Journal of Psychoactive Drugs
Journal of Psychedelic Drugs

- PsycINFO

Ovid MEDLINE Search Strategy

1 Psilocybin/

2 (psilocybin or psilocin).ti,ab,kf.

3 1 or 2

4 (random* or control* or trial or systematic or "meta analysis" or metaanalysis or medline).ti,ab,kf.

5 3 and 4

6 limit 3 to randomized controlled trial

7 limit 3 to (meta analysis or "systematic review")

8 or/5-7

9 exp risk/

10 (risk and (assess* or predict*)).ti,ab,kf.

11 3 and (9 or 10)

12 mushroom*.ti,ab,kf.

13 3 and 12

14 8 or 11 or 13

15 limit 14 to yr="2021 -Current"

16 limit 15 to english language

Cochrane Library Search Strategy

#1 MeSH descriptor: [Psilocybin] explode all trees

#2 (psilocybin or psilocin):ti,ab

#3 #1 or #2

#4 (random* or control* or trial or systematic or 'meta analysis' or metaanalysis or medline):ti,ab 1443081

#5 #3 and #4

#6 MeSH descriptor: [Risk] explode all trees

#7 (risk and (assess* or predict*)):ti,ab

#8 #3 and (#6 or #7)

#9 (mushroom*):ti,ab

#10 #3 and #9

#11 #5 or #8 or #10

with Cochrane Library publication date from January 2021 to December 2023

PsycINFO Search Strategy

1. Psilocybin/

2. (psilocybin or psilocin).ti,ab.

3. 1 or 2

4. (random* or control* or trial or systematic or "meta analysis" or metaanalysis or medline).ti,ab.

5. 3 and 4

6. (risk and (assess* or predict*)).ti,ab.

7. 3 and 6

8. mushroom*.ti,ab.

9. 3 and 8

10. 5 or 7 or 9

11. limit 10 to yr="2021 -Current"

12. limit 11 to english language

Inclusion Criteria

We included systematic reviews (with and without meta-analyses), technology assessments, and RCTs that presented results published after the literature search for the Oregon rapid evidence review and not included in that review. We included studies with human participants diagnosed with conditions from the key questions, studies that reported results from participants who used psilocybin, and studies that reported measures of interpersonal, medical, or psychological benefits or risks that were patient-important (e.g., change in scores on inventories with symptoms of depression or anxiety).

Exclusion Criteria

We excluded studies if these were not published in English, studies with nonhuman participants, studies with healthy human participants (i.e., participants were not diagnosed with any of the conditions included in the key questions), studies focused on other psychedelic interventions (e.g., ayahuasca, 3,4-methylenedioxy-methamphetamine), studies without a comparison group (i.e., single-arm studies, observational studies), studies that collected outcomes that were not patient-important measures related to interpersonal, medical, or psychological benefits or risks (e.g., cell-level information, tomography scans).

Risk of Bias Assessment

Risk of Bias of Included Studies

We assessed the risk of bias of the included studies using standard instruments developed and adapted by MED that are modifications of instruments used by several renowned, respected organizations.[2-10] Two experienced researchers independently rated all included studies. In cases in which there was disagreement about the risk of bias of a study, a third rater resolved the disagreement.

Systematic Reviews

If a meta-analysis or network meta-analysis was conducted, the risk of bias of the analyses was considered in the overall rating for the systematic review. In brief, low-risk-of-bias systematic

reviews include a clearly focused question, a literature search sufficiently rigorous to identify all relevant studies, criteria used to assess study quality and select studies for inclusion (e.g., randomized controlled trials), and assessment of similarities between studies to determine whether combining them is appropriate for evidence synthesis. Moderate-risk-of-bias systematic reviews have incomplete information about methods that might mask important limitations or a meaningful conflict of interest. High-risk-of-bias systematic reviews have clear flaws that could introduce significant bias.

Randomized Controlled Trials

Low-risk-of-bias randomized controlled trials include a clear description of the population, setting, intervention, and comparison groups; a random and concealed allocation of patients to study groups; low dropout rates; and intention-to-treat analyses. Low-risk-of-bias randomized controlled trials also have low potential for bias from conflicts of interest and funding source(s). Moderate-risk-of-bias randomized controlled trials have incomplete information about methods that might mask important limitations or a meaningful conflict of interest. High-risk-of-bias randomized controlled trials have clear flaws that could introduce significant bias.

Cohort Studies

Low-risk-of-bias cohort studies include a sample that is representative of the source population, have low loss to follow-up, and measure and consider relevant confounding factors. Low-risk-of-bias cohort studies also list their funding source(s) and have a low potential of bias from conflicts of interest. Moderate-risk-of-bias cohort studies might not have measured all relevant confounding factors or adjusted for them in statistical analyses, have loss to follow-up that could bias findings, consist of a sample that is not representative of the source population, or have potential conflicts of interest that are not addressed. High-risk-of-bias cohort studies have a clear, high risk of bias that would affect findings.

Appendix C.2 Excluded Systematic Reviews

The following list of publications were excluded from the findings in this report because the studies included in the systematic reviews overlapped with the studies included in the Oregon rapid evidence review, or because the publications provided protocols or scoping for a future systematic review.

Andersen KAA, Carhart-Harris R, Nutt DJ, Erritzoe D. Therapeutic effects of classic serotonergic psychedelics: a systematic review of modern-era clinical studies. *Acta Psychiatr Scand.* 2021;143(2):101-118. doi: 10.1111/acps.13249.

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About the Center for Evidence-based Policy

The Center for Evidence-based Policy (Center) is recognized as a national leader in evidence-based decision making and policy design. The Center understands the needs of policymakers and supports public organizations by providing reliable information to guide decisions, maximize existing resources, improve health outcomes, and reduce unnecessary costs. The Center specializes in ensuring that diverse and relevant perspectives are considered and appropriate resources are leveraged to strategically address complex policy issues with high-quality evidence and collaboration. The Center is based at Oregon Health & Science University in Portland, Oregon. Further information about the Center is available at **http://centerforevidencebasedpolicy.org/**.

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Conflict of Interest Disclosures: Bethany Godlewski has a spouse who works as a government affairs director at the Association for Washington Business, which lobbies the Washington State Legislature on issues related to energy, environment, workforce development, education, transportation, health care, employment law, land use, and tax and fiscal issues on behalf of member businesses. None of the other authors have conflicts of interest to disclose. All authors have completed and submitted the Oregon Health & Science University form for Disclosure of Potential Conflicts of Interest, and none were reported.

Appendix D: Clinical Evidence Gap Responses

Are there other *population* gaps in the clinical research that were not included in the previous question?
Responses
People with disabilities.
Elderly
People with disabilities
Population with pain related disabilities
end of life care
LGBTQ+
people with disabilities
People in whom English may not be their first language.
Spiritual and religious affiliations, incarcerated
Rural
Indigenous populations
People with bipolar and schizophrenia
End of life care
Veterans

Are there other *intervention* gaps in the clinical research that were not included in the previous question?
Responses
"set and setting"
more specifics around psilocybin type (species)
Entourage effect of secondary compounds.
Group dosing
Number of integration sessions and types of integration
Comparing different types of therapeutic modalities (e.g., CBT vs. ACT vs. supportive)
Eliminate niacin, ensure all participants obtain fungi in study.
Stamet's stack... Lions mane and psilocybin stack
Optimal post treatment psychotherapy sessions
measuring outcomes of interventions (standardization)

Are there other *comparator* gaps in the clinical research that were not included in the previous question?
Responses
n/a
Lack comparison to bipolar, schizophrenia, brain injuries
to a spiritual model
Mental Health of ancient Indigenous Communities
Baeocystin mushroom
Whole Psilocybin Baseline

Are there other *outcomes* gaps in the clinical research that were not included in the previous question?
Responses
longitudinal traumatic brain injury treatment
Treatment-resistant depression
Impacts on Families
Pain other than low back
The method of cultivation, dehydration, storage and expiration for use
Connectedness and reduced isolation
Infant or child loss grief
Ethics challenges to study bipolar schizophrenia
Multiple Family Members? Separate or together? Family systems dynamics,
Better understanding of experiences with BIPOC PTSD
Spiritual/religious health
societal trauma
Bipolar 2 and Bipolar 1 are Radically different - Serious

Appendix E: Regulatory Survey

Oregon Regulatory Feedback Survey

Introduction Washington Psilocybin Task Force - Welcome to the Regulatory Feedback Survey. One of the directives given to this workgroup by the legislature was "Reviewing and discussing regulatory structures for clinical use of psilocybin in Washington and other jurisdictions nationally and globally. This should include discussing how various regulatory structures do or do not address concerns around public health and safety the Task Force has identified." This survey will begin to address this directive.

Below are a series of sections that will ask you to review rules and regulations from Oregon's most recent rulemaking process, which occurred in December of 2022. The goal of this survey is to give Task Force members the opportunity to give their direct feedback on specific aspects of Oregon's regulatory structure. All responses will be compiled and presented along with time for discussion at the 10/5 Task Force meeting. The survey should take approximately 20-30 minutes, and all responses are anonymous.

There are 11 sections in this survey: Facilitator Training, Facilitator Conduct, Service Centers, Preparation Sessions, Administration Sessions, Group Sessions, Social Equity Guidelines, Safety, Licensing, and Manufacturing and Distribution. Each section takes information from different subdivisions within Division 333 on Psilocybin, which is within the Oregon Health Authority's Public Health rulemaking chapter. Each section will have in parenthesis the code for the subdivision on which the statements in each section are based. For example, the Facilitator Training section takes from 333-333-3010. To get the direct rulemaking language, navigate to the link below and find the corresponding subdivision.

https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=7102

Thank you all for your time.

Background (4 prompts) Below is **background information** on the Oregon Psilocybin Program. Please review each statement and record your response. There are four prompts in this section.

	Support (1)	Oppose (2)	Neutral (3)	Need more information (4)	Written Feedback (5)
OPS has created an Oregon Psilocybin Advisory Board, and divided it into four subcommittees: Equity, Licensing, Products and Research, and Strategic Planning (1)	○	○	○	○	○
The advisory board lends their expertise to the health authority, but has no regulatory power (2)	○	○	○	○	○
Advisory Board vacancies accept applications from the public (3)	○	○	○	○	○
The Oregon products and research subcommittee released a Cultural and Anthropological review in November 2022 (4)	○	○	○	○	○

Facilitator Training (10 prompts) Below are Oregon Psilocybin Services (OPS) requirements for **training program licensure**. Please review each statement and record your response. (333-333-3010 - 333-333-3060)

	Support (1)	Oppose (2)	Neutral (3)	Need more information (4)	Written feedback (5)
Facilitators must complete a minimum of 120 hours of instruction (1)	○	○	○	○	○
Facilitators must have a high school diploma (2)	○	○	○	○	○
Full exemption from training requirements, even for individuals with prior experience, is not possible (3)	○	○	○	○	○
Accelerated training hours may not exceed more than 40% of required hours (4)	○	○	○	○	○
Training programs shall set their own criteria to qualify for accelerated training (5)	○	○	○	○	○
All students are required to complete 5 modules: "Cultural Equity", "Safety & Ethics", "Preparation & Orientation", "Administration", and "Integration", which is 72 hours of total training (6)	○	○	○	○	○
All students are required to complete all 40 practicum hours (7)	○	○	○	○	○
Training programs must be approved by the Higher Education Coordinating Commission (8)	○	○	○	○	○
There is a $500 non-refundable application fee for training programs (9)	○	○	○	○	○
Training programs must renew every 5 years (10)	○	○	○	○	○

Facilitator Conduct (6 prompts) Below are regulations on **facilitator conduct**. Please review and record your response. (333-333-3070, 333-333-5120 - 333-333-5140)

	Support (1)	Oppose (2)	Neutral (3)	Need more information (4)	Written Feedback (5)
Facilitators may provide supportive touch during administration sessions when requested by the client and with the client's written consent (1)	○	○	○	○	○
Facilitators must disclose to clients in the preparation session if they are mandatory reporters (2)	○	○	○	○	○
Supportive touch is limited to hugs or placing hands on a client's hands, feet, or shoulders; other forms of touch are prohibited (3)	○	○	○	○	○
Facilitators cannot engage in financial interactions with clients (4)	○	○	○	○	○
Facilitators cannot have romantic or sexual relationships with clients, client partners, or immediate family members for one year from the date of services (5)	○	○	○	○	○
Interpreters must be accommodated by all facilitation centers: Interpreter and facilitator, along with the client, must develop a plan during the preparation session that outlines how and when the interpreter should be present (6)	○	○	○	○	○

Q10 Are there other important aspects of facilitator conduct that should be regulated in Washington State? _____

Service Centers (4 prompts) Below are OPS regulations on **service centers**. Please review and record your response. (333-333-4300, 333-333-4400, 333-333-4480)

	Support (1)	Oppose (2)	Neutral (3)	Need more information (4)	Written Feedback (5)
Local governments may adopt ordinances to prohibit service center and manufacturing licenses to be given within their jurisdiction (1)	○	○	○	○	○
50% of shares/ownership of the entity must be held by individuals who have been residents of the state for two or more years (2)	○	○	○	○	○
Service centers must annually renew their license (3)	○	○	○	○	○
Service centers may not be within 1000 ft of a school (4)	○	○	○	○	○

Preparation (6 prompts) Below are rules and regulations on **preparation sessions**. Please review record your response. (333-333-5000)

	Support (1)	Oppose (2)	Neutral (3)	Need more information (4)	Written Feedback (5)
Preparation session must occur between 90 days and 24 hours before the session (1)	○	○	○	○	○
Client must be able to meet and approve the facilitator; preparation sessions must be private to share personal information (2)	○	○	○	○	○
The facilitator and client must construct and agree on both a transportation plan and safety and support plan (3)	○	○	○	○	○
A facilitator must obtain prior written consent from a client for: Group session, use of supportive touch, participation in a training practicum, video or audio recording, use of an interpreter, sharing of identifiable client data, use of different facilitators, consuming secondary doses of psilocybin products (4)	○	○	○	○	○
If two sessions at the same service center are performed with the same client, a preparation session does not need to be performed (5)	○	○	○	○	○
Preparation sessions can occur in person or virtually (6)	○	○	○	○	○

Administration (5 prompts) Below are rules and regulations surrounding **administration sessions**. Please review and record your responses. (333-333-5200)

	Support (1)	Oppose (2)	Neutral (3)	Need more information (4)	Written Feedback (5)
A facilitator must always be present during the administration session, and an additional licensee representative of the service center must also be present (1)	○	○	○	○	○
A backup facilitator must be available to help facilitate in case of an emergency, and must be able to reach the facilitation center within a reasonable period (2)	○	○	○	○	○
Outdoor sessions may be conducted within designated outdoor administration areas at a service center (3)	○	○	○	○	○
Minimum duration of sessions by dosage: 2.5mg or less: 1 hour (30 minutes if a prior administration occurred at the same center), 2.5 – 5mg: 1 hour, 5 – 10mg: 2 hours, 10 – 25mg: 4 hours, 25 – 35mg: 5 hours, 35 – 50mg: 6 hours (4)	○	○	○	○	○
A release document must be signed at the end of the administration session, with an optional integration session being offered at this time (5)	○	○	○	○	○

Integration (2 prompts) Below are rules and regulations for **integration sessions**. Please review and record your responses. (333-333-3050, 333-333-5260)

	Support (1)	Oppose (2)	Neutral (3)	Need more information (4)	Written Feedback (5)
Follow-up contact with clients should be offered within 72 hours of the administration session, offering an optional integration session (1)	○	○	○	○	○
Facilitators must use a non-directive facilitation approach for an integration session (2)	○	○	○	○	○

Q27 The OPS training module outlines these points to be taught to facilitators on integration sessions: "Identification of appropriate resources for client integration, including resources for interpreting feelings, facilitating positive changes, and enhancing existing relationships", "Identification of client safety concerns", "Facilitator scope of practice", "Discussion of appropriate intervals between administration sessions and related safety concerns".

Q18 The rules and regulations on integration sessions in Oregon are limited in comparison to other sections. What additional rules or regulations should be included in the guidelines for integration sessions, if any?

_____

Group Sessions (6 prompts) Below are the rules and regulations for **group sessions**. Please review and record your response. (333-333-5020, 333-333-5230)

	Support (1)	Oppose (2)	Neutral (3)	Need more information (4)	Written Feedback (5)
No minimum dosage for group sessions (1)	○	○	○	○	○
25 people maximum per session (2)	○	○	○	○	○
Clients must have the opportunity to meet and interact with other clients, interpreters, or client support persons who will participate in the group administration session prior to the session commencing (3)	○	○	○	○	○
For 5mg of psilocybin analyte or less, facilitator to client ratio is 1 to 25, 5 - 10 mg: 1 to 15, 10 to 15 mg: 1 to 8, 15 to 25 mg: 1 to 6, 25 to 35 mg: 1 to 4, 35 to 50 mg: 1 to 2 (4)	○	○	○	○	○
Participants cannot touch each other unless consent is given for supportive touch from both parties (5)	○	○	○	○	○
If a client becomes disruptive, facilitators should do their best to separate the client from the group (6)	○	○	○	○	○

Social Equity (4 prompts) Below is an outline of the **equity efforts** included in the OPS's rules and regulations. Please review and record your response below. (333-333-4020 - 333-333-4070)

	Support (1)	Oppose (2)	Neutral (3)	Need More Information (4)	Written Feedback (5)
Social equity plans are required from any facilitation center applying for a license (1)	○	○	○	○	○
There will be a 15% sales tax on the sale of psilocybin products: Department of Revenue will deduct administrative costs, and the rest of the funds will support OPS (2)	○	○	○	○	○
Mobile service centers are not permitted (3)	○	○	○	○	○
A 50% reduction in the licensing fee is permitted if the entity is a non-profit, this fee reduction can also apply to those receiving social security income benefits, those enrolled in the Oregon health plan, those receiving food stamps, and those who have served in the armed forces (4)	○	○	○	○	○

Equity Text 1 OPS's guidelines for a social equity plan: "Application of diversity, equity, justice and inclusion principles to the licensee's internal practices and policies", "Objective performance measures that the licensee will use to evaluate their social equity plan". Should more criteria be added to the guidelines for a social equity plan? If so, what should be added?

_____

Equity Text 2 What else should be recommended to Washington State as methods to promote equity in a future Psilocybin program?

_____

Safety text 1 Facilitators must work with clients to develop a safety and support plan before the administration session. This includes identifying risks and challenges specific to the client's circumstances--evaluating existing support networks for the client, discussing internal resources, and mitigating risks. Are there any other specific areas that should be addressed in a safety and support plan? (333-333-5080)

_____

Safety text 2 What other safety concerns should be addressed directly in the rules and regulations process in Washington?

_____

Licensing (4 prompts) Below are rules and regulations on **licensing processes**. Please review and record your responses. (333-333-4060 - 333-333-4120)

	Support (1)	Oppose (2)	Neutral (3)	Need more information (4)	Written Feedback (5)
There will not be a finite amount of licenses to be distributed (1)	○	○	○	○	○
Licensing fees for manufacturers and service centers are $10,000 annually (2)	○	○	○	○	○
A facilitator license is $150 annually (3)	○	○	○	○	○
The Department of Health in Washington must reimburse 100% of the costs of operation (4)	○	○	○	○	○

Manufacturing (5 prompts) Below are guidelines surrounding **manufacturing and distribution**. Please review and record your response. (333-333-2010 - 333-333-2060, 333-333-2110 - 333-333-2200)

	Support (1)	Oppose (2)	Neutral (3)	Need more information (4)	Written Feedback (5)
Species are limited to psilocybe cubensis (1)	○	○	○	○	○
Manufacturers are prohibited from: Using manure in cultivation of products, Using wood chips as a growing medium, Using genetically modified organisms, Producing psilocybin by chemical synthesis (2)	○	○	○	○	○
Psilocybin-producing fungi is considered a crop, for the purposes of “farm use” (3)	○	○	○	○	○
Manufacturers can possess up to 200 grams of psilocybin analyte, Service centers can possess up to 100 grams of psilocybin analyte (4)	○	○	○	○	○
Advertising restrictions are in place to prevent false advertising, encourage illegal activity, or advertise to minors (5)	○	○	○	○	○

Appendix F: Regulatory Survey Results

This appendix includes the unedited responses from the regulatory survey that was administered to Task Force members from September 12 to September 25, 2023. The survey included a mix of support-ranking questions as well as open-ended responses. Respondents were asked to reply to the prompts listed below and document their support for the specified policy as either "support", "oppose", "neutral" or "need more information". To easily summarize group support, those responses were converted to a *calculated total score* which weighs each response in the following way:

- "support" is equal to 1
- "oppose" is equal to -1
- "neutral" or "need more information" are equal to 0

Therefore, a positive general score represents a general consensus of support for the specified regulation. A strong, positive score (8 or above) means a majority of responses were in support of the regulation.

Prompt	Calculated Total Score	Support	Oppose	Neutral	Need more info
Background					
OPS has created an Oregon Psilocybin Advisory Board, and divided it into four subcommittees: Equity, Licensing, Products and Research, and Strategic Planning	+9	10	1	2	1
The advisory board lends their expertise to the health authority, but has no regulatory power	+4	7	3	2	2
Advisory Board vacancies accept applications from the public	+8	9	1	1	3
The Oregon products and research subcommittee released a Cultural and Anthropological review in November 2022	+4	5	1	4	2
Facilitator Training					
Facilitators must complete a minimum of 120 hours of instruction	+4	6	2	3	2
Facilitators must have a high school diploma	+3	6	4	2	0

Full exemption from training requirements, even for individuals with prior experience, is not possible	0	4	4	2	2
Accelerated training hours may not exceed more than 40% of required hours	3	3	3	6	1
Training programs shall set their own criteria to qualify for accelerated training	-2	2	4	3	1
All students are required to complete 5 modules: "Cultural Equity", "Safety & Ethics", "Preparation & Orientation", "Administration", and "Integration", which is 72 hours of total training	+6	7	1	2	1
All students are required to complete all 40 practicum hours	+8	9	1	2	1
Training programs must be approved by the Higher Education Coordinating Commission	+4	6	2	2	2
There is a $500 non-refundable application fee for training programs	+1	5	4	3	0
Training programs must renew every 5 years	+4	5	1	4	2
Facilitator Conduct					
Facilitators may provide supportive touch during administration sessions when requested by the client and with the client's written consent	+8	9	1	2	2
Facilitators must disclose to clients in the preparation session if they are mandatory reporters	+10	10	0	1	2
Supportive touch is limited to hugs or placing hands on a client's hands, feet, or shoulders; other forms of touch are prohibited	+8	9	1	1	2
Facilitators cannot engage in financial interactions with clients	+7	8	1	1	4
Facilitators cannot have romantic or sexual relationships with clients, client partners, or immediate family members for one year from the date of services	+9	10	1	1	1
Interpreters must be accommodated by all facilitation centers: Interpreter and facilitator, along with the client, must develop a plan during the preparation session that outlines how and when the interpreter should be present	+11	10	0	0	1

Service Centers					
Local governments may adopt ordinances to prohibit service center and manufacturing licenses to be given within their jurisdiction	-1	5	6	3	0
50% of shares/ownership of the entity must be held by individuals who have been residents of the state for two or more years	+9	10	1	2	1
Service centers must annually renew their license	+9	9	0	3	1
Service centers may not be within 1000 ft of a school	+4	7	3	3	0
Preparation Sessions					
Preparation session must occur between 90 days and 24 hours before the session	+11	11	0	1	2
Client must be able to meet and approve the facilitator; preparation sessions must be private to share personal information	+13	13	0	0	0
The facilitator and client must construct and agree on both a transportation plan and safety and support plan	+10	10	0	2	0
A facilitator must obtain prior written consent from a client for: Group session, use of supportive touch, participation in a training practicum, video or audio recording, use of an interpreter, sharing of identifiable client data, use of different facilitators, consuming secondary doses of psilocybin products	+11	11	0	0	1
If two sessions at the same service center are performed with the same client, a preparation session does not need to be performed	+6	7	1	1	2
Preparation sessions can occur in person or virtually	+6	8	2	0	0
Administration Sessions					
A facilitator must always be present during the administration session, and an additional licensee representative of the service center must also be present	+8	9	1	3	0
A backup facilitator must be available to help facilitate in case of an emergency, and must be able to reach the facilitation center within a reasonable period	+7	8	1	3	1

Outdoor sessions may be conducted within designated outdoor administration areas at a service center	+11	12	1	0	0
Minimum duration of sessions by dosage: 2.5mg or less: 1 hour (30 minutes if a prior administration occurred at the same center), 2.5 – 5mg: 1 hour, 5 – 10mg: 2 hours, 10 – 25mg: 4 hours, 25 – 35mg: 5 hours, 35 – 50mg: 6 hours	+1	4	3	4	1
A release document must be signed at the end of the administration session, with an optional integration session being offered at this time	+11	11	0	1	1
Integration Sessions					
Follow-up contact with clients should be offered within 72 hours of the administration session, offering an optional integration session	+14	14	0	0	0
Facilitators must use a non-directive facilitation approach for an integration session	+6	8	2	2	0
Group Sessions					
No minimum dosage for group sessions	+5	6	1	2	4
25 people maximum per session	+3	5	2	2	4
Clients must have the opportunity to meet and interact with other clients, interpreters, or client support persons who will participate in the group administration session prior to the session commencing	+9	9	0	1	3
For 5mg of psilocybin analyte or less, facilitator to client ratio is 1 to 25, 5 - 10 mg: 1 to 15, 10 to 15 mg: 1 to 8, 15 to 25 mg: 1 to 6, 25 to 35 mg: 1 to 4, 35 to 50 mg: 1 to 2	+1	2	1	4	5
Participants cannot touch each other unless consent is given for supportive touch from both parties	+8	8	0	1	3
If a client becomes disruptive, facilitators should do their best to separate the client from the group	+10	10	0	1	1
Social Equity					
Social equity plans are required from any facilitation center applying for a license	+11	11	0	2	2

There will be a 15% sales tax on the sale of psilocybin products: Department of Revenue will deduct administrative costs, and the rest of the funds will support OPS	+7	9	2	1	2
Mobile service centers are not permitted	-5	3	8	1	0
A 50% reduction in the licensing fee is permitted if the entity is a non-profit, this fee reduction can also apply to those receiving social security income benefits, those enrolled in the Oregon health plan, those receiving food stamps, and those who have served in the armed forces	+7	8	1	1	3
Licensing					
There will not be a finite amount of licenses to be distributed	+9	10	1	2	0
Licensing fees for manufacturers and service centers are $10,000 annually	+6	8	2	2	0
A facilitator license is $150 annually	+7	8	1	1	1
The Department of Health in Washington must reimburse 100% of the costs of operation	+2	4	2	2	3
Manufacturing and Distribution					
Species are limited to psilocybe cubensis	-1	5	6	1	1
Manufacturers are prohibited from: Using manure in cultivation of products, Using wood chips as a growing medium, Using genetically modified organisms, Producing psilocybin by chemical synthesis	+5	6	1	2	1
Psilocybin-producing fungi is considered a crop, for the purposes of "farm use"	+9	9	0	1	2
Manufacturers can possess up to 200 grams of psilocybin analyte, Service centers can possess up to 100 grams of psilocybin analyte	+3	5	2	2	1
Advertising restrictions are in place to prevent false advertising, encourage illegal activity, or advertise to minors	+10	10	0	2	0

The rest of this section presents unedited responses to the open-ended survey questions. An additional presentation on the survey results can be found online under Meeting #3 links in Appendix I.

Question 10: Are there other important aspects of facilitator conduct that should be regulated in Washington State?
There should be some type of ongoing supervision for facilitators to engage with people with more experience and learn from others
Not sure
I am not in favor of relinquishing training to Higher Ed Board. (will take more time and more money and curriculum development is often made up - will they obtain relevant advisors?
Health and safety of the client and facilitator should both be considered.
Facilitators must be psilocybin-experienced. Ideally, they should completed a psilocybin session from supervision by an experienced psychiatrist, therapist, or medical practitioner. No facilitators who are psilocybin-naive should be given the responsibility of supervising others using psilocybin.
Facilitators should be engaged in an ongoing process of therapeutic supervision.
This assumes that the "facilitator" model with it's built in costs is the primary and best approach. Likely not the case.
Criminal background checks?

Question 18: The rules and regulations on integration sessions in Oregon are limited in comparison to other sections. What additional rules or regulations should be included in the guidelines for integration sessions, if any?
Not sure.
Integration should also include referrals to actual therapists, if warranted
I think the more open-ended the sessions are, the better.
psychospiritual care should be offered

Equity Text 1 - OPS's guidelines for a social equity plan: "Application of diversity, equity, justice and inclusion principles to the licensee's internal practices and policies", "Objective performance measures that the licensee will use to evaluate their social equity plan". Should more criteria be added to the guidelines for a social equity plan? If so, what should be added?
list of sample objective equity plans
I think it is sufficient.
Yes. A structured template for the licensee to abide by.

I am satisfied with aforementioned guidelines.
sliding scale fee
Unfortunately this is a band aid approach. The system has core issues with cost and lack of access. Creating a commercial system with tax revenues involved is fundamentally an extractive, colonialist approach and bypasses basic and necessary religious freedoms. These substances are not the equivalent of Cannabis and need far greater cultural and religious sensitivity.

Equity Text 2 - What else should be recommended to Washington State as methods to promote equity in a future Psilocybin program?
With this many prep hours expected, we can certainly allow for this part in the curriculum
The establishment of a Equity Committee that will guide every aspect of regulations
I would not add anything at this time.
Creation of a permanent equity committee to advise at all steps of regulation
The idea that this approach can achieve any functional, lasting equity is not supported by experience in Cannabis law implementation. Religious and no cost non-profit paths need to be in place before commercial interests are involved or basic religious freedoms and a whole host of other issues will likely be compromised and difficult to undo once in place
it is critical to have a psilocybin equity task force now while we are creating reports to inform legislation
sliding fee scale for low income patients

Safety text 1 - Facilitators must work with clients to develop a safety and support plan before the administration session. This includes identifying risks and challenges specific to the client's circumstances--evaluating existing support networks for the client, discussing internal resources, and mitigating risks. Are there any other specific areas that should be addressed in a safety and support plan? (333-333-5080)
Other Psychoactive drugs in system?
Should mandate referrals to therapists
An ROI should be signed giving the facilitator expression permission to speak with a first order family member or close friend of the client.
Non-intoxicating dosages of less than 1-2 mg should be exempted from having to enter a therapy training center.
My concern here is that one on one, or even one on one with a support person is inherently less stable and more prone to going awry than even a small group.
Just don't go overboard on the risk/safety plan - mushrooms have been used for spiritual and therapeutic reasons for millennia

Safety text 2 - What other safety concerns should be addressed directly in the rules and regulations process in Washington?
not sure
Who is looking out for the Children? this can't go the way of Marijuana which has become incredibly socially acceptable for minors. Maybe the OPS (or WA funding) can go towards a social norming Campaign. This can't go the way of
Limited data on high risk populations
Non-intoxicating dosages of less than 1-2 mg should be exempted from having to enter a therapy training center.
impact on other family members, especially children
Exclusion criteria should be clear and fastidiously followed.
Psilocybin mushroom possession of 100 grams or less should be permitted for personal, non-commercial use.
transportation
First peoples, religious and indigenous users must have an opportunity to contribute to the creation (or not) of rules and regulations.
All people with psychiatric disabilities to access these services, consider Medicaid coverage for SSI

Appendix G: Meeting #3 Regulatory Poll Results

This section includes the unedited responses to the regulatory structure polling exercise during meeting #3 on October 5th, 2023. Members were asked to respond to poll questions that highlight key findings from the online regulatory survey.

The Oregon Psilocybin Services (OPS) advisory board has no regulatory power. Should the advisory board to the Department of Health have regulatory power? If so, what points would this board regulate?
Responses
No
Protection of safety
Grandfathering indigenous elders to facilitator licenses
Public records identify protection
Regulate allowed home grow of fungi
Advisory board should have regulatory authority.
Licenses
I believe they should have regulatory power and speak for first peoples, indigenous, religious and Entheogenic users.
Ethical considerations
Altering best practices based on real-world experiences so we can improve the positive impact of psilocybin
use cases, licensing,

OPS rulemaking allows training programs to set their own qualification guidelines to bypass certain facilitator training sections. Should standard statewide criteria be developed for determining whether a facilitator can bypass certain training modules?
Responses
Yes - 100%
No - 0%

OPS training programs must renew every 5 years. Should Washington training programs renew every 2 years?
Responses
Yes - 33%
No - 67%

Should facilitators who speak a second language should be compensated more for their services?
Responses
Yes - 57%
No - 43%

OPS has a two-year state residency requirement for establishing a service center. Should this requirement be changed to a five-year residency requirement?
Responses
Yes - 40%
No - 60%

OPS allows local governments to adopt ordinances prohibiting service or manufacturing centers in their county. Should Washington State not allow local governments to adopt ordinances prohibiting service and manufacturing centers?
Responses
Yes - 63%
No - 13%
Other - 25%

OPS allows the preparation session to be bypassed if an individual has done a session at the same center before. Should more sessions be completed for the preparation session to be bypassed in Washington?
Responses
Yes - 29%
No - 79%

OPS allows preparation sessions to be done virtually. Should virtual preparation sessions be allowed in Washington as well?
Responses
Yes - 93%
No - 7%

What dosage bracket (ex. 2.5 mg psilocybin or less) should have a reduced (from 30 mins) administration session associated with it?
Responses
Less than 0.5gram, no facilitation necessary. A sub-peripheral dose means they don't experience a recognized feeling - why would that need facilitation?
7.5mg
Needs more research. Paul probably knows best.
Ask Paul Stamets
Do we know what strain is best for public use?
Not enough info out there to answer this question appropriately.
2mg should have reduced administrative session.
NA

OPS has made integration sessions optional. Should integration sessions be mandatory in Washington?
Responses
Yes - 85%
No - 15%

Should directive facilitation be allowed in an integration session if agreed upon in the preparation session?
Responses
Yes - 92%
No - 8%

OPS states that written consent must be given for group session participants to touch each other. If a client is disruptive, facilitators should attempt to separate the client from the group. What other safety measures should exist for group sessions?
Responses
Benzodiazepines are often used for those experiencing extreme anxiety from psilocybin.
Should have a separate space available for anyone who needs privacy, quiet, or a place to process in a way that would be disruptive to the group.
Thinking of the bi-polar who didn't know they were bi-polar
What are the state mandated regulations for other therapeutic group settings?
First aid training mandatory for all facilitators
Separate space
Separating the people into groups who face a similar challenge. mixing is problematic
Facilitator or facilitator + additional staff to client ratio
Having adequate space ..

OPS prohibits mobile service centers. Should mobile service centers be permitted in Washington if safety regulations can be properly maintained?
Responses
Yes - 91%
No - 9%

Should a future Washington psilocybin program recommend the use of a sliding scale fee in service centers?
Responses
Yes - 100%
No - 0%

OPS has established a permanent equity sub-committee. Should Washington do the same?
Responses
Yes - 100%
No - 0%

Should referrals to therapists be mandated by Washington State integration session guidelines?
Responses
Yes - 64%
No - 36%

First people, indigenous and religious users need either exemptions or should be allowed to operate fully independently from a Washington psilocybin program.
Responses
Yes - 100%
No - 0%

OPS has limited the species allowed to psilocybe cubensis. Should Washington expand the species allowed in a psilocybin program?
Responses
Yes - 100%
No - 0%

Appendix H: Summary of Results for the Final Report Feedback Survey

Following the final Washington Psilocybin Task Force meeting on October 5th, 2023, HCA and the Center constructed a brief high-level feedback survey that was distributed to all Task Force members. The survey was three questions long and was open from 10/18 to 10/27. The survey's goal was to allow Task Force members to give any final comments on the work of the Task Force. The survey received 10 responses, but no more than three comments per question.

Below are the full questions given to the Task Force, along with a consolidated summary of the feedback.

Q1 *- SB 5263 directed the Psilocybin Task Force to review available clinical information around specific clinical indications for use of psilocybin, including what co-occurring diagnoses or medical and family histories may exclude a person from use of psilocybin.*
Key areas include:

- *Populations excluded from existing clinical trials*
- *Factors that are considered during medical intervention*
- *Consideration of participant diversity in clinical trials*
- *Identify gaps in clinical research*

What, if any, recommended changes do you have in the draft report related to the review of clinical information that might better meet the intent of the legislature's directive?

Three comments were made in response to question 1. A Task Force member recommended that a future clinical review should not fully rule out psilocybin use for people predisposed to psychosis. The evidence is mixed, and some early clinical trials showed promise. The other two responses stated that pain-related clinical trials were not included in the Center's clinical review and asked for them to be included.

The Center acknowledges those comments but points out that the scope of the clinical review excluded case studies, which are currently the only study type that has resulted in publications of studies of psilocybin for pain. There is an ongoing randomized clinical trial related to chronic back pain, and the Center is aware of publications on case studies related to pain management that were out of scope for this report.

Q2 *- SB 5263 directed the Psilocybin Task Force to review and discuss regulatory structures for clinical use of psilocybin in Washington and other jurisdictions nationally and globally.*

What, if any, recommended changes do you have in the draft report related to the review of regulatory structures that might better meet the intent of the legislature's directive?

There was a recommendation that in the "Settings Gaps" section of the final report, under "Additional Gaps Identified", a comment should be added. The Task Force member recommended this statement: "Challenge of commercial/medical zoning restrictions in open rural areas (to support outdoor settings)".

Q3 *- Overall, how do think the draft report accurately captures the work of the Task Force? Are there any other changes you would recommend to better meet the intent of the legislature's directive?*

There were no relevant comments to this report given on this question. One logistical comment was made, which was managed internally.

Appendix I: Equity Survey Committee Statement

Introduction:

In the winter of 2023, an equity survey was created and distributed to the public via email. The distribution strategy was not broad enough and did not reach the right populations. As a result, there was a low response rate and respondents were mostly white high-income individuals. A small group of Task Force members who understand the implications of equity petitioned to re-create both the equity survey and the distribution plan. The team (Equity Survey Subcommittee) met every two weeks starting in late spring. Below highlights the team's background work and recommended directives.

Creation of Permanent Equity Committee and history of Oregon and Colorado implementation:

The Equity Survey Subcommittee recommends the establishment of a permanent equity sub-committee in a future Washington State psilocybin program. The two active psychedelic regulatory structures in the U.S., Oregon, and Colorado (the latter is in development), have both implemented an equity subcommittee. These groups give recommendations to both the advisory boards they are a part of, and to the operating department in their state.

The Colorado bill language in Article 170 calls for the creation of an advisory board composed of appointed members with experience in social equity, religious and spiritual use, and criminal justice. The board is responsible for developing requirements that ensure Article 170 is equitable and inclusive. This includes: "recommendations on ways to reduce the costs of licensure for low-income individuals, for providing incentives for the provision of natural medicine services at a reduced cost to individuals with low income and providing incentives for the provision of natural medicine services in geographic and culturally diverse regions of the state."

The Natural Medicine Advisory Board of Colorado has established six subcommittees, two of them being the Public Health & and Health Equity Subcommittee, and the Indigenous and Religious use and Outreach subcommittee. Both have no regulatory power and are unpaid. The primary work of these boards is to develop strategies and recommendations to achieve the focuses of the subcommittee.

Oregon State operates the only active psilocybin program in the country. The Oregon Psilocybin Advisory Board contains four sub-committees, including the Equity Subcommittee. This subcommittee has been meeting since May of 2021, and has had nearly 30 meetings. The board has no regulatory power and is unpaid. The work of the advisory board has been to make recommendations on Oregon Psilocybin Services' still developing equity policy. The group has had one meeting in 2023, in which the committee discussed the primary issues contributing to the cost and accessibility of psilocybin services and developed material to help assist the creation of social equity plans for facilitation centers.

Lastly, Washington's SB 5660 introduced the Social Opportunity Program (SOP), which was evaluated and developed by the Washington State psilocybin workgroup in 2021-2022. The SOP's main objective is to identify distressed areas using established criteria, and to administer assistance to individuals and entities. A distressed area is an area categorized by certain criteria established by the Washington State Department of Labor.

This overview provides background information on the existing equity approaches in Colorado and Oregon's psychedelic programs. The existence of these plans should illustrate the necessity to continue this work in Washington.

Proposed Equity Survey Construction: The Berkeley Survey

The Equity Survey Committee recognizes the necessary sensitivity and complexity involved in the creation of a survey in determining BIPOC, Veteran and disabled peoples' needs regarding psilocybin usage. We sought to find pre-existing surveys that might serve the purpose of preliminary data collection in preparation for more directed Washington State surveys.

The University of California Berkeley Center for the Science of Psychedelics conducted a psychedelics survey, which was published in July of 2023. (https://psychedelics.berkeley.edu/bcsp-first-study-results/#:~:text=More%20than%20six%20in%20ten,approval%20for%20psychedelics%20by%20prescription).

This survey was not directed towards BIPOC, veterans and people with disabilities but the committee saw it as an adequate starting template to which we could add more questions specifically directed at these populations. We began this process and developed a set of questions specifically targeted at the mentioned populations.

The Center at Berkley was also contacted, and a request was made for the budget associated with the creation and distribution of this survey to the 3000 people it queried. At this time, we have not heard back from the organization.

In summary, the Berkeley survey should be used as a template to which a future one would add more specific questions. The Equity Subcommittee recognized that a more formal process should be applied to formulating these specific questions, and that resources should be allocated for this.

Distribution Strategy:

To achieve equitable access, the Equity Subcommittee is recommending Outreach, Education and Community Engagement that is community-centered resulting in a survey for marginalized and underserved communities.

Such an undertaking will require collaborative efforts with trusted community health and social service providers, community leaders and their respective communities. The HCA and DoH is positioned to lead in these efforts collaboratively to enhance the health wellness and public health access for all of WA residents. A Strategic Community-Centered Outline was previously submitted, the essentials of which are provided below.

- Provide Education And Training To Community Health Workers (CHW's)
    - Provide SB5660 Education-Social Opportunity Program-Opportunity via Zoom.
    - Provide Historical context use of mushrooms within indigenous communities and psilocybin research for end-of-life care, mental health disorders and substance use disorders.
    - Provide training on how to facilitate a community-centered survey with group settings and individuals

- Strategic Plan For Dissemination of the Survey
    - CHW's regional planning for community survey.
    - The focus will be on underserved and marginalized communities in urban and rural settings. Outreach and Education prior to survey
    - Pre-Survey-Groups at this stage of survey for the intent to unearth community concerns and formulate bottom-up survey questions
    - Conduct second or Initial survey

This document represents the actions and recommendations of the Equity Survey Committee. Here is a summary of recommended directives:

- Formation of a permanent Equity Committee to work hand and hand with legislative team in creating and developing Psilocybin Services in Washington State
- Develop budget for creation of equity survey and distribution plan
- Hire team to write survey
- Hire team to put together strategy for community-based distribution of plan; identify existing community resources
- Hire team to do analysis of results
- Implement needs of BIPOC, Vet and disabled communities within Psilocybin Services plans moving forward

Appendix J: Public Comment

The comments in this section are anonymous and unedited public comments related to Task Force actions and discussions.

Date Received	Topic	Comment
8-28-2023	New study	Thanks everyone. Please see this recent article, 'Frog's umbrella' and 'ghost's face powder': the cultural roles of mushrooms and other fungi for Canadian Indigenous Peoples published by the well-respected, Dr. Nancy Turner and Alan Cuerrier. Notably, there is no evidence of psilocybin mushroom use by PNW indigenous historically (before European contact), but many other species were used. Amanita muscaria is one, although non-psilocybin. However, just because there are no documented reports, does not mean they were not used!) As a mycologist, most people do not realize native (non-imported) psilocybin-active mushrooms are very rare, and many are associated with the importation of sheep and cattle and the grass species needed to sustain them. Psilocybe semilanceata (grassland species) can be easily identified. Most others are not easy to find, and even more challenging to identify . This is not to say they are not used today. It just means there is currently a lack of evidence of them being used hundreds of years ago in the PNW. The PNW Psilocybe cyanescens is associated with woodchips and *may* be associated with beavers. This species is likely native to the PNW. Psilocybe cubensis, a tropical species, is thought to have come via the Spaniards from Africa to the Americas and throughout the world. This is the species being used >95% of the time by consumers. Now, cultivated Psilocybe cubensis is being used by the Mazatecs in Oaxaca (and elsewhere by indigenous peoples) as it can be sustainably cultivated whilst the wild species are increasingly more difficult to find, and are seasonally dependent. i am completing an extensive new book on psilocybin which should be out next year, and discusses the use of psilocybin mushrooms across the globe with many cultures.

		I am happy to help and volunteer my perspective/knowledge for advancing these discussions.
8-31-2023	Psilocybin studies	Good afternoon Psilocybin Taskforce, Apologies for the email blast to everyone - I promised this information, but I failed to note who needed it. Besides the studies and current clinical trial below, I also wanted to highlight that the recorded 'virtual' option from Psychedelic Science 2023 has launched. This MAPS hosted conference held 300 sessions, with 500 speakers, and was attended by 12,000 individuals. Yes, you must still register - however, they are operating under a "Pay what you can" model, even offering a no questions asked $0 scholarship. Of course, if you can afford to contribute, please consider doing so. https://2023.psychedelicscience.org/ MAPS is slowly releasing topics that are relevant to this group - currently available topics include harm reduction, state policy approaches, and how psychedelics work - again, with more than 300 additional sessions to come! As promised, a short list of studies related to psilocybin and pain; I hope it proves helpful: 1. Alternative options for complex, recurrent pain states using cannabinoids, psilocybin, and ketamine: a narrative review of clinical evidence 2. Lysergic acid diethylamide and psilocybin for the management of patients with persistent pain: a potential role? 5. Microdosing psilocybin for chronic pain: a case series 6. Relief from intractable phantom pain by combining psilocybin and mirror visual-feedback (MVF) 7. A systematic review to assess the use of psilocybin in the treatment of headaches 8. 9. 10. National Institutes of health psilocybin research speaker series: State of the science, regulatory and policy landscape, research gaps, and opportunities 11. 12.

		13. Mycotherapy: Potential of fungal bioactives for the treatment of mental health disorders and morbidities of chronic pain 16. Beating pain with psychedelics: Matter over mind? 17. 18. 19. Current clinical trial for Psilocybin Therapy for Chronic Low Back Pain Respectfully,
9-1-2023	New study	New RCT on Single-Dose Psilocybin Treatment for Major Depressive Disorder published in JAMA this week.
9-13-2023	Re: Task Force regulatory survey	This is fantastic thank you, Dr. Fotinos. Do we want the WA model to be similar to our friends in Oregon without medical surveillance & management? A combination or not? Very interesting.
9-14-2023	New study	Teammates This preprint suggests the natural form of psilocybin mushrooms (extracts = PME) gives greater benefit to neuroplasticity than synthetic psilocybin and longer lasting benefits. More studies are needed, especially in humans, but still very relevant. https://www.researchsquare.com/article/rs-3146433/v1 cheers
9-14-2023	Clinical gap: whole mushroom research	All, This is so important to understand that current review of clinical trials pertains only to synthetic molecules and that whole mushrooms have a different profile. As I mentioned before there needs to be immediate advocacy on whole mushroom research -- perhaps even the formation of a sub committee on how to facilitate the state agencies to move this forward. The use of information on synthetic molecules does not translate and thus has limited use in making decisions about safety and service delivery. Thanks again Paul and Task Force.
9-19-2023	Minimum dosage for supervision	Thank you. I weighed in. Most particularly, it is indefensible that a non-intoxicating dose of psilocybin requires a person to be supervised in a

		therapeutic clinic. I define a non-intoxicating dose to be less than 2 mg, or more conservatively 1 mg or less. To have microdosers who do not become intoxicated to attend an expensive clinic marginalizes those who can not afford to consume a non-intoxicating amount by placing an unfair financial burden upon them. This speaks directly to equity and access. Thank you, respectfully,
10-5-2023	Training reciprocity	Have we ever mentioned reciprocity regarding facilitator training programs in Oregon? It seems we agree that a training standard should be required for facilitators in WA. Will facilitators in Oregon have the option to bypass WA training requirements for licensure as long as the curriculum is similar? We should discuss or include something in the draft to address this now rather than later. Oregon and WA should consider making an agreement regarding cross-state training/licensure requirements. My concern is we will need more Washingtonians trained to meet public demand. We could preempt this possibility by working with Angie Allbee's shop in Oregon. Plus, we love Oregon except when they play the Dawgs!
10-11-2023	Zoning and outdoor settings	I'm not sure where this fits in or if acceptable to be included in the report, but I think it's valuable that our law makes are aware: There seems to be agreement that outdoor spaces are good locations for treatment to occur. Ideally within a 2 or 3 hour drive from large city centers. It has come to my attention that it is challenging to locate correctly zoned spaces that are commercial or zoned medical. Zoning areas will need a mechanism to be changed for remote outdoor locations for these treatments. Thank you for processing this thought.

Appendix K: Online Resources

Psilocybin Task Force Resources: https://www.hca.wa.gov/about-hca/programs-and-initiatives/clinical-collaboration-and-initiatives/psilocybin-work-group

Meeting #1 Resources (June 26, 2023):

- Agenda: **https://www.hca.wa.gov/assets/program/psilocybin-task-force-agenda-june-26-2023.pdf**
- HCA presentation: **https://www.hca.wa.gov/assets/program/psilocybin-task-force-slide-deck-june-26-2023.pdf**
- Web recording: **https://www.youtube.com/watch?v=DRqJH3N3OaU**

Meeting #2 Resources (August 28, 2023):

- Agenda: **https://www.hca.wa.gov/assets/billers-and-providers/psilocybin-task-force-agenda-august-28-2023.pdf**
- Web recording: **https://youtu.be/zDRFMVgvV4A?si=eJN4eIPVso2_5yg5**

Meeting #3 Resources (October 5, 2023):

- Agenda: **https://www.hca.wa.gov/assets/program/psilocybin-task-force-agenda-october-5-2023.pdf**
- Web recording: **https://www.youtube.com/watch?v=IEgQSzFkpQ0**