SENATE BILL REPORT
2SSB 5263

As Amended by House, April 11, 2023

Title: An act relating to access to psilocybin services by individuals 21 years of age and older.

Brief Description: Concerning access to psilocybin services by individuals 21 years of age and older.

Sponsors: Senate Committee on Ways & Means (originally sponsored by Senators Salomon, Rivers, Saldaña, Nobles, Lovick, Lovelett, Hunt, Hasegawa, Mullet, Trudeau, Robinson, Pedersen, Wellman, Muzzall, Wilson, C., Kuderer, Keiser, Liias, Van De Wege, Billig, Conway and Frame).

Brief History:

Committee Activity: Labor & Commerce: 1/30/23, 2/16/23 [DPS-WM, w/oRec]. Ways & Means: 2/21/23, 2/23/23 [DP2S, DNP, w/oRec].

Floor Activity: Passed Senate: 3/7/23, 41-7.
Passed House: 4/11/23, 87-10.

Brief Summary of Second Substitute Bill

- Establishes an advisory board within the Department of Health (DOH) to provide advice and recommendations to DOH, the Liquor and Cannabis Board (LCB), and the Washington State Department of Agriculture (WSDA), consisting of agency members and other specified members appointed by the Governor.
- Creates an interagency work group of DOH, LCB, and WSDA to provide advice and recommendations, in regular updates, to the advisory board on developing a comprehensive regulatory framework for a regulated psilocybin system, and other specified topics.
- Requires the Health Care Authority to establish a Psilocybin Task Force, which must provide a final report to the Governor and Legislature by December 1, 2023, on specified topics including, without limitation,

---

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

clinical information on psilocybin use and regulatory structures for clinical psilocybin use in Washington and elsewhere.

- Grants DOH certain duties, functions, and powers relating to studies, research, and other information regarding the safety and efficacy of using psilocybin to treat mental health conditions; rule-making authority; and other specified powers relating to psilocybin.

SENATE COMMITTEE ON LABOR & COMMERCE

Majority Report: That Substitute Senate Bill No. 5263 be substituted therefor, and the substitute bill do pass and be referred to Committee on Ways & Means.

Signed by Senators Keiser, Chair; Conway, Vice Chair; Saldaña, Vice Chair; King, Ranking Member; MacEwen, Robinson, Schoesler and Stanford.

Minority Report: That it be referred without recommendation.

Signed by Senator Braun.

Staff: Matt Shepard-Koningsor (786-7627)

SENATE COMMITTEE ON WAYS & MEANS

Majority Report: That Second Substitute Senate Bill No. 5263 be substituted therefor, and the second substitute bill do pass.

Signed by Senators Rolfes, Chair; Robinson, Vice Chair, Operating & Revenue; Mullet, Vice Chair, Capital; Wilson, L., Ranking Member, Operating; Schoesler, Ranking Member, Capital; Rivers, Assistant Ranking Member, Capital; Warnick, Assistant Ranking Member, Capital; Billig, Boehnke, Conway, Hasegawa, Hunt, Keiser, Muzzall, Nguyen, Pedersen, Saldaña, Torres, Van De Wege and Wellman.

Minority Report: Do not pass.

Signed by Senators Gildon, Assistant Ranking Member, Operating; Wagoner.

Minority Report: That it be referred without recommendation.

Signed by Senators Braun and Dhingra.

Staff: Monica Fontaine (786-7341)

Background: Psilocybin. Psilocybin is a naturally occurring, psychoactive chemical compound produced by over 200 species of mushrooms, many of which grow natively in the Pacific Northwest. Psilocybin is currently listed as a Schedule I controlled substance under the state and federal Uniform Controlled Substances Acts. Ingestion of psilocybin may produce changes in perception, mood, and cognitive processes common to other

psychedelic drugs, a class of naturally-occurring and laboratory-produced substances, which includes mescaline, LSD, MDMA, and DMT. Psilocybin can be extracted or synthesized by chemical processes.

Psilocybin Work Group. The 2022 supplemental operating budget directed the Washington State Health Care Authority (HCA) to create a Psilocybin Work Group (HCA Work Group) to study and make recommendations to the Legislature regarding psilocybin services in the state. The HCA Work Group is tasked with reviewing:

- Oregon's psilocybin rules and assess the adaptation of similar laws and rules;
- the Liquor and Cannabis Board (LCB) systems and procedures to monitor manufacturing, testing, and tracking of cannabis to determine whether they are suitable for use with psilocybin;
- the social opportunity program proposed in SB 5660 (2022), and recommend improvements or enhancements to promote equitable access to legal psilocybin; and
- options to integrate licensed behavioral health professionals into the practice of psilocybin therapy where appropriate.

The HCA Work Group met four times in 2022, currently has two meetings scheduled in 2023, and issued a preliminary report in December 2022. The HCA Work Group must deliver its final report by December 1, 2023.

Other States. On November 3, 2020, Oregon voters adopted Oregon Measure 109, a ballot initiative supported by 55.75 percent of the voters. Measure 109 legalizes psilocybin in Oregon law. On December 27, 2022, the Oregon Health Authority adopted final rules regulating the production of psilocybin products and the provision of psilocybin services in the state. The Oregon Health Authority began accepting applications for licensure on January 2, 2023.

On November 8, 2022, Colorado voters passed Proposition 122—or the Natural Medicine Health Act of 2022—a ballot initiative supported by 53.64 percent of the voters. Proposition 122 created a regulatory system, administered by the Colorado Department of Regulatory Agencies, to regulate the growth, distribution, and sale of certain hallucinogenic and entheogenic substances derived from plants and fungi. Proposition 122 decriminalized the personal use and possession, for individuals 21 years of age and older, of such substances that were previously-classified as Schedule I controlled substances under state law. While Measure 109 only included psilocybin and psilocyn, Proposition 122 includes other substances such as DMT, ibogaine, some mescaline, psilocybin, and psilocyn.

Summary of Second Substitute Bill: The legislation may be known and cited as the Washington Psilocybin Services Act (Act).

Psilocybin Advisory Board. A Psilocybin Advisory Board (Board) is established to provide advice and recommendations to the Department of Health (DOH), LCB, and the Washington State Department of Agriculture (WSDA), consisting of 17 to 20 members

appointed by the Governor. Board members must serve for four-year terms at the pleasure of the Governor. Until July 1, 2024, the Board must meet at least five times per calendar year, and at least once every calendar quarter after that date. The Board may meet at other times if directed by the chair or a majority of voting Board members.

Interagency Psilocybin Work Group. An Interagency Psilocybin Work Group (IA Work Group) of DOH, LCB, and WSDA is created to provide advice and recommendations, in regular updates, to the Board on the following:

- developing a comprehensive regulatory framework for a regulated psilocybin system, including a process to ensure clean and pesticide-free psilocybin products;
- reviewing indigenous practices with psilocybin, clinical psilocybin trials and findings;
- reviewing research of medical evidence developed on the possible use and misuse of psilocybin therapy; and
- ensuring a social opportunity program is included within any licensing program created under the Act to remedy the targeted enforcement of drug-related laws on overburdened communities.

Psilocybin Task Force. HCA must establish a Psilocybin Task Force (Task Force). The director of HCA must be a member of the Task Force and serve as chair. The Task Force must also include, without limitation, the following members :

- the secretary of DOH or their designee;
- the director of LCB or their designee;
- as appointed by the director of HCA or their designee;
    1. a military veteran, or representative of an organization that advocates on behalf of military veterans, with knowledge of psilocybin;
    2. up to two recognized indigenous practitioners with knowledge of the use of psilocybin or other psychedelic compounds in their communities;
    3. an individual with expertise in disability rights advocacy;
    4. a public health practitioner;
    5. two psychologists with knowledge of psilocybin, experience in mental and behavioral health, or experience in palliative care;
    6. two mental health counselors, marriage and family therapists, or social workers with knowledge of psilocybin, experience in mental and behavioral health, or experience in palliative care;
    7. two physicians with knowledge of psilocybin, experience in mental and behavioral health, or experience in palliative care;
    8. a health researcher with expertise in health equity or conducting research on psilocybin;
    9. a pharmacologist with expertise in psychopharmacology;
    10. a representative of the cannabis industry with knowledge of regulation of medical cannabis and the cannabis business in Washington;
    11. an advocate from the LGBTQIA community with knowledge of the experience of behavioral health issues within that community;
    12. a member of the Psychedelic Medicine Alliance of Washington; and

13. up to two members with lived experience of utilizing psilocybin.

The duties of the Task Force include, without limitation, the following activities:

- reviewing the available clinical information around specific clinical indications for the use of psilocybin, including what co-occurring diagnoses or medical and family histories may exclude a person from the use of psilocybin. Any review of clinical information should:
    1. discuss populations excluded from existing clinical trials;
    2. discuss factors considered when approval of a medical intervention is approved;
    3. consider the diversity of participants in clinical trials and the limitations of each study when applying learnings to the population at-large; and
    4. 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; and
- reviewing and discussing regulatory structures for clinical use of psilocybin in Washington and other jurisdictions nationally and globally, including how various regulatory structures do or do not address concerns around public health and safety the group has identified.

The Task Force must submit a final report to the Governor and Legislature by December 1, 2023.

Duties of the Department of Health. DOH has the following duties, functions, and powers:

- to examine, publish, and distribute to the public available medical, psychological, and scientific studies, research, and other information relating to the safety and efficacy of psilocybin in treating mental health conditions;
- to adopt, amend, or repeal rules necessary to carry out the intent and provisions of this chapter, including rules DOH considers necessary to protect the public health and safety; and
- to exercise all powers incidental, convenient, or necessary to enable it to administer or carry out the Act or other state laws relating to psilocybin and psilocybin products.

The Pharmacy Quality Assurance Commission does not share the jurisdiction, supervision, duties, functions, and powers granted to DOH under the Act.

Duties and Prohibitions of Other State Agencies. LCB and WSDA must assist and cooperate with DOH and may not refuse to perform any duty on the basis that manufacturing, distributing, dispensing, possessing, or using psilocybin products is prohibited by federal law.

Protections. Medical professionals licensed in Washington must not be subject to adverse licensing action for recommending psilocybin treatments.

Appropriation: None.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: The bill contains an emergency clause relating to sections 4 through 6, creating the Board, IA Work Group, and Task Force, which take effect immediately.

Staff Summary of Public Testimony on Original Bill (Labor & Commerce): *The committee recommended a different version of the bill than what was heard.* PRO: Washington is in a mental health crisis and this bill holds a ton of promise for mental health support. The bill sets up a supervised, consumer protection focused approach to psilocybin. This is not a recreational system and psilocybin is different from cannabis. Supervision and counseling after administration provide the benefit as opposed to taking it at a party. We are able to assist veterans obtain psilocybin therapy out-of-state and we need to be able to do that in-state. It is imperative we have better and safer options for suicide prevention. This bill will help break the cycle of organized retail theft because it provides a useful tool to help the individuals involved. Psilocybin has been buried under a Schedule I designation and we are finding psilocybin is effective at addressing substance use disorder. We see efficacy rates between 40 to 60 percent with some of these preliminary studies. We have the opioid settlement fund to assist with funding this. This bill benefits from years of discussion regarding Oregon's psilocybin laws, Colorado's ongoing implementation of Proposition 122, and the Work Group. This bill contains substantial improvements over Oregon in terms of safety and accessibility. In the Netherlands, truffles containing psilocybin are legal so there is not stigma associated with the sessions this bill creates. Imagine this metaphor, your brain is constantly building sand castles, the sand is the information coming from your senses, and the buckets are your previous knowledge. For some people, the buckets might be causing a lot of pain and psilocybin can hyperactivate the appropriate receptor in the brain allowing people to heal and move forward after trauma. This bill creates the process for individuals suffering from depression, anxiety, and PTSD to use psilocybin in a regulated setting and move past their issues. As this bill moves forward, it should include a focus on equity and at-risk populations. British Columbia is effectively addressing end-of-life distress and treatment-resistant depression with psilocybin, and many clinical trials are ongoing. Psychedelic-assisted therapy has helped me move past mental health issues. Organizations assisting veterans obtain therapy have to send them to Peru to take ayahuasca, which works similarly to psilocybin. It is important we explore new ways to help the veteran community and first-responders with their mental health crisis. Traditional methods did not help and psilocybin-assisted therapy did. This bill creates a safe setting for psilocybin use. Three psilocybin sessions in Oregon gave me more relief than years of therapy. Psilocybin is ten times more effective than the next most effective therapy for smoking cessation. Regarding psilocybin therapy, many doctors and nurses would say you need to have a guide with you who knows what they are doing. Doctors and nurses do not want a diagnosis required for psilocybin therapy because they are

concerned it would affect their professional licensure status. Psilocybin has been associated with a counterculture and was wrongly scheduled many years ago. Psilocybin is non-addictive and physically safe.

CON: This bill has internal contradictions, it cites studies with people diagnosed with psychiatric conditions to justify efficacy, but it does not have treatment providers involved. This bill is not focused on treatment, it is getting psilocybin out there for "wellness and personal growth." Psilocybin is a great drug that is not ready yet, and we should not bypass the Federal Food and Drug Administration in this way.

OTHER: There is no conclusive evidence that psilocybin can be used as a medication and is still in preliminary studies, therefore, we recommend any bill references to psilocybin being used as a mental health treatment be removed or stated as "possible." We ask that the evidence the bill requires to be disseminated to be unbiased and address any risks in addition to potential benefits. We ask that a psychiatrist with substance use treatment or psilocybin experience be included on the Board. The timelines in the bill should be extended. We have concerns about the tracking system timeline and request it be extended.

Persons Testifying (Labor & Commerce): PRO: Senator Jesse Salomon, Prime Sponsor; Anthony Back; Jonathan Drew, HAVN Healing Center; Elliot Goit, Not sure yet; Mark Johnson, Washington Retail Association; Kody Zalewski, Psychedelic Medicine Alliance of Washington; Mason Marks; Jeff Hamburg; Sarah Hashkes; Jonathan Drew; Pamela Kryskow; Lisa Price; Chester Baldwin, Personal; Alex Kaper; Corey Champagne; Matthew Griffin, Combat Flip Flops, Forty Six & 2 Transitions; Lauren Feringa, Hippie and a Veteran Foundation.

CON: Rebecca Allen.

OTHER: Avanti Bergquist, The Washington State Psychiatric Association (WSPA); Lacy Fehrenbach, Washington State Department of Health.

Persons Signed In To Testify But Not Testifying (Labor & Commerce): PRO: G Todd Williams; Nancy Connolly, University of Washington; David Heldreth; Tatiana Quintana, Psychedelic Medicine Alliance Washington; Myleea Spencer; Todd Youngs; Brookelle O'Riley; Sunil Aggarwal; Daniel Covington; Jojo Teutsch; Lilymoon Whalen; Pat Donahue, Terrapin Legal.

Staff Summary of Public Testimony on First Substitute (Ways & Means): *The committee recommended a different version of the bill than what was heard.* PRO: The current health care system doesn't have the capacity to address the mental health crisis, and psilocybin can be a resource in treatment. The original version of the bill was thoughtfully construction, and the substitute will block the provision of services to those who would benefit. Ongoing trials should be expanded to include veterans, first responders, and people with PTSD due to its promising uses.

OTHER: The fiscal note to the original bill is inaccurate because there will be differences between the cannabis industry and the psilocybin industry. More task forces and research will continue to delay services, is unnecessary due to the existing volume of research, and will increase costs to the state. The bill doesn't provide protections for religious use. Non-profit and low-income models need to be included so there are fewer impacts from taxing and licensing fees.

Persons Testifying (Ways & Means): PRO: Anthony Back; Corey Champagne.

OTHER: Mason Marks; Kody Zalewski; David Heldreth; Tatiana Quintana, Psychedelic Medicine Alliance Washington.

Persons Signed In To Testify But Not Testifying (Ways & Means): No one.

EFFECT OF HOUSE AMENDMENT(S):

- Adds the following as voting members of the Advisory Board:
    1. a military veteran, or representative of an organization that advocates on behalf of military veterans, with knowledge of psilocybin; and
    2. a social worker, mental health counselor, or marriage and family therapist.
- Replaces a reference to "psilocybin treatments" with "psilocybin therapy services" in a provision protecting Washington-licensed medical professionals from adverse licensing action for recommending such services.
- Establishes, subject to appropriation, a psilocybin therapy services (Services) pilot program (Program) to be administered by the University of Washington Department of Psychiatry and Behavioral Sciences no later than January 1, 2025, and requires the Program to:
    1. offer Services through pathways approved by the FDA to populations including first responders and veterans who are 21 or older and experiencing PTSD, mood disorders, or substance use disorders;
    2. offer Services facilitated by specified health care professionals;
    3. ensure Services are safe, accessible, and affordable;
    4. require an initial assessment before an individual receives Services and an integration session afterward; and
    5. use outreach and engagement strategies to include participants from communities and demographic groups who are more likely to be historically marginalized and less likely to be included in research and clinical trials represented by race, sex, sexual orientation, socioeconomic status, age, or geographic location.