FINAL BILL REPORT 2SSB 5263

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).

Senate Committee on Labor & Commerce Senate Committee on Ways & Means House Committee on Health Care & Wellness House Committee on Appropriations

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.

<u>Psilocybin Work Group.</u> 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.

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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.

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: The legislation may be known and cited as the Washington Psilocybin Services Act (Act).

<u>Psilocybin Advisory Board.</u> A Psilocybin Advisory Board (Board) is established 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). The Board consists of certain experts and agency officials, in addition to various stakeholders appointed by the Governor, including, without limitation:

- the Secretary of DOH, the State Health Officer, the Attorney General, or their designees;
- individuals with expertise in, or who represent, a body that provides policy advice relating to public health, health equity, palliative care, substance use disorder policy, and indigenous uses of psilocybin;
- a military veteran, or representative of an organization that advocates on behalf of military veterans, with knowledge of psilocybin;
- a social worker, mental health counselor, or marriage and family therapist;
- an individual who is a member of, or who represents, a federally-recognized tribe;
- a psychologist, a physician, and a naturopath licensed in Washington;
- individuals with experience in mycology, ethnobotany, psychopharmacology, harm reduction, or scientific research regarding the use of psychedelic compounds in clinical therapy;
- an individual with experience working with the Cannabis Central Reporting System;

and

• one to three at-large members.

Board members serve for four-year terms, at the pleasure of the Governor, and are eligible for reappointment. The Governor must appoint successor members before the current member's term expires, and when other vacancies occur. 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 adopt operating rules and establish committees and subcommittees.

<u>Interagency Psilocybin Work Group.</u> 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.

<u>Psilocybin Task Force.</u> 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;
 - 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.

<u>Duties of the Department of Health.</u> 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.

<u>Duties and Prohibitions of Other State Agencies.</u> 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.

<u>Protections.</u> Medical professionals licensed in Washington must not be subject to adverse licensing action for recommending psilocybin therapy services.

<u>Pilot Program.</u> Subject to appropriation, by January 1, 2025, the University of Washington Department of Psychiatry and Behavioral Sciences must establish and administer a Psilocybin Therapy Services Pilot Program (Pilot Program). The Pilot Program must:

- offer psilocybin therapy services through pathways approved by the federal Food and Drug Administration to populations including first responders and veterans who are 21 years of age or older and are experiencing posttraumatic stress disorder, mood disorders, or substance use disorders;
- offer psilocybin therapy services facilitated by specified health care professionals;
- ensure psilocybin therapy services are safe, accessible, and affordable;
- require an initial assessment before a participant received psilocybin therapy services and an integration session afterward; and
- use outreach and engagement strategies to include participants from communities or demographic groups who are more likely to be historically marginalized and less likely to be included in research and clinical trials.

Votes on Final Passage:

Senate 41 7 House 87 10 (House amended) Senate 40 4 (Senate concurred)

Effective: 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. The remaining sections of the bill take effect 90 days after adjournment.

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