

SENATE BILL REPORT

SB 5263

As of January 27, 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: Senators Salomon, Rivers, Saldaña, Nobles, Lovick, Lovelett, Hunt, Hasegawa, Mullet, Trudeau, Robinson, Pedersen, Wellman, Muzzall, Wilson, C., Kuderer, Keiser, Lias, Van De Wege, Billig, Conway and Frame.

Brief History:

Committee Activity: Labor & Commerce: 1/30/23.

Brief Summary of Bill

- Directs the Department of Health (DOH) to administer a regulatory system for supported adult-use of psilocybin, beginning January 1, 2024.
- Directs DOH to create standards for manufacturing, testing, packaging, and labeling psilocybin products with the assistance of a Psilocybin Advisory Board and other state agencies.
- Allows a person over the age of 21 to purchase psilocybin products in a psilocybin service center and undergo a preparation session, administration session, and integration session under the supervision of a trained and qualified facilitator.
- Restricts employment in the psilocybin industry to certain licensed or permitted individuals over the age of 21.

SENATE COMMITTEE ON LABOR & COMMERCE

Staff: Matt Shepard-Koningsor (786-7627)

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.

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. 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 to create a Psilocybin Work Group (Work Group) to study and make recommendations to the Legislature regarding psilocybin services in the state. The 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 Work Group met four times in 2022, and currently has two meetings scheduled in 2023. The 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, and establishes a regulatory structure similar to the one proposed in this legislation. 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 projected it would begin 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, Proposition 122 includes other substances such as DMT, ibogaine, some mescaline, psilocybin, and psilocyn.

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

Overview. During a two-year program development period, beginning September 1, 2023, the Department of Health (DOH) must adopt rules for the implementation of a comprehensive regulatory framework that allows individuals 21 years of age or older in Washington to be provided psilocybin services. Following the development period, and by January 2, 2024, DOH must begin licensing psilocybin service centers, psilocybin service facilitators, psilocybin service facilitator trainees, psilocybin product manufacturers, and psilocybin testing laboratories. Under this regulated system, an individual who is at least 21 years of age may purchase psilocybin products and receive psilocybin services from a center. Psilocybin services include:

- a preparation session;
- an administration session, in which the client consumes the drug at a center or other permitted location under the supervision of a facilitator, and must remain at the center or other permitted location until the facilitator certifies the session is concluded; and
- an optional integration session that must be offered to the client.

Psilocybin Advisory Board. A Psilocybin Advisory Board (Board) is established to provide advice and recommendations to DOH, consisting of 17 to 20 members appointed by the Governor. Board members must serve for four-year terms at the pleasure of the Governor. During the development period, the Board must meet at least once every two calendar months. After the development period, the Board must meet at least once every calendar quarter. The Board may meet at other times if directed by the chair or a majority of voting Board members.

Duties of the Department of Health. DOH must develop rules that include minimum standards for manufacturing, transportation, delivery, advertising, and sales of psilocybin products. These rules must prohibit advertising that is appealing to minors, promotes excessive use, or promotes illegal activity. DOH may not require psilocybin products be manufactured by chemical synthesis, prohibit the use of naturally-grown mushrooms, or mandate the use of patented products or procedures. DOH must establish the maximum concentration of psilocybin permitted in a single serving of psilocybin and the number of servings permitted in a psilocybin product package.

DOH must adopt requirements, specifications, and guidelines for psilocybin preparation sessions, administration sessions, and integration sessions. DOH must adopt rules for the conduct of centers and facilitators, and determine qualifications, training, education, and fitness standards for all psilocybin licensees. DOH must serve as the disciplinary authority for licensees under the Uniform Disciplinary Act, which also governs the uncertified practice and the issuance and denial of licenses. License fees must be calculated to cover but not exceed the cost of administration. DOH may immediately restrict, suspend, or refuse to renew a license based on probable cause that a licensee has purchased psilocybin products from an unlicensed source or has sold, stored, or transferred psilocybin products in an unauthorized manner. DOH may take any action necessary to prevent the diversion of psilocybin products from a licensee to an entity not operating legally under the laws of this state.

DOH must publish medical, psychological, and scientific studies and information relating to the safety and efficacy of psilocybin in treating behavioral health conditions. DOH may not revoke or refuse to issue or renew a psilocybin license or permit on the basis that manufacturing, distributing, dispensing, possessing, or using psilocybin products is prohibited by federal law. The legislation explicitly states the jurisdiction, supervision, duties, functions, and powers held by DOH are not shared by the Pharmacy Quality Assurance Commission.

Duties and Prohibitions of Other State Agencies. The Liquor and Cannabis Board (LCB) and the Washington State Department of Agriculture (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.

WSDA may not regulate psilocybin products or a licensee unless authorized in DOH rules. Specifically, WSDA may not establish standards for psilocybin as a food additive, consider psilocybin products to be an adulterant unless exceeding acceptable concentration levels, or apply or enforce controlled atmosphere laws to psilocybin products.

Eligibility to Become a Client of a Psilocybin Service Center. A psilocybin client is not required to be diagnosed or have any particular medical condition to receive psilocybin services. The client must prove they are at least 21 years of age, complete and sign a client information form enabling the center to determine whether the client should participate in the administration session. The client information form must include information that may identify risk factors and contraindications, health and safety warnings, and disclosures to the client as required by DOH. Neither a center nor a facilitator is liable for reasonably relying on representations made by a client in a client information form. The client must attend a preparation session with a facilitator. The initial preparation session must occur no more than 120 days before the client participates in their first administration session, but subsequent preparation sessions need only be completed every 12 months. After the administration session, the client may participate in an integration session. A preparation session and integration session may be held at a center or another location and may be held in-person or remotely. An administration session must either be held at a center or other permitted location and may not be held remotely. If a preparation, administration, or integration session is completed in accordance with all applicable requirements, specifications, and guidelines, as determined by DOH, the facilitator must certify that information.

Clients receiving psilocybin services in Washington have certain enumerated rights under the Act.

Eligibility to Hold a Psilocybin License. All psilocybin licensees must be at least 21 years of age, undergo a nationwide criminal records check, pass a DOH examination, and satisfy

other specified DOH requirements of all licensees. DOH may require applicants to disclose the names, addresses, and financial interests of each person involved in a psilocybin business. Individuals who handle psilocybin on behalf of a manufacturer must hold permits issued by DOH, proving they have complied with age verification and training requirements. A licensee or their employee is exempt from state criminal laws relating to psilocybin while complying with applicable psilocybin laws. A licensee may not retaliate or discriminate against whistleblowers. DOH must adopt rules and implement procedures for whistleblower complaints. Non-employee whistleblowers may file suit in a court of competent jurisdiction within two years of the alleged retaliation.

Psilocybin Service Facilitators. *Facilitator.* A facilitator must have at least a high school or equivalent education; pass an examination approved, administered, or recognized by DOH, and submit evidence of having completed 250 hours of supervised training, of which 48 hours must include direct co-therapy with the supervising practitioner. Examinations must be offered at least twice per year. DOH may not require a facilitator to have a degree from a university, college, or other institution of higher education. Facilitators must be trained in certain facilitation and support skills that are affirming, non-judgmental, culturally-competent, and non-directive. Facilitators must be trained on client safety, and how to interact with clients who may have behavioral health conditions. Training must be modular and able to be completed separately or as a comprehensive package. The core curriculum may be completed in-person or remotely, but the practical training portion must be completed in-person. DOH must formulate a code of professional conduct for facilitators, giving particular consideration to a code of ethics. A facilitator must renew their license annually. Until January 1, 2026, a facilitator must prove they have been a resident of the state for at least two years. DOH rules must allow a facilitator to consult with the client, and work out a dosage appropriate for the client, and may not impose a maximum dosage of psilocybin that is less than 50 milligrams.

Facilitator Trainee. A trainee must have an annual DOH-issued license and complete all the requirements for licensure of a facilitator except the supervised training requirement. DOH may not require a trainee to have a certain higher education degree. A trainee may be paid to work in the psilocybin industry as a facilitator under the supervision of a qualified supervisor. A qualified supervisor is a person who has been licensed as a facilitator for at least two years, and other DOH-identified individuals, however, DOH must waive the supervised training requirement for certain individuals it and the Board approves until a sufficient number of qualified supervisors are available.

Psilocybin Service Centers. A center must have defined boundaries, and may not be mobile. An individual may not have a financial interest in more than five centers. Administration sessions must be held at a center or other DOH-permitted location, which must be a safe and comfortable non-service center location. Permitted locations must include veterans' organizations, houses of worship, private residences, outdoor spaces, and other DOH-determined locations, but do not include vehicles or public spaces. Until January 1, 2027, at least 50 percent of the ownership shares of a center must be held by

individuals who have been residents of the state for at least two years. A center must only sell psilocybin products tested by a laboratory licensed to test psilocybin.

Psilocybin Product Manufacturers. A manufacturer may not manufacture psilocybin products outdoors. An individual may not have a financial interest in more than one manufacturer. Until January 1, 2027, more than 50 percent of the shares in a manufacturer must be held by individuals who have been residents of the state for at least two years. A manufacturer must annually renew its license. DOH must create endorsements for different types of manufacturing activities, including a microtier manufacturing endorsement with lower license fees to reduce barriers to access. A manufacturer may request an endorsement at any time by one application and license fee, and may hold multiple endorsements. Labeling for psilocybin products must be clear, precise, and not deceptive. DOH may prohibit the use of injurious or adulterated ingredients. Labels and packaging must include health and safety warnings, activation time, potency, serving size and number of servings included, and contents, to the extent applicable.

Confidential Information. A licensee may not disclose any personally-identifiable information, or any communication made by a client during the course of providing psilocybin services or selling psilocybin products to the client, except when:

- the client or an authorized individual consents to the disclosure;
- the client initiates legal action or files a complaint against the center operator, facilitator, or an employee;
- the communication reveals the intent to commit a crime harmful to the client or others;
- the communication reveals that a minor may have been a victim of a crime, abuse, or neglect; or
- responding to an inquiry by DOH during an investigation into a licensee's conduct under the Act.

Clients cannot be denied service for declining to share personal or de-identified data outside of centers or declining to participate in research. Specified information is exempt from public disclosure under the Public Records Act.

Transfer of Psilocybin Products. DOH must develop rules outlining the procedures for licensees that allow for tracking psilocybin products from manufacture to sale, which includes any intermediate sale or purchase of psilocybin products between licensees, premises, or other permitted activities. Tracking must:

- prevent the diversion of psilocybin products to other states or unauthorized users;
- protect psilocybin products from substitution or tampering;
- enable an accurate accounting of the production, processing, and sale of psilocybin products;
- ensure laboratory testing results are accurately reported; and
- ensure compliance with other applicable psilocybin laws.

When developing rules, DOH is not required to direct the use of any particular technology, platform, or system to track psilocybin products, but must consider factors such as cost, ease of administration, ease of compliance monitoring, the time available in the development period, and the risk of delaying the system's implementation. If DOH determines LCB's cannabis tracking system is suitable, cost-effective, and not unduly burdensome, it may enter into an agreement with LCB to use that system to track psilocybin products, or it may purchase, license, or develop a different system.

Testing of Psilocybin Products. DOH must establish standards in consultation with LCB and WSDA for testing psilocybin products to protect public health and safety. DOH may conduct random testing and inspections to determine the compliance of licensees.

Psilocybin Regulation by Cities and Counties. Cities and counties may adopt ordinances placing reasonable restrictions on the operation of psilocybin businesses, and where they may be located. A city or county may not require a center or manufacturer to be located at a distance greater than 1000 feet from a public, private, or parochial elementary or secondary school, or at a distance greater than 500 feet from a public, private, or parochial school if there is a physical or geographic barrier capable of preventing children from accessing the premises of the center or manufacturer. Authority to issue licenses related to psilocybin or to levy taxes and fees related to psilocybin is vested solely in the Legislature.

Social Opportunity Program. A social opportunity program is established at DOH to help remedy harms resulting from historical injustice, and the disproportionate and targeted enforcement of drug-related laws on poor and marginalized communities. To assist individuals who qualify as social opportunity applicant, and meet other licensing requirements, DOH may:

- identify distressed areas;
- establish other appropriate criteria to identify social opportunity applicants;
- provide technical assistance to social opportunity applicants directly or through a partnership network;
- provide reduced license fees for social opportunity applicants as determined by the DOH and the Board, which may not increase the fees of non-social opportunity applicants;
- establish or facilitate the provision of scholarship funding for facilitator training; and
- if applicable, create eligibility for social opportunity applicants to receive points toward a license application score.

Distressed area means an area categorized as a distressed area by the state Employment Security Department or Federal Bureau of Labor Statistics; or that is a state legislative district in which 50 percent or more of the children participate in the federal free lunch program, or at least 20 percent of the households receive assistance under the federal Supplemental Nutrition Assistance Program. Social opportunity applicant means an entity:

- in which at least 51 percent of the ownership and control is by individuals who have lived in a distressed area for five of the last ten years;

- in which at least 51 percent of the ownership and control is by individuals who are veterans;
- which petitions for acceptance as a social opportunity applicant and DOH accepts the application;
- with more than 10 full-time employees and more than half residing in a distressed area; or
- that meets other DOH criteria established in rule.

Penalties. DOH may impose civil penalties up to \$500 or \$5,000 per violation of psilocybin rules, which must be deposited into the newly-created Psilocybin Control and Regulation Account. Law enforcement officers may assist DOH in enforcing the rules. A person under the age of 21 who enters the premises of a psilocybin licensee is guilty of a class 2 civil infraction, unless the individual is coordinating with certain individuals or agencies to investigate non-compliance with applicable laws. Other specified exceptions are provided. A person who produces false identification to misrepresent their age in connection with psilocybin is guilty of a class one civil infraction. A person who sells, gives, or otherwise makes available a psilocybin product to a visibly-intoxicated person is guilty of a civil infraction. To give a psilocybin product as a prize, premium, or consideration for a game of chance or skill is a class one civil infraction

Protections. Physicians, physician assistants, advanced registered nurse practitioners, psychologists, social workers, mental health counselors, and marriage and family therapists must not be subject to arrest, prosecution, civil penalty, or adverse licensing action for recommending psilocybin to a patient if a full assessment is completed and a patient relationship exists, however, a practitioner must properly evaluate a patient's condition, and comply with the applicable standard of care in doing so. A psilocybin client is protected from criminal, civil, or adverse licensing action for the mere use of psilocybin. Primary caregivers are protected for assisting a qualifying patient with the use of psilocybin within state laws. State and local government entities are immune from suit under state law for actions taken or omitted related to state psilocybin laws. Employers may not discriminate against employees for receiving psilocybin services absent visible impairment at work, and may not test employees for psilocybin unless the employee exhibits clear, observable symptoms of impairment.

Psilocybin as Agriculture. Psilocybin-producing fungi is:

- an agricultural commodity for purposes of the Open Space Taxation Act;
- an accessory for purposes of the Growth Management Act; and
- a crop for purposes of farmland and farm product, and an agricultural activity under the state nuisance laws.

These provisions only apply as they relate to licensed manufacturers.

Other. Beginning October 1, 2023, the term controlled substance in the Uniform Controlled Substances Act does not include psilocybin, but only if and to the extent that a person

manufactures, delivers, or possesses psilocybin, psilocin, or psilocybin products in accordance with the legislation and DOH rules. Psilocybin is still included in the list of Schedule I substances. A state severability clause is included.

An emergency clause is included relating to the Psilocybin Advisory Board.

Appropriation: None.

Fiscal Note: Requested on January 11, 2023.

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

Effective Date: The bill contains several effective dates. Please refer to the bill.