

SENATE BILL REPORT

SB 5660

As of February 2, 2022

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, Lovelett, Kuderer, Pedersen, Saldaña, Trudeau and Wellman.

Brief History:

Committee Activity: Health & Long Term Care: 2/02/22.

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 government 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 facilitator.
- Restricts employment in the psilocybin industry to licensed or permitted individuals over the age of 21.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Kevin Black (786-7747)

Background: Psilocybin is a naturally occurring, psychoactive chemical compound

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.

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 may be extracted and may be synthesized by chemical processes. Many who have taken psilocybin describe having a mystical or spiritual experience, during a trip that lasts for four to six hours. Possession, manufacture, and delivery of psilocybin is illegal under both state and federal law.

Early research into the therapeutic benefit of psychedelic drugs was conducted in the 1950s and 1960s. After a fallow period, research into psilocybin made a strong resurgence. In 2019, the U.S. Food and Drug Administration designated psilocybin therapy as a "breakthrough therapy" in studies looking into its potential as a treatment for severe treatment-resistant depression and major depressive disorder. Other studies suggest therapeutic uses for psilocybin in the treatment of addiction, PTSD, obsessive-compulsive disorder, anxiety, and nicotine dependence, among other conditions. A number of U.S. cities have recently adopted resolutions expressing support for deprioritizing criminal enforcement of laws relating to psilocybin and other psychedelic drugs, including the City of Seattle in October 2021.

On November 3, 2020, Oregon voters adopted Oregon Measure 109, a ballot initiative supported by 55.75 percent of the voters. Oregon Measure 109 legalizes psilocybin in Oregon law and establishes a regulatory structure similar to the one proposed in this legislation. Oregon is scheduled to begin issuing licenses related to psilocybin on January 2, 2023.

Summary of Bill: The bill as referred to committee not considered.

Summary of Bill (Proposed Substitute): Overview. Beginning January 2, 2024, the Department of Health (DOH) must license psilocybin service centers (centers), psilocybin service facilitators (facilitators), psilocybin product manufacturers (manufacturers), and psilocybin testing laboratories. Under this regulated system, an individual who is at least 21 years of age may purchase psilocybin services from a licensed center. Psilocybin services include an administration session, in which the client consumes the drug at a center under the supervision of a facilitator, and must remain at the center until the facilitator certifies that the session is concluded.

The Psilocybin Advisory Board. A Psilocybin Advisory Board (Board) is established to provide advice and recommendations to DOH, consisting of at least 20 members appointed by the Governor. Board members must serve four year terms at the pleasure of the Governor. The Board must meet at least once every two months during the 18-month program development period starting July 1, 2022, and ending with the issuance of the first psilocybin licenses in January 2024.

Duties of the Department of Health. DOH must develop rules which include minimum standards for manufacturing, transportation, delivery, advertising, and sale 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 to be manufactured by means of 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 develop rules for the conduct of centers and facilitators, and determine qualifications, training, and education and fitness standards for all psilocybin licensees. 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 which is 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.

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 an administration session. The client information form must include information that may identify risk factors and contraindications, health and safety warnings, and disclosures required by DOH. Neither a center or 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, which may but need not be held at a center, and may be held in person or remotely. After the administration session, the client may participate in an integration session, which may but need not be held at a center, in person or remotely.

Eligibility to Hold a Psilocybin License. All psilocybin licensees must be at least 21 years of age, undergo a fingerprint background check, and satisfy DOH they have completed required education and training and are competent and of good moral character. 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 psilocybin laws and rules. A licensee may not retaliate or discriminate against whistleblowers.

Psilocybin Service Facilitators. A facilitator must have at least a high school or equivalent education and pass an examination that has been approved, administered, or recognized by DOH. 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 support skills which are affirming, nonjudgmental, culturally competent, and non-directive. They must receive training in client safety and how to interact with clients who may have behavioral health conditions. Training for facilitators must be modular, allowing pieces to be offered either separately or as part of a comprehensive package. 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 provide proof they have been a resident of the state for at least two years.

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 unless an exception applies allowing psilocybin services to be administered in the home of a client who is medically unable to travel to the center. Until January 1, 2026, 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.

A center may not disclose personally identifying information about a client except in the context of litigation, compliance with licensure requirements, or reporting a crime or evidence of criminal intent. DOH may require centers to maintain liability insurance.

Psilocybin Product Manufacturers. A manufacturer may not manufacture psilocybin products outdoors. An individual may have a financial interest in only one manufacturer. Until January 1, 2026, 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, and allow manufacturers to hold multiple endorsements. DOH may adopt rules restricting the quantity of psilocybin products kept at the premises of a manufacturer. Labeling for psilocybin products must be clear, precise, and not be 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.

Transfer of Psilocybin Products. DOH must develop a system for tracking the transfer of psilocybin products between licensed premises using the system developed by the Liquor and Cannabis Board to track cannabis products. The system must prevent diversion of psilocybin products to other states, prevent substituting or tampering, and ensure an

accurate accounting of production, processing, testing, and sale. Psilocybin products may only travel between licensed premises.

Testing of Psilocybin Products. DOH must establish standards in consultation with the Liquor and Cannabis Board and Department of Agriculture 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 regulations on the operation of psilocybin businesses and where they may be located. An ordinance that prohibits a center or manufacturer from being located within a certain distance of another psilocybin business or school may not exceed a prohibition radius of 1000 feet. In the case of a school, the distance is reduced to 500 feet if there is a physical or geographic barrier capable of preventing children from traversing onto the premises. 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 establish equity and help remedy harms resulting from historical injustice and the disproportionate and targeted enforcement of drug-related laws on poor and marginalized communities. To assist individuals who qualify as social equity applicants, DOH may provide technical assistance, including by establishing a partnership network, providing reduced license fees, and allowing applicants to receive points towards a license application score. A social opportunity applicant is defined as an entity or individual in which at least 51 percent of ownership and control come from a distressed area, or over half of its employees come from a distressed area, based on classifications made by government entities or on the local rate of participation in public assistance programs.

Penalties. DOH may impose civil penalties up to \$500 or \$5,000 per violation of psilocybin rules. Law enforcement officers may assist DOH in enforcing the rules. A person under the age of 21 who enters a psilocybin premises is guilty of a class 2 civil infraction. A person who produces false identification to misrepresent their age in connection with psilocybin is guilty of a misdemeanor. A person who makes psilocybin products available 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 1 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. A psilocybin client is protected from criminal, civil, or adverse licensure action penalties 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.

This legislation may be known and cited as the Washington Psilocybin Services Wellness and Opportunity Act.

Appropriation: None.

Fiscal Note: Requested on January 6, 2022.

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

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

Staff Summary of Public Testimony On Proposed Substitute: PRO: Clinical studies of psilocybin therapy show amazing results. Eighty clinical trials are completed or ongoing, more than for many FDA-approved medications. End-of-life patients experienced reduced depression and anxiety, and described it as one of the most meaningful experiences of their life. Psilocybin is more effective than any known intervention for tobacco cessation and addiction recovery. It has been used for thousands of years in traditional healing ceremonies, and is nothing like heroin or meth. In a controlled setting it is not addictive or dangerous, and was placed on schedule one for cultural motives. The bill's social opportunity program will help persons from disadvantaged communities become providers before competition is allowed from out-of-state interests. Science confirms psilocybin is very non-toxic and not addictive. We are in the midst of a mental health crisis with high rates of suicide and record levels of overdose deaths. Cities around the county are choosing to decriminalize psychedelic drugs. The evidence currently suggests that psilocybin, when given in a controlled environment under the care of a provider, may significantly reduce symptoms of depression, anxiety, trauma, and a range of substance abuse disorders. Despite the confusing history, these compounds help people find significant relief from disorders which are increasingly fatal. I oversee clinical trials and have seen the positive effects firsthand. The bill should address ways to monitor the development of psilocybin infrastructure and its impacts. Bringing this drug from the underground to a regulated environment can mitigate risks and prevent the greater harms that comes from illicit markets. Psilocybin may be purchased over-the-counter in the Netherlands, where studies find minimal risk to individuals or public health. Denver decriminalized two years ago and police and health officials agree there have been no issues. Many health care providers and the Washington Psychological Association have signed a letter of support. Psilocybin represents an improvement over existing therapies, with particular value for veterans. It costs \$4,000 to fly a veteran to the Amazon for legal psychedelic therapy. No poisonings, hospitalizations, or deaths from psilocybin are shown in nationwide toxicology reports from 2017-2020, and no deaths and only 103 hospitalizations nationwide over a 30-year span.

Psilocybin helped me overcome anxiety and depression after I had to close my restaurant during the pandemic. Antidepressants had failed me; now I am in the best state of mind I have ever been in. A session lasts 4 to 6 hours; microdosing can be done subperceptually while engaging in other activities. Psilocybin does not have the side effects of other medications. As an MD I have seen profound changes supervising clinical trials in Canada; I would do this work for free. It helps people get to the seeds of their addiction and heal trauma. Psilocybin saved my life after 20 years of agony from suicidal depression and treatments that didn't help. After one dose I felt like myself for the first time since I was ten. Psilocybin can be a game-changer for millions suffering from depression. My brother and his wife lost their infant child to SIDS. Psilocybin helped them see their loss from a different perspective and finally laugh again. Pass this bill so the people of Washington can heal. It is important to decriminalize psilocybin for social justice reasons. As a trained psilocybin facilitator, therapist, and trauma survivor, I have watched many psilocybin clients move from being stuck to a sense of ownership and choice in their lives. A regulated system is needed for safety, equity, and access. Our mental health system does not provide enough. Psilocybin gave me huge relief from my panic attacks. Legalizing psilocybin will create great positive economic impacts, similar to cannabis legalization. This is a job creator that will benefit Washington and keep money in local communities. People would travel to Washington for this therapy. Young people who are disaffected with politics are paying close attention to this topic. It has been demonstrated that psychedelic medicine after a single dose can be three times as effective as 12-step programs in treating substance use disorders. Oregon's program costs \$3.1 million per year. As a veteran and nurse, I see many community problems which can be healed through psilocybin. For a few hours it takes the blinders off and lets you see your life from the perspective of how much good there is and how much potential for growth there is. It allows you to figure out for yourself the best route forward. This will benefit marginalized communities, reduce incarceration, and benefit the state financially. Psilocybin has been used in religious ceremonies on every continent for thousands of years. I use psilocybin as a ceremonial sacrament. It helps me understand my place in the cosmos and reinforces my connection to nature and other human beings. The whole Legislature should go on a mushroom retreat—you will agree with each other afterwards more than you ever have in your lifetime! We must ensure everyday working class people, and especially those harmed by the war on drugs, can participate in this emerging industry. This bill raises the bar for equitable access by allowing micro-tiered licensing and the social opportunity program. Psilocybin helped me resolve childhood trauma that was directly caused by the war on drugs. Psilocybin stopped my tremors from Parkinson's Disease. Leaders benefit from psilocybin. This bill puts Washington in a great position to lead. I traveled to Peru with other veterans for psychedelic treatment, which felt like 15 years of therapy. As a business owner and veteran, the healing from psychedelic treatment trumped 12 years of treatment through the Veteran's Administration. Psilocybin gave me the tools to heal myself with speed and efficacy after five special forces deployments. It is a travesty this medicine is illegal. How can we justify jailing people for trying to heal themselves and live happier lives? Please allow possession at home and expand the bill to include other psychedelic drugs. After taking psilocybin my 12-year depression was healed, and I told my husband I never knew this was what living was

supposed to be like.

CON: I favor psilocybin legalization but am against the bill as currently written. It should allow imperceptible doses, personal possession, and home use. The cost of a regulated system may inhibit access by low-income and disadvantaged people.

OTHER: I have seen many medical fads come and go. Psilocybin-assisted therapy is not a fad. Psilocybin functions differently from SSRI medications; instead of damping down emotions, it lets people get to the heart of what is happening. I run a clinical trial for doctors and nurses to heal trauma and grief from the pandemic. There are 100 applicants for every spot in the trial. Many experience lasting relief after only one experience, while some repeat sessions. Psilocybin legalization represents a commodification of Indigenous cultural practice. Indigenous practitioners must be represented honorably and acknowledged. They may not want to embed their healing practices within an economic system. Barriers to access mean fewer people getting well. Please amend the bill to support microdosing, personal use, and possession. Twenty milligrams of psilocybin provides relief from restless sleep and suicidal ideation. I would fully support this bill if it allowed people to make decisions in their homes as free Americans. Port Townsend recently decriminalized psychedelics. Please add provisions to allow community and Indigenous ceremonies.

Persons Testifying: PRO: Senator Jesse Salomon, Prime Sponsor; Sunil Aggarwal, End of Life Washington / AIMS Institute; Emma Knighton, Psychedelic Medicine Alliance of WA; Sarit Hashkes, Red Light Holland; Steven Hernandez; Kody Zalewski, Psychedelic Medicine Alliance of Washington co-director; Eric Gaden; Dr. Mason Marks, PMAW medical providers panel; Dr. Nathan Sackett, PMAW medical provides panel; Dr. Tony Rousmaniere, PMAW medical providers panel; Ada Danelo, QLaw Association of Washington; Arrington de Dionyso; G Todd Williams; Dr. Lisa Price, Best Integrative and Holistic Care; Maria Hines; Dr. Pamela Kryskow; Alex Jones; Elyse Bais, Psychedelic Medicine Alliance Washington; Tatiana Quintana, Psychedelic Medicine Alliance Washington; Darren McCrea; Jean Sebastien Fouillade; Corey Champagne, Psychedelic Medicine Alliance veterans panel; Matthew Griffin, Psychedelic Medicine Alliance veterans panel; Alex Kaper, Psychedelic Medicine Alliance veterans panel; Cendy Ortiz, Psychedelic Medicine Alliance veterans panel; Ben Sercombe , PMAW; David Heldreth; Dana Phillips.

CON: Bailey Kotas.

OTHER: Anthony Back; Eden Zillioux, (PEAC) Psilocybin equitable access coalition; Lauren Feringa, Hippie and a Veteran Foundation; Erin Reading, Port Townsend Psychedelic Society.

Persons Signed In To Testify But Not Testifying: No one.