ARIZONA HOUSE OF REPRESENTATIVES



Fifty-sixth Legislature Second Regular Session

Senate: HHS DP 7-0-0-0 | 3rd Read 24-4-2-0 **House:** HHS DP 8-2-0-0 | 3rd Read 42-16-2-0

SB 1570: psilocybin services; regulation; licensure Sponsor: Senator Shope, LD 16

Vetoed

Overview

Directs the Arizona Department of Health Services (DHS), by January 1, 2026, to begin receiving applications to license psychedelic-assisted therapy centers and outlines licensure requirements and restrictions. Creates the Advisory Psilocybin Advisory Board (Advisory Board) and the Psilocybin Control and Regulation Fund (Fund).

History

Laws 2023, Chapter 139 appropriated \$5 million in FY 2024 to DHS to provide competitive research grants for whole mushroom psilocybin phase one, phase two and phase three clinical trials that are capable of being approved by the U.S. Food and Drug Administration (FDA) in order to evaluate the effects of whole mushroom psilocybin on treating certain disorders. The law established a four-member Psilocybin Research Advisory Council (Advisory Council) to: 1) establish criteria for the clinical trials that qualify to receive the research grants; 2) oversee the application process and review applications for the research grants to assist the DHS Director in selecting the most credible clinical trials; and 3) ensure that all council meetings are open to the public and allow for public participation. Annually on June 1, the Advisory Council makes recommendations to the Governor, Legislature and DHS on psychedelic-assisted therapies based on current and federal state research policies. Grants must be awarded by February 1 of each year and the grant program is repealed on July 1, 2026.

According to the U.S. Drug Enforcement Administration (DEA), Psilocybin is a halogenic chemical obtained from certain types of fresh or dried mushrooms it is currently a Schedule I controlled substance under federal law (<u>DEA Fact Sheet, Psilocybin</u>).

The U.S. Food and Drug Administration (FDA) published a new draft guidance on June 23, 2023, to provide considerations to researchers investigating the use of psychedelic drugs for potential treatment of medical conditions, including psychiatric or substance use disorders (FDA).

Provisions

Psilocybin Control and Regulation Fund

- 1. Establishes the Psilocybin Control and Regulation Fund (Fund) to be administered by DHS consisting of fees and civil penalties collected through the regulation of psilocybin. (Sec. 1)
- 2. Specifies that monies in the Fund are continuously appropriated and are exempt from lapsing. (Sec. 1)

3. Permits Fund monies to be used to provide grants for psilocybin clinical trials. (Sec. 1)

Arizona Psilocybin Advisory Board

- 4. Establishes the Advisory Board within DHS and outlines membership. (Sec. 1)
- 5. Requires the Advisory Board to:
 - a) publish an annual report;
 - b) approve training programs for licensees and health professionals who provide psilocybin services; and
 - c) make recommendations to DHS relating to manufacturing, cultivating, possessing and transporting psilocybin. (Sec. 1)
- 6. Allows the Advisory Board to:
 - a) advise and make recommendations to DHS regarding the implementation of the licensure and regulation of psychedelic-assisted therapy centers;
 - b) determine the health and safety warnings and other disclosures that must be made to a patient before the patient receives psilocybin services;
 - c) recommend the formulation of a code of professional conduct for licensed individuals, including a code of ethics; and
 - d) monitor and study federal laws, regulations and policies regarding psilocybin. (Sec. 1)
- 7. Directs the Governor, Speaker of the House of Representatives and President of the Senate to appoint Advisory Board members by December 31, 2024. (Sec. 1)
- 8. Requires the Advisory Board, by March 1, 2025, to hold its first meeting at a time and place specified by DHS. (Sec. 1)
- 9. Requires Advisory Board members to serve four-year terms. (Sec. 1)
- 10. Specifies that an Advisory Board member is not eligible for reappointment once the person has been appointed for two full terms, in addition to any time served on the Advisory Board to fill a vacancy. (Sec. 1)
- 11. Allows a person to be reappointed to the Advisory Board after the person has been off the Advisory Board for at least two full terms. (Sec. 1)
- 12. Directs the Advisory Board to annually elect a chairperson from among its members. (Sec. 1)
- 13. Requires the Advisory Board to meet at least once every two calendar months at a time and place determined by the Chairperson or a majority of the voting members. (Sec. 1)
- 14. Asserts that Advisory Board members are not eligible to receive compensation but are eligible for reimbursement of expenses. (Sec. 1)
- 15. Requires the Advisory Board, by July 31, 2025, and annually thereafter, in consultation with DHS, to publish and distribute to the public a report that includes:
 - a summary of available medical, psychological and scientific studies, research and other information relating to the safety and efficacy of psilocybin in treating mental health conditions, including addiction, depression, anxiety disorders and end-of-life psychological distress; and
 - b) a long-term strategic plan for ensuring that psychedelic-assisted therapy will become and remain a safe, accessible and affordable therapeutic option for all persons who

are at least 21 years of age and for whom psilocybin may be appropriate, considering federal laws, regulations and policies regarding psilocybin. (Sec. 1)

Training Programs for Psychedelic-Assisted Therapy Centers

- 16. Requires training programs for licensees and health professionals serving as medical directors of psychedelic-assisted therapy center to provide core training that consists of at least 132 hours of instruction. (Sec. 1)
- 17. Specifies, for training that is not conducted in person, at least 50% of the training must be conveyed through online synchronous learning. (Sec. 1)
- 18. Asserts that a person who applies to have the person's training program approved must demonstrate that the training program curriculum consists of the following, at minimum:
 - a) 12 hours of instruction in historical, traditional and contemporary practices and applications;
 - b) 12 hours of instruction in safety, ethics and responsibilities;
 - c) 12 hours of instruction in integration;
 - d) 20 hours of instruction in psilocybin pharmacology, neuroscience and clinical research:
 - e) 16 hours of instruction in core facilitation skills, administration, preparation and orientation;
 - f) 16 hours of instruction in group facilitation;
 - g) 4 hours of instruction in the Arizona public mental health system; and
 - h) 4 hours of instruction in the Arizona crisis mental health system. (Sec. 1)
- 19. Requires training programs to comply with the requirements specified in DHS rules to maintain approved status. (Sec. 1)
- 20. Permits training programs to offer additional modules or hours of instruction beyond those required in statute. (Sec. 1)

Licensure of Psychedelic-Assisted Therapy Centers

- 21. Directs DHS, by January 1, 2026, to begin receiving applications to license persons to operate psychedelic-assisted therapy centers as a health care institution. (Sec. 1)
- 22. Subjects all statutes relating to licensure and enforcement, including imposing civil penalties, to psychedelic-assisted therapy centers, except that all licensure, renewal fees and civil penalties collected must be deposited in the Fund. (Sec. 1)
- 23. Requires DHS to:
 - a) adopt rules, including rules deemed necessary to protect the public health and safety;
 - b) establish and collect application, licensing and renewal fees for licensees;
 - adopt rules regulating and prohibiting the advertisement of psilocybin services in a manner that is appealing to minors, promotes excessive use, promotes illegal activity or otherwise presents a significant risk to public health and safety; and
 - d) deposit collected fees in the Fund. (Sec. 1)
- 24. Prohibits DHS from requiring that a psilocybin product be manufactured by means of chemical synthesis. (Sec. 1)
- 25. Prohibits DHS from requiring a patient to be diagnosed with or have any particular medical condition in order to be provided psilocybin services. (Sec. 1)
- 26. Directs psychedelic-assisted therapy centers to be licensed as outpatient treatment centers by DHS for the premises at which psilocybin services are provided. (Sec. 1)

- 27. Requires a direct owner holding a psychedelic-assisted therapy center license to:
 - a) if a legal entity, provide proof that more than 50% of the shares, membership interests, partnership interests or other ownership interests are held, directly or indirectly by one or more individuals who have been Arizona residents for at least four years;
 - b) if a partnership, provide proof that more than 50% of the partnership interests are held, directly or indirectly, by one or more individuals who have been Arizona residents for at least four years;
 - if an individual, provide proof that the individual has been an Arizona resident for at least four years; and
 - d) meet the applicable statutes and DHS rules. (Sec. 1)
- 28. Directs psychedelic-assisted therapy centers to:
 - a) annually renew a license;
 - b) pay all required application, licensure and renewal fees;
 - c) meet any public health and safety standards and industry best practices established by DHS;
 - d) employ or contract with a health professional who is actively registered under the federal Contracted Substances Act (CSA) and eligible under DHS rule to provide indirect supervision of the psychedelic-assisted therapy center during all hours of operation as the medical director; and
 - e) maintain a record for each staff member that includes:
 - i. verification of having a current unrestricted health professional license;
 - ii. evidence of successfully completing a psilocybin services training program for any employee required to be trained; and
 - iii. evidence that the staff member holds a valid fingerprint clearance card. (Sec. 1)
- 29. Prohibits DHS from licensing an applicant under 21 years old. (Sec. 1)
- 30. Permits a psychedelic-assisted therapy center applicant to receive a license if one of the following applies:
 - a) both of the following applies:
 - i. the owner can demonstrate that the psilocybin product to be used is from a manufacturer, distributor, dispenser, imported or exporter licensed under the federal CSA; and
 - ii. the psychedelic-assisted therapy center is operating to conduct research for a clinical trial of whole mushroom psilocybin phase one, phase two and phase three clinical trials that are capable of being approved by the FDA to evaluate the effects of whole mushroom psilocybin;
 - b) a manufacturer, distributor dispenser, importer or exporter becomes available without violating the CSA; or
 - c) the applicant has received Board-approved training. (Sec. 1)
- 31. Outlines the circumstances in which DHS may refuse to issue or renew a license:
 - a) if the applicant or licensee has not completed the required training;
 - b) if the applicant or licensee has made false statements to DHS;
 - c) if the applicant or licensee has been convicted of violating a federal law, state law or local ordinance if the conviction is substantially related to the applicant's fitness and ability to lawfully carry out activities under the license;
 - d) if the applicant or licensee does not have a good record of compliance with statutes or rules relating to the licensure and regulation of psychedelic-assisted therapy centers;

- e) if the applicant or licensee is not the legitimate owner of the premises or has not disclosed that other persons have ownership interests;
- f) if the applicant or licensee has not demonstrated financial responsibility sufficient to adequately meet the requirements of the premises proposed to be licensed; or
- g) if the applicant or licensee is unable to understand state laws or adopted rules regarding psilocybin products or services. (Sec. 1)

Fingerprint Clearance Cards

- 32. Mandates that psychedelic-assisted therapy center applications must include a copy of a valid fingerprint clearance card issued to an applicant and to any of the following individuals:
 - a) if a limited partnership, each general partner;
 - b) if a manger-managed limited liability company, each manager;
 - c) if a member-managed limited liability company, each voting member;
 - d) if a corporation, each director and officer; and
 - e) any individual who holds a financial interest of at least 10% in the applying entity. (Sec. 1)

Psychedelic-Assisted Therapy Center Location Restrictions

- 33. Forbids psychedelic-assisted therapy centers from being located within 1,000 feet of a public or private K-12 school. (Sec. 1)
- 34. Permits psychedelic-assisted therapy centers to be located within 1,000 feet of a public or private K-12 school if DHS determines that there is a physical or geographic barrier capable of preventing children from traversing to the premises. (Sec. 1)
- 35. Specifies that, if a public or private K-12 school is established within 1,000 feet of a psychedelic-assisted therapy center, the center may remain at the location unless DHS revokes or refuses to renew the license under another law or rule related to psilocybin products or services. (Sec. 1)

Psychedelic-Assisted Therapy Center Employees

- 36. Allows a patient to consume a psilocybin product only at a licensed psychedelic-assisted therapy center and under supervision of a staff member and the indirect supervision of the medical director. (Sec. 1)
- 37. Prohibits a psychedelic-assisted therapy center employee from consuming psilocybin products during the administration, integration or preparation session that the employee is supervising. (Sec. 1)
- 38. Prohibits a licensee of a psychedelic-assisted therapy center from employing a person who is under 21 years of age. (Sec. 1)
- 39. Allows DHS, during an inspection of the psychedelic-assisted therapy center premises, to require proof that a person performing work at the center is at least 21 years of age. (Sec. 1)
- 40. Specifies that if the employee does not provide DHS with acceptable proof of age on request, DHS may require the person to immediately cease any activity and leave the premises until the agency receives acceptable proof of age. (Sec. 1)
- 41. Asserts that this does not apply to a person who is temporarily at the premises to make a service, maintenance or repair call or for other purposes independent of the premises operations. (Sec. 1)

42. Asserts that a licensee's failure to respond to a request for proof of age is prima facie evidence that the licensee has allowed the person to perform work at the premises in violation of the age requirement. (Sec. 1)

Miscellaneous

- 43. Forbids DHS employees from being charged with or prosecuted for possession of psilocybin products if the employee is acting in their official capacity as necessary to ensure compliance with and enforcement of laws relating to psilocybin products or services. (Sec. 1)
- 44. Defines terms. (Sec. 1-3)
- 45. Contains a severability clause. (Sec. 5)
- 46. Makes technical and conforming changes. (Sec. 2-4)

□ Prop 105 (45 votes)	□ Prop 108 (40 votes)	☐ Emergency (40 votes)	□ Fiscal Note