



ARIZONA STATE SENATE
Fifty-Sixth Legislature, Second Regular Session

AMENDED
FACT SHEET FOR S.B. 1570

psilocybin services; regulation; licensure

Purpose

Requires the Department of Health Services (DHS), by January 1, 2026, to begin the licensing of psychedelic-assisted therapy centers and prescribes licensure requirements and restrictions. Establishes the Arizona Psilocybin Advisory Board and the Psilocybin Control and Regulation Fund.

Background

The Legislature 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), to evaluate the effects of whole mushroom psilocybin on treating outlined conditions, including but not limited to: 1) post-traumatic stress disorder; 2) autoimmune disorders; 3) depression; 4) anxiety disorders; 5) substance abuse and addiction disorders; 6) chronic pain; and 7) seizure disorders. This grant program is overseen by the Psilocybin Research Advisory Council, who is charged with establishing criteria for clinical trials and grant eligibility, overseeing the application process to select credible clinical trials and make recommendations to the Governor and Legislature each year on psychedelic-assisted therapy, based on federal and state research policy. Grants must be awarded by February 1 of each year. The psilocybin research grant program is repealed on July 1, 2026 ([Laws 2023, Ch. 139](#))

On June 23, 2023, the FDA published a new draft guidance to highlight fundamental considerations to researchers investigating the use of psychedelic drugs for potential treatment of medical conditions, including psychiatric or substance use disorders. The purpose of the draft guidance is to advise researchers on study design and other considerations as they develop medications that contain psychedelics. This effectively creates a path for psychedelic drug trials to occur. The draft guidance includes guidance for the use of psilocybin as a method of treatment, as it acts on the brain's serotonin system ([FDA](#)).

If there is a cost associated with DHS licensing and oversight of psychedelic-assisted therapy centers, there may be a fiscal impact to the state General Fund.

Provisions

Arizona Psilocybin Advisory Board (Board)

1. Establishes the Board within DHS, consisting of no more than 12 members, who are appointed as follows:
 - a) four members appointed by the Governor, including a:
 - i. representative of DHS;

- ii. representative of the Arizona Health Care Cost Containment System;
 - iii. representative of the Office of the Attorney General;
 - iv. representative of DHS who is familiar with health care institution licensing; or
 - v. professor or researcher at a university under the Arizona Board of Regents;
- b) four members appointed by the President of the Senate, including:
- i. an active member or a veteran of the U.S. Armed Forces;
 - ii. a law enforcement officer in Arizona;
 - iii. a representative of Arizona firefighters;
 - iv. a legal representative of and advocate for persons with mental illness or severe mental illness; or
 - v. an enrolled member of a Native American tribe in Arizona who is experienced in the use of psilocybin in culturally and spiritually significant ceremonies;
- c) four members appointed by the Speaker of the House of Representatives, including a licensed:
- i. psychologist with professional experience in diagnosing or treating mental, emotional or behavioral conditions;
 - ii. medical or osteopathic physician experienced in psychedelic-assisted therapy;
 - iii. naturopathic physician;
 - iv. nurse practitioner;
 - v. medical or osteopathic physician with expertise in addiction treatment; or
 - vi. medical or osteopathic physician with experience conducting clinical research trials involving the use of schedule I controlled substances.
2. Requires the Governor, President of the Senate and Speaker of the House of Representatives to make appointments to the Board by December 31, 2024;
3. Requires the Board to hold its first meeting, at a time and place specified by DHS, by March 1, 2025.
4. Limits Board members to two four-year terms, in addition to any time served on the Board to fill a vacancy.
5. Allows a person to be reappointed to the Board after the person has been off the Board for at least two full terms.
6. Requires the Board to annually elect a chairperson among members of the Board.
7. Requires the 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 Board members.
8. States that Board members are ineligible to receive compensation but are eligible for reimbursement of expenses.
9. Prescribes duties of the Board, including:
- a) publishing an annual report;
 - b) approving training programs for licensees and health professionals who provide psilocybin services; and
 - c) making recommendations to DHS relating to manufacturing, cultivating, possessing and transporting psilocybin.

10. Empowers the 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 providing psilocybin services;
 - c) recommend the formulation of a code of professional conduct for licensees, including a code of ethics; and
 - d) monitor and study federal laws, regulations and policies regarding psilocybin.
11. Requires, By July 31, 2025, and each subsequent July 31, the Board, in consultation with DHS, to publish and distribute a public report that includes:
 - a) 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 individuals who are at least 21 years old who may benefit from psilocybin, considering federal laws, regulations and policies.
12. Requires training programs for licensees and health professionals serving as medical directors of psychedelic-assisted therapy centers to provide core training with at least 132 hours of instruction.
13. Stipulates that, if a training program is not conducted in person, then at least 50 percent of the training must be conveyed through online synchronous learning.
14. Requires a person applying to have a training program approved by the Board to demonstrate that the program curriculum consists of, at a 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) 20 hours of instruction in psilocybin pharmacology, neuroscience and clinical research;
 - d) 16 hours of instruction in core facilitation skills;
 - e) 16 hours of instruction in preparation and orientation;
 - f) 16 hours of instruction in administration;
 - g) 12 hours of instruction in integration;
 - h) 16 hours of instruction in group facilitation;
 - i) 4 hours of instruction in the Arizona public mental health system; and
 - j) 4 hours of instruction in the Arizona crisis mental health system.
15. Requires training programs to comply with DHS rules to maintain approved status.
16. Allows training programs to offer additional modules or hours of instruction beyond those required in statute.

Psychedelic-Assisted Therapy Centers

17. Requires DHS, by January 1, 2026, to begin receiving applications to license persons to operate psychedelic-assisted therapy centers as a health care institution.

18. Applies all statutes relating to licensure and enforcement of health care institutions, including imposing civil penalties, to psychedelic-assisted therapy centers.
19. Directs 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 licenses;
 - c) adopt rules regulating and prohibiting the advertisement of psilocybin services in a way that appeals to minors, promotes excessive use or illegal activity, or otherwise presents a significant risk to public health and safety; and
 - d) deposit collected fees in the Fund.
20. Prohibits DHS from requiring:
 - a) that psilocybin products be manufactured by means of chemical synthesis; or
 - b) a patient to be diagnosed with or have any particular medical condition in order to be provided psilocybin services.
21. Requires psychedelic-assisted therapy centers to be licensed as outpatient treatment centers by DHS for the premises at which psilocybin services are provided.
22. Requires the owner of a psychedelic-assisted therapy center, as a condition of licensure, to:
 - a) if a legal entity, provide proof that more than 50 percent 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 percent of the partnership interests are held, directly or indirectly, by one or more individuals who have been Arizona residents for at least four years;
 - c) if an individual, provide proof that the individual has been an Arizona resident for at least four years; and
 - d) meet the applicable requirements of statute and Board rules.
23. Requires each psychedelic-assisted therapy center to:
 - a) annually renew the psychedelic-assisted therapy center's license;
 - b) pay all required application, licensure and renewal fees established by DHS rule;
 - c) meet any public health and safety standards and industry best practices established by DHS;
 - d) employ or contract with a licensed health professional who is actively registered under the federal Controlled Substances Act 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 verification of current unrestricted licensure, evidence of completion of a psilocybin services training program and evidence that the staff member holds a valid fingerprint clearance card.
24. Prohibits DHS from licensing an applicant under 21 years old.
25. Allows a psychedelic-assisted therapy center license applicant to receive a license if one of the following applies:
 - a) both of the following apply:

- i. the owner can demonstrate that the psilocybin product to be used at the psychedelic-assisted therapy center is from a manufacturer, distributor, dispenser, importer or exporter that is licensed under the federal Controlled Substances Act; 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 capable of being approved by the FDA to evaluate the effectiveness of whole mushroom psilocybin;
 - b) a manufacturer, distributor, dispenser, importer or exporter becomes available without violating the federal Controlled Substances Act; or
 - c) the applicant has received Board-approved training.
26. Allows DHS to refuse to issue or renew a license if it is found that the applicant or licensee:
- a) has not completed required training;
 - b) has made false statements to DHS;
 - c) 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) does not have a good record of compliance with statutes or rules relating to the licensure and regulation of psychedelic-assisted therapy centers;
 - e) is not the legitimate owner of the proposed premises or has not disclosed that other persons have ownership interests;
 - f) has not demonstrated financial responsibility sufficient to adequately meet the requirements of the proposed premises to be licensed; or
 - g) is unable to understand state laws or adopted rules relating to psilocybin products or services.
27. Prohibits a DHS employee from being charged with or prosecuted for possession of psilocybin products if the employee is acting in an official capacity as necessary to ensure compliance with and the enforcement of laws relating to psilocybin products or services.
28. Requires psychedelic-assisted therapy center license applications to include a copy of a fingerprint clearance card issued to the applicant and to:
- a) if a limited partnership, each general partner;
 - b) if a manager-managed limited liability company, each manager;
 - c) if a manager-managed limited liability company, each voting member;
 - d) if a corporation, each director and officer; or
 - e) an individual who holds a financial interest of at least 10 percent in the applying entity.
29. Prohibits psychedelic-assisted therapy centers from being located within 1,000 feet of a public or private K-12 school.
30. Allows 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.
31. Stipulates that, if a public or private K-12 school opens within 1,000 feet of a psychedelic-assisted therapy center, the center may remain at that location unless DHS revokes or refuses to renew licensure under another law or rule related to psilocybin products or services.

32. Limits the consumption of a psilocybin product to only at a licensed psychedelic-assisted therapy center and only under the supervision of a staff member and the indirect supervision of the medical director.
33. Prohibits an employee of a psychedelic-assisted therapy center from consuming psilocybin products during the administration, integration or preparation session that the employee is supervising.
34. Prohibits a licensee from employing a person under 21 years old on the premises of a psychedelic-assisted therapy center.
35. Allows DHS, during an inspection, to require proof from an employee or licensee that a person working at a psychedelic-assisted therapy center is at least 21 years old.
36. Allows DHS to require a person that fails to provide acceptable proof of age to immediately cease any activity and leave the premises until receipt of proof of age.
37. Exempts, from the outlined age verification requirements, individuals temporarily on the premises of a psychedelic-assisted therapy center to make a service, maintenance or repair call or some other purpose independent of operations.
38. Specifies 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.

Psilocybin Control and Regulation Fund (Fund)

39. Establishes the Fund, consisting of fees and civil penalties collected through the regulation of psilocybin.
40. Specifies that monies in the Fund are continuously appropriated and exempt from lapsing.
41. Allows Fund monies to be used to provide grants for psilocybin clinical trials.

Miscellaneous

42. Contains a severability clause.
43. Defines terms.
44. Makes technical and conforming changes.
45. Becomes effective on the general effective date.

Amendments Adopted by Committee of the Whole

- Adds, to the list of potential appointments to the Board by the President of the Senate, an enrolled member of a Native American tribe in Arizona who is experienced in the use of psilocybin in culturally and spiritually significant ceremonies.

Senate Action

HHS 2/13/24 DP 7-0-0

Prepared by Senate Research
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