

HOUSE REPUBLICAN STAFF ANALYSIS

Bill:	House File 978	House Committee:	PASSED on 3/27/25 (23-0)
Committee:	Ways & Means	House Floor:	
Floor Manager:	Rep. Wills	Senate Floor:	
Date:	April 21, 2025	Governor:	
Staff:	Kristi Kious (2-5290)		

Psilocybin

- Provides for production of psilocybin and administration of psilocybin to persons age 21 and over with post-traumatic stress disorder.

Section by Section Analysis

Section 1 – Prohibited acts — manufacture, delivery, possession — counterfeit substances, simulated controlled substances, imitation controlled substances — penalties (124F.401)

(New paragraph) This section legalizes the production, transportation, and use of psilocybin in accordance with new chapter 124F.

Section 2 – Definitions (124F.1)

(New section) This section provides definitions for new Iowa Code Chapter 124F.

Section 3 – Inventory control system (124F.2)

(New section) This section requires a psilocybin production establishment or a qualified therapy provider location to include an inventory control system that tracks psilocybin product in real time; maintains access records; and includes a video recording system. It requires a psilocybin production establishment or qualified therapy provider location to allow DHHS to access the inventory control system at any time.

Section 4 – Notice to prospective and current public employees (124F.3)

(New section) This section requires a state employer or political subdivision employer to inform an employee or prospective employee prior to assigning a duty related to the administration of the chapter that the employee's or prospective employee's job duties may require the employee or prospective employee to engage in conduct in violation of the criminal laws of the United States.

Section 5 – Psilocybin production establishment licensing board (124F.4)

(New section) This section creates within the department the psilocybin production establishment licensing board (board), with members appointed by the director of the department. Members of the board shall serve without compensation, although they may be reimbursed for actual expenses, and the director may remove a member of the board for cause, neglect of duty, inefficiency, or malfeasance. This section provides that the

board shall meet as called by the chairperson to review psilocybin license applications, conduct public hearings on applications, and make determinations on license applications.

Section 6 – Psilocybin production establishment—license (124F.5)

(New section) This section provides that a person shall not operate a production establishment without a license. It also sets forth criteria for revoking a license.

Section 7 – Psilocybin production establishment owners and directors—criminal background checks (124F.6)

(New section) This section provides that DCI shall conduct investigations of each applicant and report to DHHS.

Section 8 – License renewal (124F.7)

(New section) This section requires a person applying for a psilocybin production establishment license or license renewal to submit a proposed operating plan, including certain information about the facility, the facility's officers and employees, a security plan, a description of the inventory control system, and storage protocols. It requires psilocybin cultivation facilities and psilocybin testing laboratories to submit additional information particular to the type of psilocybin production establishment.

Section 9 – Operating plan (124F.8)

(New section) This section requires a psilocybin production establishment to operate in accordance with the operating plan submitted by the psilocybin production establishment and to inform the department prior to implementing any changes to the plan.

Section 10 – Psilocybin cultivation facilities—number of licenses (124F.9)

(New section) This section provides that the board shall not issue more than two licenses to operate a psilocybin cultivation facility.

Section 11 – Psilocybin production establishment agent—registration (124F.10)

(New section) This section prohibits a person from acting as a psilocybin production establishment or qualified therapy provider agent unless the person is registered as a psilocybin production establishment agent with the board. The section prohibits certain persons from acting as a psilocybin production establishment agent

Section 12 – Psilocybin production establishment—general operation requirements (124F.11)

(New section) This section requires a psilocybin production establishment to operate in a facility that is accessible only by an individual with a valid psilocybin production establishment registration card, except that a psilocybin production establishment may authorize a person who is at least 18 years of age who is not a psilocybin production establishment agent to access the psilocybin production establishment if the psilocybin production establishment tracks and monitors the individual at all times. A psilocybin production establishment shall not employ a person who is under 21 years of age or who has been convicted of a misdemeanor for drug distribution or any felony.

Section 13 – Inspections (124F.12)

(New section) This section provides that DHHS may inspect the records and facility of a psilocybin production establishment at any time during business hours.

Section 14 – Advertising (124F.13)

(New section) This section bans advertisement of psilocybin to the general public.

Section 15 – Psilocybin transportation (124F.14)

(New section) This section restricts who can transport psilocybin.

Section 16 – Psilocybin—excess and disposal (124F.15)

(New section) This section provides that a person disposing of psilocybin waste to render the psilocybin waste unusable and unrecognizable and to dispose of it in compliance with applicable state and federal law.

Section 17 – Psilocybin production establishment—local control (124F.16)

(New section) This section requires a local government to allow a psilocybin production establishment to operate in any zone designated for industrial or agricultural use, unless the local government has designated at least one industrial or agricultural zone for the operation of a psilocybin production establishment prior to the receipt of an application for the establishment of a psilocybin production establishment by the local government. It allows a psilocybin production establishment to operate on land that has not been zoned. It prohibits local governments from imposing certain restrictions on the establishment of a psilocybin production establishment.

Section 18 – Psilocybin cultivation facility—growing and harvesting. (124F.17)

(New section) This section requires a psilocybin cultivation facility to use unique identifiers to identify certain classifications of psilocybin.

Section 19 – Psilocybin cultivation facilities—sales (124F.18)

(New section) This section prohibits a psilocybin cultivation facility from selling any product other than a psilocybin product or educational material related to psilocybin and from selling to a person other than a qualified therapy provider or a registered agent of a qualified therapy provider.

Section 20 – Psilocybin cultivation facility—labeling (124F.19)

(New section) This section includes certain labeling requirements for psilocybin products.

Section 21 – Independent psilocybin testing laboratory—psilocybin and psilocybin product testing (124F.20)

(New section) This section requires the department to adopt rules for the testing of psilocybin by an independent psilocybin testing laboratory. It allows the department to require an independent psilocybin testing laboratory to test for a toxin if the department receives information about the presence of the toxin.

It prohibits a psilocybin production establishment from transferring psilocybin to a qualified therapy provider until a sample of the psilocybin has been tested by an independent psilocybin testing laboratory. This section allows the department to require an independent psilocybin testing laboratory to participate in a proficiency evaluation.

Section 22 – Independent psilocybin testing laboratory—inspections (124F.21)

(New section) This section provides that if an independent psilocybin testing laboratory determines that a psilocybin product is unsafe for human use, the section requires the independent psilocybin testing laboratory to inform the department and the psilocybin cultivation facility from which the batch originated, and the department shall place a hold on the sale and use of the psilocybin product until the department completes an investigation.

Section 23 – Psilocybin electronic verification system (124F.22)

(New section) This section requires the department, in consultation with the departments of agriculture and public safety, to adopt rules for the creation and operation of an electronic verification system. The electronic verification system shall, at a minimum, allow a medical psilocybin provider to engage in patient management; allow access by the department and the department of inspections, appeals, and licensing; create a record

each time a person accesses the system; and keeps a current record of the total number of individuals who have a psilocybin recommendation.

Section 24 – Psilocybin recommendation—limitations—expiration (124F.23)

(New section) This section limits the number of psilocybin recommendations in the state to 5,000 patients. An individual's psilocybin recommendation expires if the individual has not received treatment from a qualified therapy provider with psilocybin or a psilocybin product by the later of one year from the day a qualified medical psilocybin provider provided the recommendation or one year from the day of the individual's most recent administration of psilocybin or a psilocybin product by a qualified therapy provider.

Section 25 – Qualified medical psilocybin provider registration—continuing education—treatment recommendation (124F.24)

(New section) This section prohibits a person from recommending the use of psilocybin unless the person is a qualified medical psilocybin provider, defined in the bill as a physician and surgeon or osteopathic physician and surgeon, a physician assistant, an advanced registered nurse practitioner, or an advanced practice registered nurse who is registered by the department to recommend treatment with psilocybin. It requires the department to issue a qualified medical psilocybin provider registration card to an individual if the individual applies, provides a report detailing the completion of continuing education requirements regarding the use of psilocybin listed in the bill, provides evidence that the person holds an appropriate license, and pays an application fee.

Section 26 – Standard of care—provider not liable—no private right of action (124F.25)

(New section) This section provides that a qualified medical psilocybin provider shall not be subject to a professional, civil, or criminal penalty solely for violating a federal law or regulation that would prohibit recommending, prescribing, possessing, or dispensing psilocybin.

Section 27 – Nondiscrimination for medical care or government employment (124F.26)

(New section) This section prohibits discrimination against a person in the provision of medical care, including organ or tissue transplantation, on the basis of the usage of psilocybin as provided in the bill. It also prohibits the state or a political subdivision of the state from discriminating against an employee on the basis of the employee's use of psilocybin as provided in the bill except under certain circumstances, as provided in the bill.

Section 28 – Insurance—coverage requirement (124F.27)

(New section) This section does not require an insurer, a third-party administrator, or an employer to pay or reimburse for psilocybin.

Section 29 – Approved drugs (124F.28)

(New section) This section provides that the bill does not restrict the prescription, distribution, or dispensing of a product that the United States food and drug administration has approved.

Section 30 – Qualified therapy provider registration—continuing education—psilocybin administration (124F.29)

(New section) This section provides that the department shall register a person as a qualified medical psilocybin therapist if the person submits an application, provides the address of the clinic where psilocybin will be administered, provides a report detailing the completion of continuing education requirements regarding the use of psilocybin listed in the bill, certifies that the individual has an inventory control system, provides evidence that person has an appropriate license, pays an application fee, and provides an emergency transport plan.

Section 31 – Qualified therapy provider agent—registration (124F.30)

(New section) This section prohibits an individual from acting as a qualified therapy provider agent unless the department registers them as a qualified therapy provider agent.

Section 32 – Reports (124F.31)

(New section) The section requires DHHS to submit a report to the general assembly on or before November 1, 2025, and annually by November 1 thereafter, regarding participation in the medical psilocybin program. The section also requires the department to submit a report regarding the medical efficacy of psilocybin to the general assembly, including recommendations, by June 1, 2028.

Section 33 – Enforcement (124F.32)

(New section) This section grants DHHS enforcement authority for the enforcement of the bill, including by disciplining licenses and registrations, imposing fees, and seizing and destroying psilocybin. The department shall not revoke a license or registration issued pursuant to the bill without first conducting a contested case proceeding.

A person who violates a provision of the bill for which another penalty is not provided is guilty of a simple misdemeanor punishable by a fine of \$100, except that a person who intentionally or knowingly violates a provision of the bill for which no other penalty is provided three or more times is guilty of a serious misdemeanor punishable by a fine of \$1,000.

Amendment Analysis

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This amendment makes several technical changes. Additionally, it allows the board to issue a provisional license to an applicant that does not yet know where the establishment will be located. The amendment also provides that a child cannot be removed from a home based solely upon a parent's possession of psilocybin. The amendment also directs HHS to conduct a study regarding the use of psychedelic compounds other than psilocybin in the treatment of medical conditions.

The amendment strikes section 24 of the bill that limited the program to 5,000 individuals and removes the requirement that patients have verified PTSD.

