

1 STATE OF OKLAHOMA

2 2nd Session of the 58th Legislature (2022)

3 HOUSE BILL 3414

By: Pae

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6 AS INTRODUCED

7 An Act relating to public health and safety;
8 providing for the establishment of statewide
9 investigational clinical trials; authorizing
10 physicians to serve as principal investigators for
11 clinical trials under certain circumstances;
12 directing investigators to adhere to certain rules
13 and regulations; permitting Oklahoma State Bureau of
14 Narcotics and Dangerous Drugs Control to inspect
15 facilities and certain samples; providing guidelines
16 for conducting clinical trials; providing exemptions
17 from criminal or civil penalties; permitting
18 Commissioner of Health to perform certain acts;
19 requiring clinical trials to comply with certain
20 standards; providing termination date; requiring
21 certain approval for continuation of clinical trials;
22 requiring submission of certain report; specifying
23 contents of report; directing promulgation of rules
24 by certain entities; providing for codification;
providing an effective date; and declaring an
emergency.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified
in the Oklahoma Statutes as Section 3600 of Title 63, unless there
is created a duplication in numbering, reads as follows:

A. Universities, institutions of higher education located in
Oklahoma, and research facilities that have entered into a

1 memorandum of agreement with a university or institution of higher
2 education located in Oklahoma are hereby authorized to conduct
3 scientific research and medical trials on psilocybin and psilocin
4 for the treatment of persons eighteen (18) years of age or older who
5 suffer from the following:

- 6 1. Post-traumatic stress disorder;
- 7 2. Treatment-resistant/refractory depression;
- 8 3. Treatment-resistant/refractory anxiety;
- 9 4. Treatment-resistant/refractory obsessive compulsive
10 disorder;
- 11 5. Traumatic brain injury;
- 12 6. Early stage dementia;
- 13 7. Palliative care;
- 14 8. End-of-life care;
- 15 9. Opioid use disorder; or
- 16 10. Moderate to severe chronic pain.

17 B. Each university and institution of higher education located
18 in Oklahoma shall be permitted to enter into no more than one
19 memorandum of agreement with a research facility for the purposes of
20 conducting research pursuant to this act.

21 C. In conducting such research as described in subsection A of
22 this section, the studies shall:

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1 1. Perform clinical trials on the therapeutic efficacy of using
2 psilocybin or psilocin in the treatment of the aforementioned
3 medical conditions;

4 2. Review the current literature regarding:

5 a. the safety and efficacy of using psilocybin or
6 psilocin in the treatment of the aforementioned
7 medical conditions, and

8 b. the access persons have to psilocybin and psilocin for
9 the treatment of the aforementioned medical
10 conditions; and

11 3. Examine the science of cultivation, synthesis, extraction,
12 and processing of psilocybin and psilocin as well as the fungi,
13 yeasts, and other naturally occurring source organisms of these
14 molecules.

15 D. 1. Eligible entities as described in subsection A of this
16 section shall apply to the State Department of Health for a license
17 prior to and for the purposes of growing, studying, processing,
18 and/or dispensing psilocybin containing fungi or other naturally
19 occurring source organisms, or studying, extracting, synthesizing,
20 and/or dispensing psilocybin or psilocin. The application shall
21 include:

22 a. the name and address of the research facility,

23 b. a one- to three-page research prospectus, and
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1 c. if part of a postsecondary institution, proper
2 certification from the institution's internal review
3 board if human trials are to be part of the research.

4 2. By submitting the application, the applicant acknowledges
5 and agrees that:

6 a. the information contained in the application may be
7 provided to law enforcement agencies,

8 b. the applicant and any entities contracting with the
9 applicant shall allow and fully cooperate with any
10 inspections and sampling the Department deems
11 necessary, and

12 c. the applicant shall, should its application be
13 approved, submit all required reports by the
14 applicable deadlines specified by the Department.

15 3. The Department shall collect a one-time nonrefundable fee of
16 Five Hundred Dollars (\$500.00) from the applicant at the time of
17 application, and the applicant shall, upon approval, register with
18 the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control
19 with a fee of Five Hundred Dollars (\$500.00), to be paid annually so
20 long as the research remains active. Denied applications for a
21 license may be resubmitted. The Department may waive the fee for
22 resubmitting applications. The Department may only reject an
23 application based upon failure to meet the criteria stated herein or
24 improper completion of the application.

1 4. A license issued pursuant to this act is valid for one (1)
2 year, effective from the approval date of this act, and may be
3 renewed if the licensee remains in good standing. The Department
4 may set a separate fee schedule for renewals of existing licenses.

5 5. Within fourteen (14) business days of receiving their State
6 Department of Health license and receipt of confirmation of Oklahoma
7 State Bureau of Narcotics and Dangerous Drugs Control registration,
8 cultivators of psilocybin- or psilocin-containing fungi or plants
9 shall also register with the Oklahoma Department of Agriculture,
10 Food, and Forestry (ODAFF). ODAFF registrations shall include:

- 11 a. the name and address of the cultivation facility,
- 12 b. a copy of the research prospectus submitted to the
13 State Department of Health, and
- 14 c. copies of the State Department of Health license and
15 Bureau registration;

16 6. The ODAFF shall collect a one-time nonrefundable fee of One
17 Hundred Dollars (\$100.00) from the cultivator licensee at the time
18 of registration.

19 7. Should the licensee change facility locations for the
20 cultivation, testing, synthesis, storage or dispensing of psilocybin
21 or psilocin, it shall report such changes within fourteen (14)
22 business days to the Department and to the Oklahoma State Bureau of
23 Narcotics and Dangerous Drugs Control.

1 8. The Department shall promulgate rules and regulations
2 necessary to implement the program authorized herein within ninety
3 (90) days of the effective date of this act.

4 9. Researchers and medical practitioners operating under a
5 valid license issued in accordance with this act shall not be
6 subject to arrest, prosecution, or any civil or administrative
7 penalty, for the possession, cultivation, synthesis, extraction, or
8 distribution of psilocybin and psilocin insofar as their conduct is
9 in compliance with the provisions of this act.

10 10. The State Department of Health may deny, revoke, or suspend
11 a license if the licensee violates any provisions of this act,
12 engages in fraud or deception with respect to any reporting
13 requirements stipulated by the State Department of Health or the
14 Bureau, refuses or fails to cooperate with an inspection, is no
15 longer operating within or under a memorandum of agreement with an
16 Oklahoma university or research facility, or refuses or fails to
17 provide any information required or requested by the State
18 Department of Health or the Bureau for purposes related to this act,
19 or refuses or fails to pay fees required under this act.

20 E. 1. A written certification shall be issued to persons
21 qualifying for participation in a clinical trial described herein.
22 Such written certification shall contain the following:

23 a. the name, address, and telephone number of the issuing
24 physician,

- b. the name and address of the patient issued the certification,
- c. the date on which the written certification was made,
- d. the signature of the physician,
- e. the quantity of psilocybin or psilocin to be dispensed, and
- f. the form of psilocybin or psilocin to be dispensed.

2. Such written certification issued pursuant to this act shall expire no later than one (1) year after its issuance unless such written certification specifies an earlier date of expiration.

F. Persons with a valid written certification for participation in a clinical trial as authorized by this act shall not be subject to arrest, prosecution, or any civil or administrative penalty, for the possession of psilocybin and psilocin insofar as their possession is in compliance with the provisions of this act. A person without a valid license as described in subsection D of this section, without a written certification for participation in a clinical trial as described in subsection E of this section, or otherwise not in compliance with the provisions of this act who is in possession of less than one and one-half (1.5) ounces of psilocybin- or psilocin-containing fungi or plants shall be subject to no more than a civil penalty of Four Hundred Dollars (\$400.00); however possession in amounts more than one and one-half (1.5) ounces of psilocybin- or psilocin-containing fungi or plants or

1 their unlawful distribution shall remain subject to the penalties as
2 stated under this act.

3 G. In any prosecution involving psilocybin or psilocin as
4 those terms are defined in subsection C of Section 2-204 of Title 63
5 of the Oklahoma Statutes, it shall be an affirmative defense that
6 the person is in possession of psilocybin or psilocin pursuant to
7 this act. Researchers so charged shall file a copy of their State
8 Department of Health and Bureau licenses pursuant to this act with
9 the court of jurisdiction at least ten (10) days prior to trial.
10 Such licenses shall be presumptive evidence that the psilocybin or
11 psilocin was possessed pursuant to this act. Persons participating
12 in a clinical trial who are so charged shall file a copy of their
13 written certification pursuant to this act with the court of
14 jurisdiction at least ten (10) days prior to trial. Such written
15 certification shall be presumptive evidence that psilocybin or
16 psilocin was possessed pursuant to this act.

17 H. Study researchers shall submit a written report containing
18 the results of the studies conducted under this act and any
19 recommendations for legislative or other actions not later than
20 December 1, 2025.

21 I. Investigating entities shall ensure any protected health
22 information collected during the clinical trials done in accordance
23 with this act does not personally identify any individual.

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1 J. The State Department of Health, the Oklahoma State Bureau
2 of Narcotics and Dangerous Drugs Control, the Oklahoma Department of
3 Agriculture, Food, and Forestry, and any other state agency with
4 access to the research programs authorized by this act shall not
5 release or allow to be released through inaction any protected
6 health information. The protected health information of clinical
7 trial participants shall be exempt from the Oklahoma Open Records
8 Act.

9 SECTION 2. This act shall become effective July 1, 2022.

10 SECTION 3. It being immediately necessary for the preservation
11 of the public peace, health or safety, an emergency is hereby
12 declared to exist, by reason whereof this act shall take effect and
13 be in full force from and after its passage and approval.

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