

1 ENGROSSED HOUSE
2 BILL NO. 3414

By: Pae, Phillips, Rosecrants,
McEntire, Martinez,
Dempsey, Dollens, Humphrey,
Echols, Talley, McDugle,
Davis, Manger, Walke,
Brewer, and Munson of the
House

and

Paxton of the Senate

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10 An Act relating to public health and safety;
11 authorizing certain governmental entities to conduct
12 research or medical trials related to psilocybin and
13 psilocin; specifying certain medical conditions for
14 which research or clinical trials authorized;
15 authorizing universities or institutions of higher
16 education to enter into memoranda of agreement;
17 imposing requirements with respect to studies;
18 requiring registration with the Oklahoma State
19 Department of Health; ~~requiring license;~~ prescribing
20 requirements for registration information; providing
21 for nonrefundable fee; specifying fee amount;
22 providing for duration of registration; requiring
23 additional registration with the Oklahoma Department
24 of Agriculture, Food, and Forestry; prescribing
25 content of registration; authorizing nonrefundable
26 fee; prescribing fee amount; requiring administrative
27 rules; providing immunity for certain persons
28 conducting activity pursuant to valid ~~license~~
29 **registration**; providing for written certifications;
30 prescribing content thereof; providing for
expiration of certifications; providing immunity to
certain persons for participation in clinical
trials; providing for certain quantities of
substance as basis for immunity; providing for
applicability of Uniform Controlled Dangerous
Substances Act; providing for assertion of
affirmative defense; providing for effect of
registrations; requiring written reports; imposing
deadline; providing for confidentiality of

1 certain personal information; requiring enumerated
2 agencies to maintain confidentiality with respect to
3 information; and providing for codification.
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5 BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

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

9 A. Universities, institutions of higher education located in
10 Oklahoma, and research facilities that have entered into a
11 memorandum of agreement with a university or institution of higher
12 education located in Oklahoma are hereby authorized to conduct
13 scientific research and medical trials on psilocybin and psilocin
14 for the treatment of persons eighteen (18) years of age or older who
15 ~~suffer from~~ experience any of the following:

- 16 1. Post-traumatic stress disorder;
- 17 2. Treatment-resistant/refractory depression;
- 18 3. Treatment-resistant/refractory anxiety;
- 19 4. Treatment-resistant/refractory obsessive compulsive
20 disorder;
- 21 5. Traumatic brain injury;
- 22 6. Early stage dementia;
- 23 7. Palliative care;
- 24 8. End-of-life care;

1 9. Opioid use disorder; or

2 10. Moderate to severe chronic pain.

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

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

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

12 2. Review the current literature regarding:

13 a. the safety and efficacy of using psilocybin or
14 psilocin in the treatment of the aforementioned
15 medical conditions, and

16 b. the access persons have to psilocybin and psilocin for
17 the treatment of the aforementioned medical
18 conditions; and

19 3. Examine the science of cultivation, synthesis, extraction,
20 and processing of psilocybin and psilocin as well as the fungi,
21 yeasts, and other naturally occurring source organisms of these
22 molecules.

23 D. 1. Eligible entities as described in subsection A of this
24 section shall register with the State Department of Health ~~for a~~

1 ~~license~~ prior to and for the purposes of growing, studying,
2 processing, and/or dispensing psilocybin-containing fungi or other
3 naturally occurring source organisms, or studying, extracting,
4 synthesizing, and/or dispensing psilocybin or psilocin. The
5 registration submission information shall include:

- 6 a. the name and address of the research facility,
- 7 b. a ~~research-~~university- or institution of higher
8 education-approved research prospectus, and
- 9 c. certification from the university's or institution of
10 higher education's institutional review board if human
11 trials are part of the research.

12 2. By registering, the registrant acknowledges and agrees that:

- 13 a. the information contained in the registration
14 submissions may be provided to law enforcement
15 agencies, and
- 16 b. the registrant shall submit an annual report detailing
17 compliance with annual regulation requirements.

18 3. The Department shall collect a one-time nonrefundable fee of
19 Five Hundred Dollars (\$500.00) from the registrant at the time of
20 application, and the applicant shall, upon completion of
21 registration, register with the Oklahoma State Bureau of Narcotics
22 and Dangerous Drugs Control with a fee of Five Hundred Dollars
23 (\$500.00), to be paid annually so long as the research remains
24 active.

1 4. Registration pursuant to this act is valid for one (1) year,
2 effective from confirmation and of receipt of both the State
3 Department of Health registration and Oklahoma State Bureau of
4 Narcotics and Dangerous Drugs Control registration.

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

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

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

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

1 8. The State Department of Health shall promulgate rules and
2 regulations necessary to implement the program authorized herein.

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

9 E. 1. A written certification shall be issued to persons
10 qualifying for participation by a physician participating in a
11 clinical trial described herein. Such written certification shall
12 contain the following:

- 13 a. the name, address, and telephone number of the issuing
14 physician,
- 15 b. the name and address of the patient issued the
16 certification,
- 17 c. the date on which the written certification was made,
- 18 d. the signature of the physician,
- 19 e. the quantity of psilocybin or psilocin to be
20 dispensed, and
- 21 f. the form of psilocybin or psilocin to be dispensed.

22 2. Such written certification issued pursuant to this act shall
23 expire one (1) year after its issuance unless such written
24 certification specifies an earlier date of expiration.

1 F. Persons with a valid written certification for participation
2 in a clinical trial as authorized by this act shall not be subject
3 to arrest, prosecution, or any civil or administrative penalty, for
4 the possession of psilocybin and psilocin insofar as their
5 possession is in compliance with the provisions of this act. A
6 person without a registration ~~license~~ as described in subsection D
7 of this section, without a written certification for participation
8 in a clinical trial as described in subsection E of this section, or
9 otherwise not in compliance with the provisions of this act who is
10 in possession of less than one and one-half (1.5) ounces of
11 psilocybin- or psilocin-containing fungi or plants shall be subject
12 to no more than a civil penalty of Four Hundred Dollars (\$400.00);
13 however possession in amounts more than one and one-half (1.5)
14 ounces of psilocybin- or psilocin-containing fungi or plants or
15 their unlawful distribution shall remain subject to the penalties as
16 stated under the Uniform Controlled Dangerous Substances Act.

17 G. In any prosecution involving psilocybin or psilocin as
18 those terms are defined in subsection C of Section 2-204 of Title 63
19 of the Oklahoma Statutes, it shall be an affirmative defense that
20 the person is in possession of psilocybin or psilocin pursuant to
21 this act. Researchers so charged shall file a copy of their State
22 Department of Health registration and Bureau registration pursuant
23 to this act with the court of jurisdiction at least ten (10) days
24 prior to trial. Such registrations shall be presumptive evidence

1 that the psilocybin or psilocin was possessed pursuant to this act.
2 Persons participating in a clinical trial who are so charged shall
3 file a copy of their written certification pursuant to this act with
4 the court of jurisdiction at least ten (10) days prior to trial.
5 Such written certification shall be presumptive evidence that
6 psilocybin or psilocin was possessed pursuant to this act.

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

11 I. Researching entities shall ensure any protected health
12 information collected during the clinical trials done in accordance
13 with this act does not personally identify any individual.

14 J. The State Department of Health, the Oklahoma State Bureau
15 of Narcotics and Dangerous Drugs Control, the Oklahoma Department of
16 Agriculture, Food, and Forestry, and any other state agency with
17 access to the research programs authorized by this act shall not
18 release or allow to be released through inaction any protected
19 health information. The protected health information of clinical
20 trial participants shall be exempt from the Oklahoma Open Records
21 Act.

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1 Passed the House of Representatives the 7th day of March, 2022.

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4 Presiding Officer of the House
of Representatives

5 Passed the Senate the ____ day of _____, 2022.

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9 Presiding Officer of the Senate