

1 ENGROSSED HOUSE
2 BILL NO. 2107

By: Pae, Talley, Hefner and
Deck of the House

3 and

4 Brooks of the Senate
5
6

7 [controlled dangerous substances - Oklahoma
8 Psilocybin Research Pilot Program - scientific
9 research related to psilocybin and psilocyn -
10 memoranda of agreement - studies - registration -
11 nonrefundable fees - written certifications -
12 immunity - written reports - providing for
13 confidentiality of personal information -
14 promulgation of rules - codification - effective
15 date]
16
17

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

19 SECTION 1. NEW LAW A new section of law to be codified
20 in the Oklahoma Statutes as Section 2-811 of Title 63, unless there
21 is created a duplication in numbering, reads as follows:

22 A. This act shall be known and may be cited as the "Oklahoma
23 Psilocybin Research Pilot Program".
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1 B. A university or other institution of higher education
2 located in this state, or a research facility that has entered into
3 a memorandum of agreement with a university or institution of higher
4 education located in this state, may conduct scientific research on
5 psilocybin and psilocyn for the treatment of persons eighteen (18)
6 years of age or older who experience any of the following medical
7 conditions:

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

19 C. The university or institution of higher education may enter
20 into no more than one memorandum of agreement with a research
21 facility for the purposes of conducting scientific research under
22 this section.

23 D. In conducting such scientific research as described in
24 subsection B of this section, the studies shall:

1 1. Study the therapeutic efficacy of using psilocybin or
2 psilocyn in the treatment of the medical conditions listed in
3 subsection B of this section;

4 2. Review the current literature regarding:

5 a. the safety and efficacy of using psilocybin or
6 psilocyn in the treatment of the medical conditions
7 listed in subsection B of this section, and

8 b. the access persons have to psilocybin and psilocyn for
9 the treatment of the medical conditions listed in
10 subsection B of this section; and

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

15 E. 1. Eligible entities as described in subsection B of this
16 section shall register with the State Department of Health and the
17 Oklahoma Department of Agriculture, Food, and Forestry prior to and
18 for the purposes of growing, studying, processing, or dispensing
19 psilocybin-containing fungi or other naturally occurring source
20 organisms, or studying, extracting, synthesizing, or dispensing
21 psilocybin or psilocyn. The registration submission information
22 shall include:

23 a. the name and address of the research facility,
24

- 1 b. a prospectus approved by a university or other
2 institution of higher education, and
3 c. certification from the institutional review board of
4 the university or institution of higher education if
5 human trials are part of the research.

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

- 7 a. the information contained in the registration
8 submissions may be provided to law enforcement
9 agencies, and
10 b. the registrant shall submit an annual report detailing
11 compliance with annual regulation requirements.

12 3. The State Department of Health shall collect a one-time,
13 nonrefundable fee of Five Hundred Dollars (\$500.00) from the
14 registrant at the time of registration and the Oklahoma Department
15 of Agriculture, Food, and Forestry shall collect a one-time
16 nonrefundable fee of One Hundred Dollars (\$100.00) from the
17 registrant at the time of registration. The registrant shall, upon
18 completion of registration with the State Department of Health and
19 the Oklahoma Department of Agriculture, Food, and Forestry, register
20 with the Oklahoma State Bureau of Narcotics and Dangerous Drugs
21 Control as provided by Section 2-301 et seq. of Title 63 of the
22 Oklahoma Statutes annually for as long as the research remains
23 active.

1 4. Registration under this subsection is valid for one (1)
2 year, effective upon confirmation and receipt of all registrations
3 required by this subsection. Notwithstanding the registration fee
4 listed in Section 2-303 of Title 63 of the Oklahoma Statutes, the
5 registration required by this subsection shall satisfy and supersede
6 all other registration and reporting requirements otherwise imposed
7 by state law.

8 5. Should the registrant change facility locations for the
9 cultivation, testing, synthesis, storage, or dispensing of
10 psilocybin or psilocyn, it shall report such changes within fourteen
11 (14) business days to the State Department of Health, the Oklahoma
12 Department of Agriculture, Food, and Forestry, and the Oklahoma
13 State Bureau of Narcotics and Dangerous Drugs Control.

14 F. 1. A written certification shall be issued to persons
15 qualifying for participation in the pilot program described in this
16 section by a physician participating in the pilot program. The
17 written certification shall contain the following:

- 18 a. the name, address, and telephone number of the issuing
19 physician,
- 20 b. the name and address of the patient to whom the
21 written certification is issued,
- 22 c. the date on which the written certification was made,
- 23 d. the signature of the physician,

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1 e. the quantity of psilocybin or psilocyn to be
2 dispensed, and

3 f. the form of psilocybin or psilocyn to be dispensed.

4 2. The written certification issued under this subsection shall
5 expire one (1) year after its issuance unless the written
6 certification specifies an earlier date of expiration.

7 G. 1. A scientific researcher or physician operating under a
8 valid registration issued in accordance with this section shall not
9 be subject to arrest, prosecution, or any civil or administrative
10 penalty for the possession, cultivation, synthesis, extraction, or
11 distribution of psilocybin or psilocyn insofar as the scientific
12 researcher's or physician's conduct is in compliance with the
13 provisions of this section.

14 2. A patient participating in the pilot program under a valid
15 written certification issued in accordance with this section shall
16 not be subject to arrest, prosecution, or any civil or
17 administrative penalty for the use or possession of psilocybin or
18 psilocyn insofar as the patient's conduct is in compliance with the
19 provisions of this section.

20 3. In any prosecution involving possession of psilocybin or
21 psilocyn as those terms are specified in subsection C of Section 2-
22 204 of Title 63 of the Oklahoma Statutes, it shall be an affirmative
23 defense if a person can demonstrate by clear and convincing evidence
24 that he or she has one or more of the qualifying medical conditions

1 or circumstances listed in subsection B of this section. This
2 subsection shall not be understood to be the decriminalization of
3 psilocybin or psilocyn.

4 H. Researching entities shall submit a written report to the
5 President Pro Tempore of the Oklahoma State Senate and the Speaker
6 of the Oklahoma House of Representatives containing the results of
7 the studies conducted under this section and any recommendations for
8 legislative or other actions not later than December 1, 2026.

9 I. Researching entities shall ensure any protected health
10 information collected during the pilot program done in accordance
11 with this section does not personally identify any individual.

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

20 K. The State Commissioner of Health, the State Board of
21 Agriculture, and the Director of the Oklahoma State Bureau of
22 Narcotics and Dangerous Drugs Control shall promulgate rules
23 necessary to implement the program authorized in this section.

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1 SECTION 2. AMENDATORY 63 O.S. 2021, Section 2-303, is
2 amended to read as follows:

3 Section 2-303. A. The Director of the Oklahoma State Bureau of
4 Narcotics and Dangerous Drugs Control shall register an applicant to
5 own a medical facility as described in subsection C of Section 2-302
6 of this title, or to manufacture, distribute, dispense, prescribe,
7 administer or use for scientific purposes controlled dangerous
8 substances included in Schedules I through V of Section 2-101 et
9 seq. of this title unless the Director determines that the issuance
10 of such registration is inconsistent with the public interest. In
11 determining the public interest, the following factors shall be
12 considered:

13 1. Maintenance of effective controls against diversion of
14 particular controlled dangerous substances and any Schedule I or II
15 substance compounded therefrom into other than legitimate medical,
16 scientific or industrial channels, including examination of the
17 fitness of his or her employees or agents to handle dangerous
18 substances;

19 2. Compliance with applicable state and local law;

20 3. Has been found guilty of, entered a plea of guilty or nolo
21 contendere to a charge under the Uniform Controlled Dangerous
22 Substances Act or any other state or federal law relating to any
23 substance defined herein as a controlled dangerous substance or any
24 felony under the laws of any state or the United States;

1 4. Furnishing by the applicant false or fraudulent material
2 information in any application filed under Section 2-101 et seq. of
3 this title;

4 5. Past experience in the manufacture, distribution,
5 dispensing, prescribing, administering or use for scientific
6 purposes of controlled dangerous substances, and the existence in
7 the establishment of effective controls against diversion;

8 6. Denial, suspension or revocation of the applicant's federal
9 registration to manufacture, distribute or dispense controlled
10 dangerous substances as authorized by federal law; and

11 7. Such other factors as may be relevant to and consistent with
12 the public health and safety.

13 Nothing herein shall be deemed to require individual licensed
14 pharmacists to register under the provisions of the Uniform
15 Controlled Dangerous Substances Act.

16 B. Registration granted under subsection A of this section
17 shall not entitle a registrant to manufacture, distribute, dispense,
18 prescribe, administer or use for scientific purposes controlled
19 dangerous substances in Schedule I or II other than those specified
20 in the registration.

21 C. Practitioners shall be registered to dispense, prescribe,
22 administer or use for scientific purposes controlled dangerous
23 substances in Schedules II through V if they are authorized to carry
24 on their respective activities under the laws of this state. A

1 registration application by a practitioner who wishes to conduct
2 research with Schedule I substances shall be accompanied by evidence
3 of the applicant's federal registration to conduct such activity and
4 shall be referred to the Medical Research Commission for advice.
5 The Medical Research Commission shall promptly advise the Director
6 concerning the qualifications of each practitioner requesting such
7 registration. Registration for the purpose of bona fide research or
8 of use for scientific purposes with Schedule I substances by a
9 practitioner deemed qualified by the Medical Research Commission may
10 be denied only on a ground specified in subsection A of Section 2-
11 304 of this title or if there are reasonable grounds to believe that
12 the applicant will abuse or unlawfully transfer such substances or
13 fail to safeguard adequately such applicant's supply of such
14 substances against diversion from legitimate medical or scientific
15 use.

16 D. 1. The Director shall initially permit persons to register
17 who own or operate any establishment engaged in the manufacture,
18 distribution, dispensing, prescribing, administering or use for
19 scientific purposes of any controlled dangerous substances prior to
20 June 4, 1991, and who are registered or licensed by the state. Fees
21 for registration under this section shall be as follows:

22 Practitioners and mid-level

23 practitioners

\$140.00 per year

24 of registration

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|----|-------------------------------------|-----------------|-----------------|
| 1 | Home Care Agencies, Hospices & | | |
| 2 | Home Care Services | \$140.00 | annually |
| 3 | Medical Facility Owners | \$300.00 | annually |
| 4 | Distributors | \$300.00 | annually |
| 5 | Manufacturers | \$500.00 | annually |
| 6 | Manufacturer, Wholesaler, or | | |
| 7 | Distributor of drug products | | |
| 8 | containing pseudoephedrine | | |
| 9 | or phenylpropanolamine | \$300.00 | annually |
| 10 | <u>Researchers of psilocybin or</u> | | |
| 11 | <u>psilocyn</u> | <u>\$140.00</u> | <u>annually</u> |

12 2. A registrant shall be required to pay double the amount of
13 the above-listed fee for any renewal of registration received more
14 than thirty (30) days late.

15 3. A Ten Dollar (\$10.00) fee shall be charged for a duplicate
16 registration certificate.

17 E. Compliance by manufacturers and distributors with the
18 provisions of the Federal Controlled Substances Act, 21 U.S.C.,
19 Section 801 et seq., respecting registration, excluding fees, shall
20 be deemed sufficient to qualify for registration under ~~this act~~
21 Section 2-101 et seq. of this title.

22 SECTION 3. This act shall become effective November 1, 2023.

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1 Passed the House of Representatives the 9th day of March, 2023.

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3 _____
4 Presiding Officer of the House
5 of Representatives

6 Passed the Senate the ____ day of _____, 2023.

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8 _____
9 Presiding Officer of the Senate