

1 **HOUSE OF REPRESENTATIVES - FLOOR VERSION**

2 STATE OF OKLAHOMA

3 1st Session of the 59th Legislature (2023)

4 COMMITTEE SUBSTITUTE
5 FOR
6 HOUSE BILL NO. 2107

By: Pae

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8 COMMITTEE SUBSTITUTE

9 An Act relating to controlled dangerous substances;
10 creating the Oklahoma Psilocybin Research Pilot
11 Program; authorizing certain entities to conduct
12 scientific research related to psilocybin and
13 psilocyn; specifying certain uses for which
14 scientific research is authorized; limiting number of
15 memoranda of agreement that universities or
16 institutions of higher education may enter into;
17 imposing requirements with respect to studies;
18 requiring registration with the State Department of
19 Health and the Oklahoma Department of Agriculture,
20 Food, and Forestry; prescribing requirements for
21 registration information; providing for specified
22 nonrefundable fees; requiring additional registration
23 with the Oklahoma State Bureau of Narcotics and
24 Dangerous Drugs Control; stipulating duration of
 registration; requiring certain notification of
 change of facility location; requiring written
 certifications for Pilot Program participants;
 prescribing content of written certifications;
 providing for expiration of certifications; providing
 immunity to persons conducting or participating in
 the Pilot Program; requiring submission of written
 reports by certain date; providing for
 confidentiality of certain personal information;
 requiring specified agencies to maintain
 confidentiality with respect to information;
 directing promulgation of rules; amending 63 O.S.
 2021, Section 2-303, which relates to Oklahoma State
 Bureau of Narcotics and Dangerous Drugs Control

1 registration; creating certain fee; providing for
2 codification; and providing an effective date.

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

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

8 A. This act shall be known and may be cited as the "Oklahoma
9 Psilocybin Research Pilot Program".

10 B. A university or other institution of higher education
11 located in this state, or a research facility that has entered into
12 a memorandum of agreement with a university or institution of higher
13 education located in this state, may conduct scientific research on
14 psilocybin and psilocyn for the treatment of persons eighteen (18)
15 years of age or older who experience any of the following medical
16 conditions:

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

- 1 8. End-of-life care;
- 2 9. Opioid use disorder; or
- 3 10. Moderate to severe chronic pain.

4 C. The university or institution of higher education may enter
5 into no more than one memorandum of agreement with a research
6 facility for the purposes of conducting scientific research under
7 this section.

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

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

13 2. Review the current literature regarding:

14 a. the safety and efficacy of using psilocybin or
15 psilocyn in the treatment of the medical conditions
16 listed in subsection B of this section, and

17 b. the access persons have to psilocybin and psilocyn for
18 the treatment of the medical conditions listed in
19 subsection B of this section; and

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

1 E. 1. Eligible entities as described in subsection B of this
2 section shall register with the State Department of Health and the
3 Oklahoma Department of Agriculture, Food, and Forestry prior to and
4 for the purposes of growing, studying, processing, or dispensing
5 psilocybin-containing fungi or other naturally occurring source
6 organisms, or studying, extracting, synthesizing, or dispensing
7 psilocybin or psilocyn. The registration submission information
8 shall include:

- 9 a. the name and address of the research facility,
- 10 b. a prospectus approved by a university or other
11 institution of higher education, and
- 12 c. certification from the institutional review board of
13 the university or institution of higher education if
14 human trials are part of the research.

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

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

21 3. The State Department of Health shall collect a one-time,
22 nonrefundable fee of Five Hundred Dollars (\$500.00) from the
23 registrant at the time of registration and the Oklahoma Department
24 of Agriculture, Food, and Forestry shall collect a one-time

1 nonrefundable fee of One Hundred Dollars (\$100.00) from the
2 registrant at the time of registration. The registrant shall, upon
3 completion of registration with the State Department of Health and
4 the Oklahoma Department of Agriculture, Food, and Forestry, register
5 with the Oklahoma State Bureau of Narcotics and Dangerous Drugs
6 Control as provided by Section 2-301 et seq. of Title 63 of the
7 Oklahoma Statutes annually for as long as the research remains
8 active.

9 4. Registration under this subsection is valid for one (1)
10 year, effective upon confirmation and receipt of all registrations
11 required by this subsection. Notwithstanding the registration fee
12 listed in Section 2 of this act, the registration required by this
13 subsection shall satisfy and supersede all other registration and
14 reporting requirements otherwise imposed by state law.

15 5. Should the registrant change facility locations for the
16 cultivation, testing, synthesis, storage, or dispensing of
17 psilocybin or psilocyn, it shall report such changes within fourteen
18 (14) business days to the State Department of Health, the Oklahoma
19 Department of Agriculture, Food, and Forestry, and the Oklahoma
20 State Bureau of Narcotics and Dangerous Drugs Control.

21 F. 1. A written certification shall be issued to persons
22 qualifying for participation in the pilot program described in this
23 section by a physician participating in the pilot program. The
24 written certification shall contain the following:

- a. the name, address, and telephone number of the issuing physician,
- b. the name and address of the patient to whom the written certification is issued,
- c. the date on which the written certification was made,
- d. the signature of the physician,
- e. the quantity of psilocybin or psilocyn to be dispensed, and
- f. the form of psilocybin or psilocyn to be dispensed.

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

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

2. A patient participating in the pilot program under a valid written certification issued in accordance with this section shall not be subject to arrest, prosecution, or any civil or administrative penalty for the use or possession of psilocybin or

1 psilocyn insofar as the patient's conduct is in compliance with the
2 provisions of this section.

3 3. In any prosecution involving possession of psilocybin or
4 psilocyn as those terms are specified in subsection C of Section 2-
5 204 of Title 63 of the Oklahoma Statutes, it shall be an affirmative
6 defense if a person can demonstrate by clear and convincing evidence
7 that he or she has one or more of the qualifying medical conditions
8 or circumstances listed in subsection B of this section. This
9 subsection shall not be understood to be the decriminalization of
10 psilocybin or psilocyn.

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

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

19 J. The State Department of Health, the Oklahoma Department of
20 Agriculture, Food, and Forestry, the Oklahoma State Bureau of
21 Narcotics and Dangerous Drugs Control, and any other state agency
22 with access to the research programs authorized by this section
23 shall not release or allow to be released through inaction any
24 protected health information. The protected health information of

1 pilot program participants shall be exempt from the Oklahoma Open
2 Records Act.

3 K. The State Commissioner of Health, the State Board of
4 Agriculture, and the Director of the Oklahoma State Bureau of
5 Narcotics and Dangerous Drugs Control shall promulgate rules
6 necessary to implement the program authorized in this section.

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

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

19 1. Maintenance of effective controls against diversion of
20 particular controlled dangerous substances and any Schedule I or II
21 substance compounded therefrom into other than legitimate medical,
22 scientific or industrial channels, including examination of the
23 fitness of his or her employees or agents to handle dangerous
24 substances;

1 2. Compliance with applicable state and local law;

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

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

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

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

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

19 Nothing herein shall be deemed to require individual licensed
20 pharmacists to register under the provisions of the Uniform
21 Controlled Dangerous Substances Act.

22 B. Registration granted under subsection A of this section
23 shall not entitle a registrant to manufacture, distribute, dispense,
24 prescribe, administer or use for scientific purposes controlled

1 dangerous substances in Schedule I or II other than those specified
2 in the registration.

3 C. Practitioners shall be registered to dispense, prescribe,
4 administer or use for scientific purposes controlled dangerous
5 substances in Schedules II through V if they are authorized to carry
6 on their respective activities under the laws of this state. A
7 registration application by a practitioner who wishes to conduct
8 research with Schedule I substances shall be accompanied by evidence
9 of the applicant's federal registration to conduct such activity and
10 shall be referred to the Medical Research Commission for advice.
11 The Medical Research Commission shall promptly advise the Director
12 concerning the qualifications of each practitioner requesting such
13 registration. Registration for the purpose of bona fide research or
14 of use for scientific purposes with Schedule I substances by a
15 practitioner deemed qualified by the Medical Research Commission may
16 be denied only on a ground specified in subsection A of Section 2-
17 304 of this title or if there are reasonable grounds to believe that
18 the applicant will abuse or unlawfully transfer such substances or
19 fail to safeguard adequately such applicant's supply of such
20 substances against diversion from legitimate medical or scientific
21 use.

22 D. 1. The Director shall initially permit persons to register
23 who own or operate any establishment engaged in the manufacture,
24 distribution, dispensing, prescribing, administering or use for

1 scientific purposes of any controlled dangerous substances prior to
2 June 4, 1991, and who are registered or licensed by the state. Fees
3 for registration under this section shall be as follows:

4 Practitioners and mid-level

5 practitioners \$140.00 per year
6 of registration

7 Home Care Agencies, Hospices &

8 Home Care Services \$140.00 annually

9 Medical Facility Owners \$300.00 annually

10 Distributors \$300.00 annually

11 Manufacturers \$500.00 annually

12 Manufacturer, Wholesaler, or

13 Distributor of drug products

14 containing pseudoephedrine

15 or phenylpropanolamine \$300.00 annually

16 Researchers of psilocybin or

17 psilocyn \$140.00 annually

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

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

23 E. Compliance by manufacturers and distributors with the
24 provisions of the Federal Controlled Substances Act, 21 U.S.C.,

1 Section 801 et seq., respecting registration, excluding fees, shall
2 be deemed sufficient to qualify for registration under ~~this act~~
3 Section 2-101 et seq. of this title.

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

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6 COMMITTEE REPORT BY: COMMITTEE ON ALCOHOL, TOBACCO AND CONTROLLED
7 SUBSTANCES, dated 02/15/2023 - DO PASS, As Amended.

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