STATE OF OKLAHOMA

2nd Session of the 58th Legislature (2022)

COMMITTEE SUBSTITUTE
FOR ENGROSSED
HOUSE 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

COMMITTEE SUBSTITUTE

An Act relating to controlled dangerous substances; authorizing certain entities to conduct research and clinical trials related to psilocybin and psilocin; specifying certain uses for which research or clinical trials are authorized; limiting number of memoranda of agreement that universities or institutions of higher education may enter into; imposing requirements with respect to studies; requiring registration with the State Department of Health and the Oklahoma Department of Agriculture, Food, and Forestry; prescribing requirements for registration information; providing for specified nonrefundable fees; requiring additional registration with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control; stipulating duration of registration; requiring certain notification of change of facility location; requiring written certifications for clinical trial participants; prescribing content of written certifications; providing for expiration of certifications; providing immunity to persons conducting or participating in research or clinical trials; 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 registration; creating certain fee; and providing for codification.

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 2-811 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. A university or other institution of higher education located in this state, or a research facility that has entered into a memorandum of agreement with a university or institution of higher education located in this state, may conduct scientific research and clinical trials on persons eighteen (18) years of age or older to study the use of psilocybin for palliative care or end-of-life care or for treatment of the following medical conditions:

1. Post-traumatic stress disorder;

2. Treatment-resistant/refractory depression;

3. Treatment-resistant/refractory anxiety;

4. Treatment-resistant/refractory obsessive-compulsive disorder;

5. Traumatic brain injury;

6. Early stage dementia;

7. Opioid use disorder; or

8. Moderate to severe chronic pain.

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

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

1. Perform clinical trials on the efficacy of using psilocybin or psilocin for palliative care or end-of life care or in the treatment of the medical conditions listed in subsection A of this section;

2. Review the current literature regarding:

a. the safety and efficacy of using psilocybin or psilocin for palliative care or end-of life care or in the treatment of the medical conditions listed in subsection A of this section, and

b. the access persons have to psilocybin and psilocin for palliative care or end-of life care or in the treatment of the medical conditions listed in subsection A of this section; and

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

D. 1. Eligible entities as described in subsection A of this section shall register with the State Department of Health and the Oklahoma Department of Agriculture, Food, and Forestry prior to and for the purposes of growing, studying, processing, or dispensing psilocybin-containing fungi or other naturally occurring source organisms, or studying, extracting, synthesizing, or dispensing psilocybin or psilocin. The registration submission information shall include:

a. the name and address of the research facility,

b. a prospectus approved by a university or other institution of higher education, and

c. certification from the institutional review board of the university or institution of higher education if human trials are part of the research.

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

a. the information contained in the registration submissions may be provided to law enforcement agencies, and

b. the registrant shall submit an annual report detailing compliance with annual regulation requirements.

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

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

4. Registration under this subsection is valid for one year, effective upon confirmation and receipt of the final of the three registrations required by this subsection.

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

E. 1. A written certification shall be issued to persons qualifying for participation in a clinical trial described in this section by a physician participating in the clinical trial. The 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 issued the written 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. The written certification issued under this subsection shall expire one year after the date of its issuance unless the written certification specifies an earlier date of expiration.

F. 1. A 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 psilocin as long as the researcher's or physician's conduct is in compliance with the provisions of this section.

2. A patient participating in a clinical trial 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 psilocin as long as the patient's conduct is in compliance with the provisions of this section.

G. Researching entities shall submit a written report to the President Pro Tempore of the Senate and the Speaker of the House of Representatives containing the results of the studies conducted under this section and any recommendations for legislative or other actions not later than December 1, 2025.

H. Researching entities shall ensure any protected health information collected during the clinical trials done in accordance with this section does not personally identify any individual.

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

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

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

Section 2-303. A. The Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control shall register an applicant to

own a medical facility as described in subsection C of Section 2-302 of this title, or to manufacture, distribute, dispense, prescribe, administer or use for scientific purposes controlled dangerous substances included in Schedules I through V of Section 2-101 et seq. of this title unless the Director determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

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

2. Compliance with applicable state and local law;

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

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

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

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

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

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

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

C. Practitioners shall be registered to dispense, prescribe, administer or use for scientific purposes substances in Schedules II through V if they are authorized to carry on their respective activities under the laws of this state. A registration application by a practitioner who wishes to conduct research with Schedule I substances shall be accompanied by evidence of the applicant's federal registration to conduct such activity and shall be referred

to the Medical Research Commission for advice. The Medical Research Commission shall promptly advise the Director concerning the qualifications of each practitioner requesting such registration. Registration for the purpose of bona fide research or of use for scientific purposes with Schedule I substances by a practitioner deemed qualified by the Medical Research Commission may be denied only on a ground specified in subsection A of Section 2-304 of this title or if there are reasonable grounds to believe that the applicant will abuse or unlawfully transfer such substances or fail to safeguard adequately such applicant's supply of such substances against diversion from legitimate medical or scientific use.

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

Practitioners and mid-level practitioners	$140.00	per year of registration
Home Care Agencies, Hospices & Home Care Services	$140.00	annually
Medical Facility Owners	$300.00	annually
Distributors	$300.00	annually

Manufacturers	$500.00	annually
Manufacturer, Wholesaler, or Distributor of drug products containing pseudoephedrine or phenylpropanolamine	$300.00	annually
Researcher of psilocybin or psilocin	$140.00	annually

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

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

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

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