STATE OF OKLAHOMA

2nd Session of the 58th Legislature (2022)

COMMITTEE SUBSTITUTE
FOR
HOUSE BILL NO. 3414 By: Pae

COMMITTEE SUBSTITUTE

An Act relating to public health and safety; providing for the establishment of statewide investigational clinical trials; authorizing physicians to serve as principal investigators for clinical trials under certain circumstances; directing investigators to adhere to certain rules and regulations; permitting Oklahoma State Bureau of Narcotics and Dangerous Drugs Control to inspect facilities and certain samples; providing guidelines for conducting clinical trials; providing exemptions from criminal or civil penalties; permitting Commissioner of Health to perform certain acts; requiring clinical trials to comply with certain standards; providing termination date; requiring certain approval for continuation of clinical trials; requiring submission of certain report; specifying contents of report; directing promulgation of rules 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 memorandum of agreement with a university or institution of higher education located in Oklahoma are hereby authorized to conduct scientific research and medical trials on psilocybin and psilocin for the treatment of persons eighteen (18) years of age or older who suffer from the following:

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. Palliative care;

8. End-of-life care;

9. Opioid use disorder; or

10. Moderate to severe chronic pain.

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

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

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

2. Review the current literature regarding:

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

b. the access persons have to psilocybin and psilocin for the treatment of the aforementioned medical conditions; 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 apply to the State Department of Health for a license prior to and for the purposes of growing, studying, processing, and/or dispensing psilocybin containing fungi or other naturally occurring source organisms, or studying, extracting, synthesizing, and/or dispensing psilocybin or psilocin. The application shall include:

a. the name and address of the research facility,

b. a one- to three-page research prospectus, and

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

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

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

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

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

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

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

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

a. the name and address of the cultivation facility,

b. a copy of the research prospectus submitted to the State Department of Health, and

c. copies of the State Department of Health license and Bureau registration;

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

7. Should the licensee 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 Department and to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

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

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

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

E. 1. A written certification shall be issued to persons qualifying for participation in a clinical trial described herein. Such 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 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

their unlawful distribution shall remain subject to the penalties as stated under the Uniform Controlled Dangerous Substances Act.

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

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

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

J. The State Department of Health, the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, the Oklahoma Department of Agriculture, Food, and Forestry, and any other state agency with access to the research programs authorized by this act 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.

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

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

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