HB3414 FA1 PhillipsLo-KN(Untimely Filed)
3/7/2022 1:19:39 pm

FLOOR AMENDMENT

HOUSE OF REPRESENTATIVES
State of Oklahoma

SPEAKER:

CHAIR:

I move to amend HB3414 Of the printed Bill

Page _____ Section _____ Lines _____ Of the Engrossed Bill

By striking the Title, the Enacting Clause, the entire bill, and by inserting in lieu thereof the following language:

AMEND TITLE TO CONFORM TO AMENDMENTS

Amendment submitted by: Logan Phillips

Adopted: _____

_____
Reading Clerk

STATE OF OKLAHOMA

2nd Session of the 58th Legislature (2022)

FLOOR SUBSTITUTE
FOR
HOUSE BILL NO. 3414

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

and

Paxton of the Senate

FLOOR 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 register with 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 registration submission information shall include:

a. the name and address of the research facility,

b. a research-university-approved prospectus, and

c. certification from the university's or institution of higher education's institutional review board 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 Department shall collect a one-time nonrefundable fee of Five Hundred Dollars ($500.00) from the registrant at the time of application, and the applicant shall, upon completion of registration, 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.

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

5. Within fourteen (14) business days of receiving their State Department of Health registration 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 approved research prospectus submitted to the State Department of Health, and

c. copies of the State Department of Health registration 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 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 and to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

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

9. Researchers and physicians operating under a valid registration 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.

E. 1. A written certification shall be issued to persons qualifying for participation by a physician participating 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 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 registration 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 registration and Bureau registration pursuant to this act with the court of jurisdiction at least ten (10) days prior to trial. Such registrations 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. Researching 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.

58-2-11046 KN 03/07/22