STATE OF OKLAHOMA

2nd Session of the 58th Legislature (2022)

HOUSE BILL 3174 By: Phillips

AS INTRODUCED

An Act relating to public health; defining terms; providing for the establishment of statewide investigational new drug applications for psilocybin clinical trials; authorizing physicians to serve as principal investigators for clinical trials under certain circumstances; providing for subinvestigators; directing investigators and subinvestigators to adhere to certain rules and regulations; permitting Oklahoma State Bureau of Narcotics and Dangerous Drugs Control to inspect certain samples; providing guidelines for conducting clinical trials; exempting person acting in compliance from criminal or civil penalties; permitting State 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; authorizing Commissioner to disclose certain data; directing promulgation of rules by certain entities; providing for codification; and providing an effective date.

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 2-821 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. As used in this section:

1. "Academic medical center" means a medical school and its affiliated teaching hospitals and clinics in this state that:

a. operate a medical residency program for physicians, and

b. conduct research that is overseen by the United States Department of Health and Human Services and involves human subjects;

2. "Approved source" means a provider approved by the United States Food and Drug Administration (FDA) which produces psilocybin that:

a. has been manufactured and tested in a facility approved or certified by the FDA or similar national regulatory agency in another country which has been approved by the FDA, and

b. has been tested on animals to demonstrate preliminary effectiveness and to ensure that it is safe to administer to humans;

3. "Physician" means a doctor of medicine or doctor of osteopathic medicine licensed by the State Board of Medical Licensure and Supervision or the State Board of Osteopathic Examiners;

4. "Psilocybin" means a hallucinogenic chemical compound obtained from certain types of fresh and dried mushrooms; and

5. "Qualifying patient" means any person eighteen (18) years of age or older who is a veteran of the United States Armed Forces or the Oklahoma National Guard who suffers from major depressive disorder, severe depression, or any other form of depression or anxiety that is not adequately treated by traditional medical therapies.

B. A statewide investigational new drug application may be established in this state, if approved by the FDA, to conduct clinical trials using psilocybin on qualifying patients.

C. Any physician licensed by the State Board of Medical Licensure and Supervision or the State Board of Osteopathic Examiners, practicing in this state, and treating qualifying patients may serve as the principal investigator for such clinical trials if such physician:

1. Applies to and is approved by the FDA as the principal investigator in a statewide investigational new drug application;

2. Receives a license from the United States Drug Enforcement Administration; and

3. Receives a registration from the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

D. Such physician, acting as principal investigator, may include subinvestigators who are also board certified, practice in an academic medical center in this state, and treat qualifying patients. Subinvestigators shall comply with the licensing

requirement provided in paragraphs 2 and 3 of subsection C of this section.

E. The principal investigator and all subinvestigators shall adhere to the rules and regulations established by the relevant institutional review board for each participating academic medical center and by the FDA, the United States Drug Enforcement Administration, the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, and the National Institute on Drug Abuse.

F. Nothing in this section shall be construed to prohibit a physician licensed in Oklahoma from applying for Investigational New Drug authorization from the FDA.

G. The Oklahoma State Bureau of Narcotics and Dangerous Drugs Control shall have the authority to inspect and test samples of psilocybin used in this state pursuant to the provisions of this section.

H. Clinical trials conducted pursuant to a statewide Investigational New Drug application established pursuant to the provisions of this section shall only utilize psilocybin which is:

1. From an approved source; and

2. Approved by the FDA to be used for treatment of a condition specified in an Investigational New Drug application.

I. The principal investigator and any subinvestigator may receive psilocybin directly from an approved source or authorized distributor for an approved source for use in the clinical trials.

J. A person acting in compliance with the provisions of this section shall not be subject to arrest, prosecution, or any civil or administrative penalty, including, but not limited to, a civil penalty or disciplinary action by a professional licensing board, or be denied any right or privilege, for the use, prescription, administration, possession, manufacture, or distribution of medical psilocybin.

K. The State Commissioner of Health shall have the authority to approve physicians conducting clinical trials performed pursuant to the provisions of this section. In the event of a substantial violation of this section, the Commissioner shall provide written notice to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control and the Governor. The Governor, upon receipt of a notice from the Commissioner, shall have the authority to terminate the operations of a clinical trial found to be in violation of any provision of this section.

L. The clinical trials and related research authorized by this section shall adhere to the highest standards of academic research including, but not limited to, peer review of research conducted pursuant to this section.

M. The State Commissioner of Health shall submit a report to the Speaker of the Oklahoma House of Representatives and the President Pro Tempore of the Oklahoma State Senate on or before December 31, 2023. The report shall include a summary of findings

from clinical trials authorized by this section. The Commissioner shall, upon request by the Speaker or President Pro Tempore, make available any data, excluding individual health records, relating to clinical trials authorized by this section.

N. The Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, the Oklahoma State Department of Health, and the Oklahoma State Regents for Higher Education shall promulgate rules to implement the provisions of this section.

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

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