HOUSE SUBSTITUTE AMENDMENT NO. _____

for

HOUSE _____ AMENDMENT NO.____

Offered By

_____ _____

AMEND House Bill No. 1154, Page 1, Section A, Line 2, by inserting after all of said section and line the following:

"191.479. 1. For the purpose of this section, a "bona fide physician-patient relationship" means a relationship between a physician and a patient in which the physician:

(1) Has completed an assessment of the patient's medical history and current medical condition, including an in-person examination of the patient;

(2) Has consulted with the patient with respect to the patient's medical condition; and

(3) Is available to provide follow-up care and treatement to the patient.

2. Notwithstanding the provisions of chapter 195 or 579 or any other provision of law to the contrary, any entity or person who acquires, produces, possesses, transfers, or administers psilocybin for the purpose of conducting a clinical trial to study the use of psilocybin to treat posttraumatic stress disorder, major depressive disorder, or substance use disorder or for end-of-life care shall not be in violation of state or local law so long as the following conditions are met:

(1) The person is twenty-one years of age or older and is a veteran of the United States Armed Forces or National Guard;

(2) The person suffers from posttraumatic stress disorder, major depressive disorder, or a substance use disorder or requires end-of-life care;

(3) The person:

(a) Has enrolled in a clinical trial to study the use of psilocybin to treat posttraumatic stress disorder, major depressive disorder, or substance use disorders or for end-of-life care; or

(b) Provides the department of health and senior services with documentation from a physician with whom the patient has a bona fide physician-patient relationship that the person suffers from posttraumatic stress disorder, major depressive disorder, or a substance use disorder or requires end-of-life care;

(c) Ensures that a laboratory licensed by the state to test controlled substances tests the psilocybin the person intends to ingest; and

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(d) Limits the use of psilocybin to no more than one hundred and fifty milligrams of psilocybin analyte (4-phosphoryloxy-N, N-dimethyltryptamine) during any twelve-month period.

3. Subject to appropriation, the department of health and senior services shall provide grants totaling two million dollars for research on the use and efficacy of psilocybin for persons described in subsection 2 of this section.

4. The department of health and senior services shall prepare and submit to the governor, lieutenant governor, and the general assembly annual reports on any information collected by the department on the implementation and outcomes of the use of psilocybin as described in subsection 2 of this section.

5. The department of health and senior services shall maintain the confidentiality of any personally identifiable protected information collected from any persons who provide information to the department under subsection 2 of this section.

6. Notwithstanding any other provision of law to the contrary, a physician shall not be subject to criminal or civil liability or sanction under the laws of this state for providing documentation that a person suffers from posttraumatic stress disorder, major depressive disorder, or a substance use disorder or requires end-of-life care, and no state agency or regulatory board shall revoke, fail to renew, or take any other action against a physician's license issued under chapter 334 based solely on the physician's provision of documentation that a person suffers from posttraumatic stress disorder, major depressive disorder, or a substance use disorder or requires end-of-life care.

7. Notwithstanding any other provision of law to the contrary, no state agency, including employees therein, shall disclose to the federal government, any federal government employee, or any unauthorized third party the statewide list or any individual information of persons who meet the requirements of this section.

191.480. 1. For purposes of this section, the following terms shall mean:

(1) "Eligible patient", a person who meets all of the following:

(a) Has a terminal, life threatening, or severely debilitating condition or illness;

(b) Has considered all other treatment options currently approved by the United States Food and Drug Administration and all relevant clinical trials conducted in this state;

(c) Has received a prescription or recommendation from the person's physician for an investigational drug, biological product, or device;

(d) Has given written informed consent which shall be at least as comprehensive as the consent used in clinical trials for the use of the investigational drug, biological product, or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written informed consent on the patient's behalf; and

(e) Has documentation from the person's physician that the person has met the requirements of this subdivision;

(2) "Investigational drug, biological product, or device", a drug, biological product, or device, any of which are used to treat the patient's terminal illness, that has successfully completed phase one of a clinical trial but has not been approved for general use by the United States Food and

Drug Administration and remains under investigation in a clinical trial[~~. The term shall not include Schedule I controlled substances~~];

(3) "Life-threatening", diseases or conditions:

(a) Where the likelihood of death is high unless the course of the disease is interrupted; and

(b) With potentially fatal outcomes, where the end point of clinical trial analysis is survival;

(4) "Severely debilitating", diseases or conditions that cause major irreversible morbidity;

(5) "Terminal illness", a disease that without life-sustaining procedures will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

2. A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients under this section. This section does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient. A manufacturer may:

(1) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation; or

(2) Require an eligible patient to pay the costs of or associated with the manufacture of the investigational drug, biological product, or device.

3. This section does not require a health care insurer to provide coverage for the cost of any investigational drug, biological product, or device. A health care insurer may provide coverage for an investigational drug, biological product, or device.

4. This section does not require the department of corrections to provide coverage for the cost of any investigational drug, biological product, or device.

5. Notwithstanding any other provision of law to the contrary, no state agency or regulatory board shall revoke, fail to renew, or take any other action against a physician's license issued under chapter 334 based solely on the physician's recommendation to an eligible patient regarding prescription for or treatment with an investigational drug, biological product, or device. Action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device is prohibited.

6. If a provision of this section or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this section that can be given effect without the invalid provision or application, and to this end the provisions of this section are severable.

7. If the clinical trial is closed due to lack of efficacy or toxicity, the drug shall not be offered. If notice is given on a drug, product, or device taken by a patient outside of a clinical trial, the pharmaceutical company or patient's physician shall notify the patient of the information from the safety committee of the clinical trial.

8. Except in the case of gross negligence or willful misconduct, any person who manufactures, imports, distributes, prescribes, dispenses, or administers an investigational drug or device to an eligible patient with a terminal illness in accordance with this section shall not be liable in any action under state law for any loss, damage, or injury arising out of, relating to, or resulting from:

(1) The design, development, clinical testing and investigation, manufacturing, labeling, distribution, sale, purchase, donation, dispensing, prescription, administration, or use of the drug or device; or

(2) The safety or effectiveness of the drug or device."; and

Further amend said bill and page, Section 192.950, Lines 3-8, by deleting all of said lines and inserting in lieu thereof the following:

"by an institution of higher education in this state or contract research organizations conducting trials approved by the United States Food and Drug Administration, may conduct a study on the efficacy of using alternative medicine and therapies, including the use of psilocybin, in the treatment of patients who suffer from posttraumatic stress disorder, major depressive disorder, or substance use disorders or who"; and

Further amend said bill, page, and section, Line 12, by deleting the word "shall" and inserting in lieu thereof the word "may"; and

Further amend said bill, page, and section, Lines 14 to 15, by deleting the phrase "treatment-resistant depression" and inserting in lieu thereof the phrase "major depressive disorder"; and

Further amend said bill, page, and section, Line 15, by deleting the word "abuse" and inserting in lieu thereof the word "use"; and

Further amend said bill and section, Page 2, Line 17, by deleting the phrase "MDMA, psilocybin, and ketamine" and inserting in lieu thereof the word "psilocybin"; and

Further amend said bill, page, and section, Lines 18 to 19, by deleting the phrase "treatment-resistant depression" and inserting in lieu thereof the phrase "major depressive disorder"; and

Further amend said bill, page, and section, Line 19, by deleting the word "abuse" and inserting in lieu thereof the word "use"; and

Further amend said bill, page, and section, Line 20, by deleting the phrase "MDMA, psilocybin, and ketamine" and inserting in lieu thereof the word "psilocybin"; and

Further amend said bill, page, and section, Lines 25-27, by deleting all of said lines and inserting in lieu thereof the following:

"(b) A written report, submitted one year following the commencement of the study, which shall:

a. Contain the results of the study and any recommendations for legislative or regulatory action; and

b. Highlight those clinical practices that appear to be most successful as well as any safety or health concerns."; and

Further amend said bill, page, and section, Line 36, by inserting after all of said line the following:

"5. Notwithstanding any other provision of law to the contrary, a physician shall not be subject to criminal or civil liability or sanction under the laws of this state for referring a patient to the clinical trial under this section, and no state agency or regulatory board shall revoke, fail to renew, or take any other action against a physician's license issued under chapter 334 based solely on the physician's referral of a patient to the clinical trial under this section."; and

Further amend said bill by amending the title, enacting clause, and intersectional references accordingly.

THIS SUBSTITUTES FOR 2459H01.14H