House _____ **Amendment NO.**____

Offered By

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AMEND House Committee Substitute for House Bill Nos. 3068 & 3049, Page 7, Section 43.530, Line 23, by inserting after said section and line the following:

"191.479. 1. As used in this section, the following terms mean:

(1) "Bona fide physician-patient relationship", a relationship between a physician and a patient in which the physician:

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

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

(c) Is available to provide follow-up care and treatment to the patient;

(2) "Facilitator", an individual who is present with a person who uses psilocybin in order to facilitate the therapeutic use of the psilocybin for the person;

(3) "First responder", any police officer; firefighter; dispatcher for police, fire, or emergency medical services purposes; emergency medical technician or responder; ambulance or air ambulance operator; or emergency room physician or nurse;

(4) "Veteran", any person defined as a veteran by the United States Department of Veterans Affairs or its successor agency.

2. Notwithstanding the provisions of chapter 195 or 579 or any other provision of law to the contrary, any person who acquires, uses, produces, possesses, transfers, or administers psilocybin for the person's own therapeutic use shall not be in violation of state or local law and shall not be subject to a civil fine, penalty, or sanction so long as the following conditions are met:

(1) The person is a veteran or first responder and is twenty-one years of age or older;

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

(4) The person informs the department of mental health that the person plans to acquire, use, produce, possess, transfer, or administer psilocybin in accordance with this section;

(5) The person provides the department of mental health with:

Action Taken_____ Date _____

(a) 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;

(b) The name of the individual who will serve as the person's facilitator;

(c) The address of the location where the use of psilocybin will take place; and

(d) The time period, not to exceed twelve months, during which the person will use psilocybin;

(6) The person's use of psilocybin occurs only in the presence of a facilitator who meets the following requirements:

(a) Is:

a. A licensed physician;

b. A licensed mental health professional who earned a doctor of psychology degree or a doctor of philosophy degree in psychology;

c. A mental health therapist who has a master's degree in a relevant field and who has full clinical licensure including, but not limited to, a licensed clinical social worker, a licensed marital and family therapist, a licensed professional counselor, or an art therapist;

d. A licensed nurse who holds a doctorate in nursing practice;

e. A licensed physician assistant;

f. A psychiatric mental health nurse practitioner; or

g. A licensed advanced practice registered nurse;

(b) Has completed a training program that is specific to psilocybin and that:

a. Is consistent with the current professional practice guidelines for psychedelic-assisted therapy published by the American Psychological Association or the American Psychedelic Practitioners Association and complies with each such guideline;

b. Covers all content areas set forth in the professional practice guidelines of the American Psychological Association or the American Psychedelic Practitioners Association; and

c. Consists of at least thirty hours of synchronous learning;

(c) Except for psychiatrists, psychiatric mental health nurse practitioners, and holders of a doctorate degree in psychology, completes ninety minutes of continuing education on the Diagnostic and Statistical Manual of Mental Disorders before serving as a facilitator for any person and during each relevant licensure renewal period; and

(d) Has received training in end-of-life care or in one or more of the following diagnostic categories:

a. Posttraumatic stress disorder;

b. Complex posttraumatic stress disorder;

c. Major depressive disorder; or

d. Substance use disorder;

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

(8) The person limits the use of psilocybin to no more than one hundred fifty milligrams of psilocybin analyte (4-phosphoryloxy-N, N-dimethyltryptamine) during any twelve-month period.

3. Notwithstanding the provisions of chapter 195 or 579 or any other provision of law to the contrary:

(1) Any person twenty-one years of age or older who assists another person in any of the acts allowed under subsection 2 of this section shall not be in violation of state or local law and shall not be subject to a civil fine, penalty, or sanction; and

(2) Any laboratory licensed by the state to test controlled substances or cannabis that tests psilocybin for a person engaged in acts allowed under subsection 2 of this section shall not be in violation of state or local law and shall not be subject to a civil fine, penalty, or sanction.

4. Subject to appropriation, the department of mental health 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.

5. The department of mental health 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.

6. The department of mental health 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.

7. Notwithstanding any other provision of law to the contrary, the department of mental health, any health care providers, and any other person involved in the acts described in subsection 2 of this section shall not be subject to criminal or civil liability or sanction under the laws of this state for providing care to a person engaged in acts allowed under subsection 2 of this section, except in cases of gross negligence or willful misconduct. No health care provider shall be subject to discipline against his or her professional license for providing care to a person engaged in acts allowed under subsection 2 of this section.

8. 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.

9. Notwithstanding any other provision of law to the contrary, no state agency or employee of a state agency 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 condition or illness, a life-threatening condition or illness, or a 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 condition or illness, life-threatening condition or illness, or severely debilitating condition or 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 condition or illness", a disease or condition:

(a) In which 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 condition or illness", a disease or condition that causes major irreversible morbidity;

(5) "Terminal condition or illness", a disease or condition 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 <u>condition or</u> illness<u>, a life-threatening condition or illness, or a severely debilitating condition</u> 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, Page 39, Section 589.417, Line 27, by inserting after said section and line the following:

"630.1170. 1. Notwithstanding the provisions of chapter 195 or 579 to the contrary, the department of mental health, in collaboration with a hospital operated by an institution of higher education in this state or with contract research organizations conducting studies approved by the United States Food and Drug Administration, shall conduct a study on the efficacy of using alternative medicine and therapies, including the use of psilocybin, in the treatment of veterans who suffer from posttraumatic stress disorder, major depressive disorder, or substance use disorders or who require end-of-life care.

2. (1) In conducting the study, the department of mental health, in collaboration with the hospital or contract research organizations described in subsection 1 of this section and subject to appropriations, shall:

(a) Perform a study on the therapeutic efficacy of using psilocybin in the treatment of veterans who suffer from posttraumatic stress disorder, major depressive disorder, or substance use disorders or who require end-of-life care; and

(b) Review current literature regarding:

a. The safety and efficacy of psilocybin in the treatment of veterans who suffer from posttraumatic stress disorder, major depressive disorder, or substance use disorders or who require end-of-life care; and

b. The access that veterans have to psilocybin for such treatment.

(2) The department of mental health shall prepare and submit to the governor, lieutenant governor, and the general assembly the following:

(a) Quarterly reports on the progress of the study; and

(b) A written report, submitted one year following the commencement of the study, that 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.

3. The department of mental health shall maintain the confidentiality of any personally identifiable protected information collected during the study under this section.

4. Notwithstanding any other provision of law to the contrary, the department of mental health, any health care providers, and any other person involved in the study under this section shall not be subject to criminal or civil liability or sanction under the laws of this state for participating in the study, except in cases of gross negligence or willful misconduct. No health care provider shall be subject to discipline against his or her professional license for participation in the study.

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 veteran to the study 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 veteran to the study under this section."; and

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