SENATE COMMITTEE SUBSTITUTE

FOR

SENATE BILL NO. 768

AN ACT

To repeal sections 191.480 and 196.1050, RSMo, and to enact in lieu thereof four new sections relating to alternative therapies.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 191.480 and 196.1050, RSMo, are repealed and four new sections enacted in lieu thereof, to be known as sections 191.479, 191.480, 196.1050, and 630.1170, to read as follows:

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 treatment to the patient.

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, as defined in section 42.002, who resides in Missouri;

(2) The person is twenty-one years of age or older;

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

(4) The person:

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

(b) Sought to enroll in a study described in paragraph (a) of this subdivision but was declined due to lack of space or lack of existing studies for which the person was eligible;

(5) 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;

(6) The person provides the department with:

(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 facilitator who will be present with the person when they use psilocybin, who is one of the following:

a. A physician licensed under chapter 334;

b. A psychologist licensed under chapter 337;

c. A master's-level mental health therapist with full clinical experience such as a licensed clinical social worker, marital and family therapist, or professional counselor, as such professions are licensed under chapter 337, or a registered art therapist;

d. A nurse licensed under chapter 335 with a doctor of nursing practice degree;

e. A physician assistant licensed under chapter 334; or

f. An advanced practice registered nurse licensed under chapter 335, including, but not limited to, a psychiatric-mental health nurse practitioner;

(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;

(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 and fifty milligrams of psilocybin analyte (4-phosphoryloxy-N, N-dimethyltryptamine) during any twelve-month period.

3. (1) A facilitator described under subsection 2 of this section, in order to serve as a facilitator, shall have completed a training program specific to psilocybin consistent with the most current American Psychedelic Practitioners Association Professional Practice Guidelines for Psychedelic-Assisted Therapy and shall comply with such guidelines. The curriculum of a training program under this subsection shall cover all content areas set forth in the guidelines and shall consist of no less than eighty hours of synchronous learning. Facilitators, excluding those who are psychologists, psychiatrists, or psychiatric-mental health nurse practitioners, shall complete one and one half continuing education hours of training on the most current version of the Diagnostic and Statistical Manual of Mental Disorders within the facilitator's respective licensure

renewal period and prior to facilitating a psilocybin session.

(2) An individual shall have training in posttraumatic stress disorder, complex posttraumatic stress disorder, major depressive disorder, substance use disorder, or end-of-life care in order to serve as a facilitator for a person seeking psilocybin-assisted psychotherapy to treat such conditions.

4. 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.

5. Subject to appropriation, the department shall provide grants totaling three million dollars for research on the use and efficacy of psilocybin for persons described in subsection 2 of this section. Such appropriation shall be made from the opioid addiction treatment and recovery fund created in section 196.1050.

6. The department 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.

7. The department 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.

8. Notwithstanding any other provision of law to the contrary, the department, 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.

9. 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.

10. 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.

196.1050. 1. The proceeds of any monetary settlement or portion of a global settlement between the attorney general of the state and any drug manufacturers, distributors, pharmacies, or combination thereof to resolve an opioid-related cause of action against such drug manufacturers, distributors, pharmacies, or combination thereof in a state or federal court shall only be utilized to pay for opioid addiction treatment and prevention services **[**and**]**, health care and law enforcement costs related to opioid addiction treatment and prevention, and grants for research on the use and efficacy of certain substances as alternative therapies for Missouri veterans as provided in section 191.479. Under no circumstances shall such settlement moneys be utilized to fund other services, programs, or expenses not reasonably related to opioid addiction treatment and prevention and therapies as described in this subsection.

2. (1) There is hereby established in the state treasury the "Opioid Addiction Treatment and Recovery Fund", which shall consist of the proceeds of any settlement described in subsection 1 of this section, as well as any funds appropriated by the general assembly, or gifts, grants, donations, or bequests. The state treasurer shall be custodian of the fund. In accordance with sections 30.170 and 30.180, the state treasurer may approve disbursements. The fund shall be a dedicated fund and money in the fund shall be used by the department of mental health, the department of health and senior services, the department of social services, the department of public safety, the department of corrections, and the judiciary for the purposes set forth in subsection 1 of this section.

(2) Notwithstanding the provisions of section 33.080 to the contrary, any moneys remaining in the fund at the end

of the biennium shall not revert to the credit of the general revenue fund.

(3) The state treasurer shall invest moneys in the fund in the same manner as other funds are invested. Any interest and moneys earned on such investments shall be credited to the fund.

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 contract research organizations conducting trials 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 patients who suffer from posttraumatic stress disorder, major depressive disorder, or substance abuse disorders or who require end-of-life care.

2. (1) In conducting this study, the department, in collaboration with the hospitals or research organizations described in subsection 1 of this section and subject to appropriation, shall:

(a) Perform a study on the therapeutic efficacy of using psilocybin in the treatment of patients 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 patients 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 patients have to psilocybin for such treatment.

(2) The department 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, 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.

3. The department shall maintain the confidentiality of any personally identifiable protected information collected during the study described in this section.

4. Notwithstanding any other provision of law to the contrary, the department, any health care providers, and any other person involved in the study described in 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 patient to the study described in 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 study described in this section.