

FIRST REGULAR SESSION

[PERFECTED]

HOUSE BILL NO. 1154

102ND GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE HOUX.

2459H.01P

DANA RADEMAN MILLER, Chief Clerk

AN ACT

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

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

Section A. Section 191.480, RSMo, is repealed and three new sections enacted in lieu thereof, to be known as sections 191.479, 191.480, and 192.950, to read as follows: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 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;

EXPLANATION — Matter enclosed in bold-faced brackets ~~thus~~ in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

17 **(3) The person:**

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

21 **(b) Sought to enroll in a clinical trial described in paragraph (a) of this**
22 **subdivision but was declined due to lack of space or lack of existing clinical trials for**
23 **which the person was eligible;**

24 **(4) The person informs the department of health and senior services that the**
25 **person plans to acquire, use, produce, possess, transfer, or administer psilocybin in**
26 **accordance with this section;**

27 **(5) The person provides the department of health and senior services with:**

28 **(a) Documentation from a physician with whom the patient has a bona fide**
29 **physician-patient relationship that the person suffers from posttraumatic stress**
30 **disorder, major depressive disorder, or a substance use disorder or requires end-of-**
31 **life care;**

32 **(b) The name of a person who will be present with the person when they use**
33 **psilocybin who is one of the following;**

34 **a. A licensed physician;**

35 **b. A licensed therapist; or**

36 **c. Licensed by the federal government or other government entity in the**
37 **therapeutic use of psilocybin;**

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

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

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

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

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

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

51 **(2) Any laboratory licensed by the state to test controlled substances or cannabis**
52 **that tests psilocybin for a person engaged in acts allowed under subsection 2 of this**

53 section shall not be in violation of state or local law and shall not be subject to a civil
54 fine, penalty, or sanction.

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

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

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

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

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

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

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

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

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

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

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

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

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

14 (2) "Investigational drug, biological product, or device", a drug, biological product, or
15 device, any of which are used to treat the patient's terminal illness, that has successfully
16 completed phase one of a clinical trial but has not been approved for general use by the
17 United States Food and Drug Administration and remains under investigation in a clinical
18 trial~~].—The term shall not include Schedule I controlled substances];~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

66 (2) The safety or effectiveness of the drug or device.

**192.950. 1. Notwithstanding the provisions of chapter 195 or 579 to the contrary,
2 the department of health and senior services, in collaboration with a hospital operated
3 by an institution of higher education in this state or contract research organizations
4 conducting trials approved by the United States Food and Drug Administration, shall
5 conduct a study on the efficacy of using alternative medicine and therapies, including,
6 the use of psilocybin, in the treatment of patients who suffer from posttraumatic stress
7 disorder, major depressive disorder, or substance abuse disorders or who require end-
8 of-life care.**

**9 2. (1) In conducting this study, the department of health and senior services, in
10 collaboration with the hospitals or medical center described in subsection 1 of this
11 section and subject to appropriations, shall:**

12 **(a) Perform a clinical trial on the therapeutic efficacy of using psilocybin in the**
13 **treatment of patients who suffer from posttraumatic stress disorder, major depressive**
14 **disorder, or substance use disorders or who require end-of-life care; and**

15 **(b) Review current literature regarding:**

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

19 **b. The access that patients have to psilocybin for such treatment.**

20 **(2) The department of health and senior services shall prepare and submit to the**
21 **governor, lieutenant governor, and the general assembly the following:**

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

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

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

27 **b. Highlight those clinical practices that appear to be most successful as well as**
28 **any safety or health concerns.**

29 **3. The department of health and senior services shall maintain the**
30 **confidentiality of any personally identifiable protected information collected during**
31 **the clinical trial under this section.**

32 **4. Notwithstanding any other provision of law to the contrary, the department of**
33 **health and senior services, any health care providers, and any other person involved in**
34 **the clinical trial under this section shall not be subject to criminal or civil liability or**
35 **sanction under the laws of this state for participating in the trial, except in cases of gross**
36 **negligence or willful misconduct. No health care provider shall be subject to discipline**
37 **against his or her professional license for participation in the trial.**

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

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