

SECOND REGULAR SESSION
SENATE COMMITTEE SUBSTITUTE FOR
HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILLS NOS. 1717 & 1643

103RD GENERAL ASSEMBLY

4914S.04C

KRISTINA MARTIN, Secretary

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Section A. Section 191.480, RSMo, is repealed and three
2 new sections enacted in lieu thereof, to be known as sections
3 191.479, 191.480, and 630.1170, to read as follows:

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

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

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

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

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

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

EXPLANATION-Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

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

21 (4) "Veteran", any person defined as a veteran by the
22 U.S. Department of Veterans Affairs or its successor agency.

23 2. Notwithstanding the provisions of chapter 195 or
24 579 or any other provision of law to the contrary, any
25 person who acquires, uses, produces, possesses, transfers,
26 or administers psilocybin for the person's own therapeutic
27 use shall not be in violation of state or local law and
28 shall not be subject to a civil fine, penalty, or sanction
29 so long as the following conditions are met:

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

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

35 (3) The person has enrolled in a study on the use of
36 psilocybin to treat posttraumatic stress disorder, major
37 depressive disorder, or substance use disorders or for end-
38 of-life care;

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

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

45 (a) Documentation from a physician with whom the
46 patient has a bona fide physician-patient relationship that
47 the person suffers from posttraumatic stress disorder, major

48 depressive disorder, or a substance use disorder or requires
49 end-of-life care;

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

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

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

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

59 (a) Is:

60 a. A licensed physician;

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

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

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

71 e. A licensed physician assistant;

72 f. A psychiatric mental health nurse practitioner; or

73 g. A licensed advanced practice registered nurse;

74 (b) Has completed a training program that is specific
75 to psilocybin and that has been approved by the department;

76 (c) Except for psychiatrists, psychiatric mental
77 health nurse practitioners, and holders of a doctorate
78 degree in psychology, completes ninety minutes of continuing
79 education on the Diagnostic and Statistical Manual of Mental

80 Disorders before serving as a facilitator for any person and
81 during each relevant licensure renewal period; and

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

- 84 a. Posttraumatic stress disorder;
- 85 b. Complex posttraumatic stress disorder;
- 86 c. Major depressive disorder; or
- 87 d. Substance use disorder;

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

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

95 3. Notwithstanding the provisions of chapter 195 or
96 579 or any other provision of law to the contrary:

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

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

107 4. Subject to appropriation, the department of mental
108 health shall provide grants totaling two million dollars for
109 research on the use and efficacy of psilocybin for persons
110 described in subsection 2 of this section.

111 5. The department of mental health shall prepare and
112 submit to the governor, lieutenant governor, and the general
113 assembly annual reports on any information collected by the
114 department on the implementation and outcomes of the use of
115 psilocybin as described in subsection 2 of this section.

116 6. The department of mental health shall maintain the
117 confidentiality of any personally identifiable protected
118 information collected from any persons who provide
119 information to the department under subsection 2 of this
120 section.

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

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

143 **disorder, or a substance use disorder or requires end-of-**
144 **life care.**

145 **9. Notwithstanding any other provision of law to the**
146 **contrary, no state agency or employee of a state agency**
147 **shall disclose to the federal government, any federal**
148 **government employee, or any unauthorized third party the**
149 **statewide list or any individual information of persons who**
150 **meet the requirements of this section.**

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

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

5 (a) Has a terminal **condition or illness, a life-**
6 **threatening condition or illness, or a severely debilitating**
7 **condition or illness;**

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

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

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

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

24 (2) "Investigational drug, biological product, or
25 device", a drug, biological product, or device, any of which
26 are used to treat the patient's terminal **condition or**
27 **illness, life-threatening condition or illness, or severely**
28 **debilitating condition or illness**, that has successfully
29 completed phase one of a clinical trial but has not been
30 approved for general use by the United States Food and Drug
31 Administration and remains under investigation in a clinical
32 trial[. The term shall not include Schedule I controlled
33 substances];

34 (3) "**Life-threatening condition or illness**", a **disease**
35 **or condition**:

36 (a) In which the likelihood of death is high unless
37 the course of the disease is interrupted; and

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

40 (4) "**Severely debilitating condition or illness**", a
41 **disease or condition that causes major irreversible**
42 **morbidity**;

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

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

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

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

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

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

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

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

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

92 8. Except in the case of gross negligence or willful
93 misconduct, any person who manufactures, imports,
94 distributes, prescribes, dispenses, or administers an
95 investigational drug or device to an eligible patient with a
96 terminal **condition or illness, a life-threatening condition**
97 **or illness, or a severely debilitating condition** in
98 accordance with this section shall not be liable in any
99 action under state law for any loss, damage, or injury
100 arising out of, relating to, or resulting from:

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

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

630.1170. 1. Notwithstanding the provisions of
2 **chapter 195 or 579 to the contrary, the department of mental**
3 **health, in collaboration with a hospital operated by an**
4 **institution of higher education in this state or with**
5 **contract research organizations conducting studies approved**
6 **by the U.S. Food and Drug Administration, shall conduct a**
7 **study on the efficacy of using alternative medicine and**
8 **therapies, including the use of psilocybin, in the treatment**
9 **of veterans and first responders who suffer from**
10 **posttraumatic stress disorder, major depressive disorder, or**
11 **substance use disorders or who require end-of-life care.**

12 2. (1) In conducting the study, the department of
13 mental health, in collaboration with the hospital or
14 contract research organizations described in subsection 1 of
15 this section and subject to appropriations, shall:

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

21 (b) Review current literature regarding:

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

26 b. The access that veterans and first responders have
27 to psilocybin for such treatment.

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

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

32 (b) A written report, submitted one year following the
33 commencement of the study, that shall:

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

36 b. Highlight those clinical practices that appear to
37 be most successful as well as any safety or health concerns.

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

41 4. Notwithstanding any other provision of law to the
42 contrary, the department of mental health, any health care
43 providers, and any other person involved in the study under

44 this section shall not be subject to criminal or civil
45 liability or sanction under the laws of this state for
46 participating in the study, except in cases of gross
47 negligence or willful misconduct. No health care provider
48 shall be subject to discipline against his or her
49 professional license for participation in the study.

50 5. Notwithstanding any other provision of law to the
51 contrary, a physician shall not be subject to criminal or
52 civil liability or sanction under the laws of this state for
53 referring a veteran to the study under this section, and no
54 state agency or regulatory board shall revoke, fail to
55 renew, or take any other action against a physician's
56 license issued under chapter 334 based solely on the
57 physician's referral of a veteran or first responder to the
58 study under this section.

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