

House _____ Amendment NO. _____

Offered By

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

3
4 "191.479. 1. For the purpose of this section, a "bona fide physician-patient relationship"
5 means a relationship between a physician and a patient in which the physician:

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

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

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

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

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

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

17 (3) The person:

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

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

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

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

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

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

30 a. A licensed physician;

Action Taken _____ Date _____

1 b. A licensed therapist; or

2 c. Licensed by the federal government or other government entity in the therapeutic use of
3 psilocybin;

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

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

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

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

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

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

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

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

22 5. The department of health and senior services shall prepare and submit to the governor,
23 lieutenant governor, and the general assembly annual reports on any information collected by the
24 department on the implementation and outcomes of the use of psilocybin as described in subsection
25 2 of this section.

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

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

36 8. Notwithstanding any other provision of law to the contrary, a physician shall not be
37 subject to criminal or civil liability or sanction under the laws of this state for providing
38 documentation that a person suffers from posttraumatic stress disorder, major depressive disorder, or
39 a substance use disorder or requires end-of-life care, and no state agency or regulatory board shall

1 revoke, fail to renew, or take any other action against a physician's license issued under chapter 334
 2 based solely on the physician's provision of documentation that a person suffers from posttraumatic
 3 stress disorder, major depressive disorder, or a substance use disorder or requires end-of-life care.

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

8 191.480. 1. For purposes of this section, the following terms shall mean:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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33 Further amend said bill and page, Section 192.950, Lines 3-4, by deleting all of said lines and
34 inserting in lieu thereof the following:

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36 "by an institution of higher education in this state or contract research organizations conducting
37 trials approved by the United States Food and Drug Administration, shall"; and

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39 Further amend said bill, page, and section, Lines 6 to 7, by deleting all of said lines and inserting in
40 lieu thereof the following:

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1 "the use of psilocybin, in the treatment of patients who suffer from posttraumatic"; and
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3 Further amend said bill, page, and section, line 8, by deleting the phrase "treatment-resistant
4 depression" and inserting in lieu thereof the phrase "major depressive disorder"; and
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6 Further amend said bill, page, and section, Lines 14 to 15, by deleting the phrase "treatment-
7 resistant depression" and inserting in lieu thereof the phrase "major depressive disorder"; and
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9 Further amend said bill, page, and section, Line 15, by deleting the word "abuse" and inserting in
10 lieu thereof the word "use"; and
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12 Further amend said bill and section, Page 2, Line 17, by deleting the phrase "MDMA, psilocybin,
13 and ketamine" and inserting in lieu thereof the word "psilocybin"; and
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15 Further amend said bill, page, and section, Lines 18 to 19, by deleting the phrase "treatment-
16 resistant depression" and inserting in lieu thereof the phrase "major depressive disorder"; and
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18 Further amend said bill, page, and section, Line 19, by deleting the word "abuse" and inserting in
19 lieu thereof the word "use"; and
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21 Further amend said bill, page, and section, Line 20, by deleting the phrase "MDMA, psilocybin, and
22 ketamine" and inserting in lieu thereof the word "psilocybin"; and
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24 Further amend said bill, page, and section, Lines 25-27, by deleting all of said lines and inserting in
25 lieu thereof the following:
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27 "(b) A written report, submitted one year following the commencement of the study, which
28 shall:

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

31 b. Highlight those clinical practices that appear to be most successful as well as any safety
32 or health concerns."; and
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34 Further amend said bill, page, and section, Line 36, by inserting after all of said line the following:
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36 "5. Notwithstanding any other provision of law to the contrary, a physician shall not be
37 subject to criminal or civil liability or sanction under the laws of this state for referring a patient to
38 the clinical trial under this section, and no state agency or regulatory board shall revoke, fail to
39 renew, or take any other action against a physician's license issued under chapter 334 based solely
40 on the physician's referral of a patient to the clinical trial under this section."; and
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42 Further amend said bill by amending the title, enacting clause, and intersectional references
43 accordingly.