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Date: 4/18/22

(Filing No. S-567)

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STATE OF MAINE
SENATE
130TH LEGISLATURE
SECOND REGULAR SESSION

SENATE AMENDMENT " A " to COMMITTEE AMENDMENT "A" to S.P. 496,
L.D. 1582, "An Act To Enact the Maine Psilocybin Services Act"

Amend the amendment by striking out the substitute title and replacing it with the following:

'An Act To Enact the Psilocybin Patient Care Act'

Amend the amendment by striking out all of sections 1 to 5 and inserting the following:

'Sec. 1. 5 MRSA §12004-I, sub-§47-J is enacted to read:

47-J.

<u>Human</u>	<u>Maine Psilocybin Advisory Board</u>	<u>Expenses/Legislative</u>	<u>22 MRSA</u>
<u>Services</u>		<u>Per Diem</u>	<u>§2331</u>

Sec. 2. 22 MRSA c. 555-A is enacted to read:

CHAPTER 555-A

PSILOCYBIN PATIENT CARE ACT

SUBCHAPTER 1

PSILOCYBIN PATIENT CARE

§2321. Short title

This chapter may be known and cited as "the Psilocybin Patient Care Act."

§2322. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Administration session. "Administration session" means a session held at a location identified to the department in accordance with section 2326, subsection 3,

SENATE AMENDMENT

1 paragraph D at which a psilocybin patient purchases, consumes and experiences the effects
 2 of a psilocybin product under the supervision of a psilocybin service facilitator.

3 **2. Manufacture.** "Manufacture" means the cultivation, harvesting, production,
 4 preparation, propagation, compounding, conversion or processing of a psilocybin product
 5 by extraction from substances of natural origin or by means of chemical synthesis, or by a
 6 combination of extraction and chemical synthesis.

7 **3. Medical provider.** "Medical provider" means a physician or physician assistant
 8 licensed under Title 32, chapter 36 or 48, a naturopathic doctor licensed under Title 32,
 9 chapter 113-B or a certified nurse practitioner licensed under Title 32, chapter 31.

10 **4. Medical use.** "Medical use" means the acquisition, possession, manufacture, use,
 11 delivery, transfer or transportation of psilocybin relating to the administration of psilocybin
 12 to treat or alleviate a psilocybin patient's medical condition or symptoms for which a
 13 medical provider has provided the psilocybin patient a written recommendation under this
 14 chapter.

15 **5. Patient information form.** "Patient information form" means the form required to
 16 be completed by a patient under section 2326.

17 **6. Preparation session.** "Preparation session" means a meeting between a psilocybin
 18 patient and a psilocybin service facilitator that occurs before the psilocybin patient
 19 participates in an administration session.

20 **7. Psilocybin.** "Psilocybin" means the naturally occurring compound produced by
 21 various species of fungi as well as psilocin, the substance into which psilocybin is
 22 converted in the human body.

23 **8. Psilocybin patient.** "Psilocybin patient" means an individual who is recommended
 24 psilocybin by a medical provider in accordance with section 2323.

25 **9. Psilocybin product.** "Psilocybin product" means psilocybin-producing fungi or
 26 mixtures or substances containing a detectable amount of psilocybin. "Psilocybin product"
 27 does not include psilocybin services.

28 **10. Psilocybin service facilitator.** "Psilocybin service facilitator" means a person or
 29 entity licensed in accordance with section 2325.

30 **11. Psilocybin services.** "Psilocybin services" means services provided to a
 31 psilocybin patient before, during and after the psilocybin patient's consumption of a
 32 psilocybin product, including a preparation session and administration session.

33 **12. Written recommendation.** "Written recommendation" means a recommendation
 34 for the medical use of psilocybin issued pursuant to section 2323.

35 **§2323. Authorized psilocybin patient care**

36 **1. Medical recommendation authorized.** A medical provider may provide a written
 37 recommendation in accordance with this section for the medical use of psilocybin under
 38 this chapter and, after having done so, may otherwise state that in the medical provider's
 39 professional opinion a patient is likely to receive therapeutic or palliative benefit from the
 40 medical use of psilocybin to treat or alleviate the patient's medical condition.

41 **2. Age requirement.** A medical provider may provide a written recommendation only
 42 to a person who is 21 years of age or older.

1 3. Disclosures. Prior to providing a written recommendation under this section, a
 2 medical provider shall inform the patient or the patient's legal guardian or representative of
 3 the risks and benefits of the medical use of psilocybin and that the patient may benefit from
 4 the medical use of psilocybin.

5 4. Substance use disorder. Prior to providing a written recommendation under this
 6 section for a medical diagnosis of substance use disorder that, in the medical provider's
 7 professional opinion, may be alleviated by the therapeutic or palliative medical use of
 8 psilocybin, the medical provider shall develop a recovery plan with the patient. For
 9 purposes of this subsection, "substance use disorder" means a diagnosis related to alcohol
 10 or drug use covered by Title 5, chapter 521.

11 5. Bona fide provider-patient relationship. A written recommendation may be made
 12 only in the course of a bona fide medical provider-patient relationship after the medical
 13 provider has completed a full assessment of the patient's medical history. If a patient has
 14 not provided a medical provider who is not the patient's primary care provider with the
 15 name and contact information of the patient's primary care provider, a medical provider
 16 shall conduct an in-person consultation with the patient prior to providing a written
 17 recommendation.

18 6. Expiration. A written recommendation under this section is valid for 12 months.

19 7. Form; content. A written recommendation under this section:

20 A. Must be in the form required by rule adopted by the department;

21 B. May not require a psilocybin patient's medical provider to state the patient's specific
 22 medical diagnosis; and

23 C. Must include a recommendation of the amount of psilocybin a patient may need to
 24 treat or alleviate the patient's medical condition.

25 8. Possible sanctions. Nothing in this chapter prevents a professional licensing board
 26 from sanctioning a medical provider for failing to properly evaluate or treat a patient's
 27 medical condition or otherwise violating the applicable standard of care for evaluating or
 28 treating a medical condition.

29 9. Patient referral disclosure of interest. Prior to providing a referral to a psilocybin
 30 patient for psilocybin services associated with a written recommendation to a psilocybin
 31 service facilitator in which the medical provider has a direct or indirect financial interest, a
 32 medical provider shall provide written disclosure to the psilocybin patient regarding any
 33 direct or indirect financial interest the medical provider has or may have in the resulting
 34 referral and shall maintain a copy of this disclosure in the psilocybin patient's record.

35 10. Continuing medical education. A medical provider who has not previously
 36 provided a written recommendation to a patient shall, prior to providing a written
 37 recommendation to a patient, submit evidence satisfactory to the department of successful
 38 completion of a one-hour course of continuing medical education relating to psilocybin
 39 within the preceding 24 months.

40 §2324. Authorized psilocybin conduct

41 1. Psilocybin use prohibited; exception. A person may not use, possess or
 42 manufacture psilocybin except in accordance with this chapter.

- 1 **2. Use of psilocybin.** A person may use psilocybin if the person is a psilocybin patient
- 2 who:
- 3 A. Has obtained a written recommendation in accordance with section 2323; and
- 4 B. Is in the presence of a psilocybin service facilitator licensed in accordance with
- 5 section 2325.
- 6 **3. Possession of psilocybin.** A person may possess psilocybin if the person:
- 7 A. Is a psilocybin patient and possesses only the amount necessary for medical use in
- 8 accordance with the patient's written recommendation and in accordance with rules
- 9 adopted by the department; or
- 10 B. Is licensed as a psilocybin service facilitator in accordance with section 2325 and
- 11 possesses only the amount necessary for medical use in accordance with the facilitator's
- 12 psilocybin patients' written recommendations and in accordance with rules adopted by
- 13 the department.
- 14 **4. Manufacture of psilocybin.** A person may manufacture psilocybin if the person:
- 15 A. Is a psilocybin patient and manufactures, only for the patient's personal use, the
- 16 amount necessary for medical use in accordance with the patient's written
- 17 recommendation and in accordance with rules adopted by the department; or
- 18 B. Is a psilocybin service facilitator and manufactures, only for use by the facilitator's
- 19 psilocybin patients, the amount necessary for the patients' medical use in accordance
- 20 with the patients' written recommendations and in accordance with rules adopted by
- 21 the department.
- 22 **§2325. Psilocybin service facilitator license**
- 23 1. License required. The department shall adopt rules in accordance with this chapter
- 24 establishing a license for a person to be a psilocybin service facilitator.
- 25 2. Qualifications. An applicant for a psilocybin service facilitator license must meet
- 26 any requirements established by the department by rule relating to education, training,
- 27 skills, examination or fitness.
- 28 3. Professional conduct. The department shall establish by rule a code of professional
- 29 conduct, including a code of ethics, for psilocybin service facilitators. The department shall
- 30 establish standards of practice and professional responsibility for psilocybin service
- 31 facilitators.
- 32 **§2326. Psilocybin services**
- 33 1. Requirements. A psilocybin service facilitator shall comply with the requirements
- 34 of this section. The department shall adopt rules regarding the provision of psilocybin
- 35 services to a psilocybin patient by a psilocybin service facilitator. The rules must, at least:
- 36 A. Require a psilocybin service facilitator to hold a preparation session with a
- 37 psilocybin patient before the psilocybin patient participates in an administration
- 38 session; and
- 39 B. Require a psilocybin service facilitator to certify, in a form and manner prescribed
- 40 by the department, that the psilocybin patient completed a preparation session.

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1 **2. Patient information form.** The department shall adopt rules governing psilocybin
2 patient information. The rules must:

3 **A. Require a psilocybin patient to complete and sign a psilocybin patient information**
4 **form prescribed by the department before a psilocybin patient participates in an**
5 **administration session. The form must:**

6 **(1) Solicit from the psilocybin patient such information as may be necessary to**
7 **enable a psilocybin service facilitator to determine whether the psilocybin patient**
8 **should participate in an administration session, including information that may**
9 **identify risk factors and contraindications, or that will assist the psilocybin service**
10 **facilitator in meeting any public health and safety standards and industry best**
11 **practices during the administration session; and**

12 **(2) Contain health and safety warnings and disclosures to the psilocybin patient;**
13 **and**

14 **B. Require a psilocybin patient to deliver a copy of the completed and signed psilocybin**
15 **patient information form to the psilocybin service facilitator.**

16 **3. Administration session.** The department shall adopt rules governing
17 administration sessions. The rules must:

18 **A. Require that a psilocybin patient complete a preparation session and a patient**
19 **information form prior to an administration session;**

20 **B. Require a psilocybin service facilitator to certify, in a form and manner prescribed**
21 **by the department, that the psilocybin patient completed an administration session;**

22 **C. Prohibit a psilocybin service facilitator from consuming a psilocybin product during**
23 **an administration session that the psilocybin service facilitator is supervising; and**

24 **D. Require an administration session to be held in a location identified to the**
25 **department that ensures psilocybin patient safety.**

26 **4. Confidentiality.** A psilocybin service facilitator may not disclose any information
27 **that may be used to identify a psilocybin patient or any communication made by a**
28 **psilocybin patient during the course of providing psilocybin services, except when:**

29 **A. The psilocybin patient or a person authorized to act on behalf of the psilocybin**
30 **patient gives consent to the disclosure;**

31 **B. The psilocybin patient initiates legal action or makes a complaint against the**
32 **psilocybin service facilitator;**

33 **C. The communication reveals the intent to commit a crime harmful to the psilocybin**
34 **patient or others;**

35 **D. The communication reveals that a minor may have been the victim of a crime or**
36 **physical, sexual or emotional abuse or neglect; or**

37 **E. Responding to an inquiry by the department made during the course of an**
38 **investigation into the conduct of the psilocybin service facilitator under this chapter.**

39 **§2327. Contingent effective date**

40 **This subchapter takes effect only when the department finally adopts rules in**
41 **accordance with subchapter 3. The commissioner shall notify the Secretary of State, the**

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1 Secretary of the Senate, the Clerk of the House of Representatives and the Revisor of
2 Statutes when the rules have been finally adopted.

3 **SUBCHAPTER 2**

4 **MAINE PSILOCYBIN ADVISORY BOARD**

5 **§2331. Establishment; purposes**

6 The Maine Psilocybin Advisory Board, established in Title 5, section 12004-I,
7 subsection 47-J and referred to in this subchapter as "the board," is established within the
8 department for the purposes of advising and making recommendations to the department
9 regarding the administration of this chapter in a manner that promotes the public health and
10 safety. Recommendations by the board require the approval of a majority of the board's
11 voting members.

12 **§2332. Membership**

13 The board consists of 16 members in accordance with this section.

14 **1. Ex officio nonvoting members.** The following members serve as ex officio
15 nonvoting members:

16 A. The Director of the Maine Center for Disease Control and Prevention or the
17 director's designee;

18 B. The Director of the Office of Behavioral Health or the director's designee, who must
19 be a physician licensed in accordance with Title 32, chapter 36 or 48; and

20 C. The chair of the Statewide Coordinating Council for Public Health, established in
21 Title 5, section 12004-G, subsection 14-G.

22 **2. Ex officio voting member.** The Attorney General or the Attorney General's
23 designee serves as an ex officio voting member.

24 **3. Voting members appointed by Governor.** The Governor shall appoint voting
25 members in accordance with this subsection. The Governor shall appoint:

26 A. Any 4 of the following individuals:

27 (1) A representative from a district coordinating council for public health
28 established pursuant to Title 22, section 412, subsection 4;

29 (2) A representative of one of the federally recognized Indian tribes in the State;

30 (3) A member of the Substance Use Disorder Services Commission, established
31 in Title 5, section 12004-G, subsection 13-C;

32 (4) A member of the Permanent Commission on the Status of Racial, Indigenous
33 and Tribal Populations, established in Title 5, section 12004-J, subsection 19;

34 (5) A member of the Palliative Care and Quality of Life Interdisciplinary Advisory
35 Council, established in Title 5, section 12004-I, subsection 47-I; or

36 (6) A representative of individuals who provide public health services directly to
37 the public;

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- 1 B. A psychologist licensed under Title 32, chapter 56 who has professional experience
2 engaging in behavioral health or assisted therapy;
- 3 C. A physician licensed under Title 32, chapter 48;
- 4 D. A naturopathic doctor licensed under Title 32, chapter 113-B;
- 5 E. A person with expertise in the field of public health who has a background in
6 academia;
- 7 F. Any one of the following:
- 8 (1) A person with professional expertise conducting scientific research regarding
9 the use of psychedelic compounds in clinical therapy;
- 10 (2) A person who has experience in the field of mycology;
- 11 (3) A person who has experience in the field of ethnobotany;
- 12 (4) A person who has experience in the field of psychopharmacology; or
- 13 (5) A person who has experience in the field of psilocybin harm reduction; and
- 14 G. Three at-large members.
- 15 **4. Terms; vacancies.** Board members, other than ex officio members, serve 4-year
16 terms and are eligible for reappointment. Before the expiration of the term of a member,
17 the Governor shall appoint a successor, whose term begins on the next January 1st. Board
18 members serve at the pleasure of the Governor and are not subject to legislative
19 confirmation. If there is a vacancy for cause, the Governor shall make an appointment to
20 become immediately effective for the unexpired term.
- 21 **5. Chair.** The board shall elect one of its voting members to serve as chair. The chair
22 serves a one-year term in that office and is eligible for reelection.
- 23 **6. Meeting frequency.** Until all rules necessary to implement this chapter have been
24 adopted, the board shall meet at least once every 2 months at a time and place determined
25 by the chair or a majority of the voting members of the board. Thereafter, the board shall
26 meet at least 4 times each year at regular intervals at a time and place determined by the
27 chair or a majority of the voting members of the board. The board may meet at other times
28 and places by the call of the chair or a majority of the voting members of the board.
- 29 **7. Quorum.** A majority of the board's voting members constitutes a quorum.
- 30 **8. Establishment of subcommittees.** The board may establish subcommittees
31 necessary for the operation of the board.
- 32 **9. Expenses; reimbursement.** Board members are entitled to compensation for service
33 on the board and for travel and board-related expenses in accordance with Title 5, section
34 12004-I, subsection 47-J.
- 35 **§2333. Powers and duties; report**
- 36 **1. Powers.** The board may adopt rules necessary for the operation of the board. Rules
37 adopted pursuant to this subsection are routine technical rules pursuant to Title 5, chapter
38 375, subchapter 2-A.
- 39 **2. Duties.** The board shall:
- 40 **A. Make recommendations to the department related to:**

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- (1) Administration of this chapter;
- (2) Available medical, psychological and scientific studies, research and other information on the safety and efficacy of psilocybin in treating behavioral health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress;
- (3) Working with psilocybin patients receiving psilocybin services, including:
 - (a) The requirements, specifications and guidelines for providing psilocybin services to a psilocybin patient, including but not limited to holding and verifying the completion of a preparation session and an administration session;
 - (b) The information that must be provided to a psilocybin patient before the psilocybin patient participates in an administration session, including health and safety warnings or other disclosures;
 - (c) The information that must be received from a psilocybin patient to determine whether the psilocybin patient should participate in an administration session, including information that may identify risk factors and contraindications and information related to any public health or safety standards or industry best practices during the administration session; and
 - (d) Transportation needs of a psilocybin patient after the completion of an administration session;
- (4) Public health and safety standards and industry best practices; and
- (5) Required qualifications and practices of psilocybin service facilitators, including:
 - (a) Adherence to a code of professional and ethical conduct;
 - (b) Required education and training; and
 - (c) Holding an administration session, including but not limited to:
 - (i) Individual or group administration sessions; or
 - (ii) Circumstances under which an administration session is considered complete;
- B. Develop and maintain a long-term strategic plan for ensuring that psilocybin services will become and remain a safe, accessible and affordable therapeutic option for all persons for whom psilocybin services may be appropriate; and
- C. Monitor and study federal laws, regulations and policies regarding psilocybin.
- 3. Report.** The board shall submit annually a report to the department that contains the recommendations to the department described in subsection 2, paragraph A, the board's long-term strategic plan described in subsection 2, paragraph B and information and updates on federal laws, regulations and policies regarding psilocybin described in subsection 2, paragraph C.

SUBCHAPTER 3

SENATE AMENDMENT

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RULEMAKING

§2341. Rules

No later than January 15, 2025 and after receipt of the recommendations of the Maine Psilocybin Advisory Board submitted to the department pursuant to section 2333, subsection 2, paragraph A, the department shall adopt rules to implement this chapter. In adopting rules, the department shall consider the recommendations of the Maine Psilocybin Advisory Board. Rules adopted by the department pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 3. Maine Psilocybin Advisory Board; initial board. Notwithstanding the Maine Revised Statutes, Title 22, chapter 555-A, subchapter 2, the following provisions apply to the Maine Psilocybin Advisory Board.

1. Staggered terms for members of the Maine Psilocybin Advisory Board. Except as provided in subsection 2, at the first meeting of the Maine Psilocybin Advisory Board, board members shall draw lots to determine members' initial term lengths so that the initial terms of 4 members expire after one year, the initial terms of 4 members expire after 2 years, the initial terms of 4 members expire after 3 years and the initial terms of 4 members expire after 4 years.

2. Initial appointments to the Maine Psilocybin Advisory Board. The Governor shall appoint the initial board members to the Maine Psilocybin Advisory Board no later than October 15, 2022; the initial appointment of at-large members must include the Legislator who sponsored this legislation, who serves a 4-year term, and 2 other at-large members. At the end of that Legislator's 4-year term on the board, the Governor shall appoint another at-large member.

3. Initial meeting of the Maine Psilocybin Advisory Board. The Maine Psilocybin Advisory Board shall hold its first meeting no later than November 15, 2022 at a time and place specified by the Governor.

4. Initial reports of the Maine Psilocybin Advisory Board. The Maine Psilocybin Advisory Board shall submit no later than April 15, 2023 its findings and recommendations to the Department of Health and Human Services regarding available medical, psychological and scientific studies, research and other information related to the safety and efficacy of psilocybin in treating mental health conditions, including but not limited to substance use disorder, depression, anxiety disorders and end-of-life psychological distress. The Maine Psilocybin Advisory Board shall submit no later than April 15, 2024 its findings and recommendations to the Department of Health and Human Services regarding the board's long-term strategic plan described in the Maine Revised Statutes, Title 22, section 2333, subsection 2, paragraph B, information and updates on federal laws, regulations and policies regarding psilocybin as described in Title 22, section 2333, subsection 2, paragraph C and proposed rules for the implementation of this Act.'

Amend the amendment by relettering or renumbering any nonconsecutive Part letter or section number to read consecutively.

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SUMMARY

2 This amendment replaces Committee Amendment "A." It enacts the Psilocybin Patient
3 Care Act, which accomplishes the following.

4 1. It authorizes certain patients who are 21 years of age or older to obtain a medical
5 recommendation from certain medical providers for the medical use of psilocybin and
6 establishes requirements for medical providers who recommend psilocybin for medical use.

7 2. It authorizes and provides requirements on the use, possession and manufacture of
8 psilocybin by psilocybin patients.

9 3. It establishes a psilocybin service facilitator license to provide psilocybin services
10 to a psilocybin patient and provides qualifications and requirements for a psilocybin service
11 facilitator.

12 4. It authorizes and provides requirements on the possession and manufacture of
13 psilocybin by psilocybin service facilitators and establishes requirements on the provision
14 of psilocybin services to psilocybin patients.

15 5. It establishes the Maine Psilocybin Advisory Board. The board consists of 16
16 members, including the Director of the Maine Center for Disease Control and Prevention
17 and the Director of the Office of Behavioral Health within the Department of Health and
18 Human Services, the Attorney General and various representatives of public health
19 interests, among other related interests. The board also consists of various medical
20 providers, experts in fields relating to psilocybin and at-large members, including, among
21 the initial appointments, the sponsor of this legislation. It establishes the powers and duties
22 of the board, which include annual reporting and making recommendations to the
23 Department of Health and Human Services on rulemaking to implement the Act.

24 6. It provides that the provisions of the Act that authorize and implement the medical
25 use of psilocybin take effect after the Department of Health and Human Services finally
26 adopts rules to implement the Act. The department is directed to adopt rules no later than
27 January 15, 2025, after receiving the recommendations on rulemaking from the Maine
28 Psilocybin Advisory Board. It provides that rules adopted by the department to implement
29 the Act are routine technical rules.

30 SPONSORED BY:  _____

31 (Senator BAILEY, D.)

32 COUNTY: York