

STATE OF NEW YORK

8569--A

2021-2022 Regular Sessions

IN ASSEMBLY

December 13, 2021

Introduced by M. of A. BURKE, LUPARDO -- read once and referred to the Committee on Health -- recommitted to the Committee on Health in accordance with Assembly Rule 3, sec. 2 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law and the state finance law, in relation to medical use of psilocybin

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. Article 33 of the public health law is amended by adding a
2 new title 5-B to read as follows:

3 TITLE V-B

4 MEDICAL USE OF PSILOCYBIN

5 Section 3369-aa. Definitions.

6 3369-bb. Certification of patients.

7 3369-cc. Lawful medical use.

8 3369-dd. Certification of facilitators.

9 3369-ee. Evaluation; research programs; report by department.

10 3369-ff. Relation to other laws.

11 3369-gg. Protections for the medical use of psilocybin.

12 3369-hh. Regulations.

13 3369-ii. Psilocybin therapy grant program.

14 3369-jj. Naturally grown medical psilocybin pilot.

15 3369-kk. Psilocybin therapy advisory board.

16 § 3369-aa. Definitions. For the purposes of this title, the following
17 terms shall have the following meanings:

18 1. "Psilocybin" means a naturally occurring psychedelic prodrug
19 compound produced by fungi, including but not limited to members of the
20 genus Psilocybe. Such term shall include psilocin, the substance into
21 which psilocybin is converted in the human body.

EXPLANATION--Matter in italics (underscored) is new; matter in brackets
[-] is old law to be omitted.

LBD11894-07-2

- 1 2. "Psilocybin product" means psilocybin, concentrated psilocybin, and
2 psilocybin-infused products for use by a certified patient.
- 3 3. "Caring for" means treating a patient, in the course of which the
4 practitioner has completed a full assessment of the patient's medical
5 history and current medical condition.
- 6 4. "Certified medical use" includes the acquisition, cultivation,
7 manufacture, delivery, harvest, possession, preparation, transfer,
8 transportation, or use of medical psilocybin for a certified patient to
9 treat or alleviate a certified patient's medical condition or symptoms
10 associated with the patient's medical condition.
- 11 5. "Certified patient" means a patient who is a resident of New York
12 state or receiving care and treatment in New York state as determined by
13 the board in regulation, and is certified under this chapter.
- 14 6. "Condition" means having a life threatening or disrupting condition
15 certified by the facilitator.
- 16 7. "License" means a written authorization as provided under this
17 title permitting persons to engage in a specified activity authorized
18 pursuant to this title.
- 19 8. "Licensee" means an individual or an entity who has been granted a
20 license under this title.
- 21 9. "Medical psilocybin" means psilocybin as defined in this section,
22 intended for a certified medical use, as determined by the department.
- 23 10. "Package" means any container or receptacle used for holding
24 psilocybin or psilocybin products.
- 25 11. "Facilitator" means a mental health counselor, psychoanalyst,
26 physician, physician assistant, registered professional nurse, clinical
27 nurse specialist, nurse practitioner, occupational therapist, occupa-
28 tional therapy assistant, or licensed clinical social worker
- 29 12. "Terminally ill" means an individual has a medical prognosis that
30 the individual's life expectancy is approximately two years or less if
31 the illness runs its normal course.
- 32 § 3369-bb. Certification of patients. 1. A patient certification may
33 only be issued if:
- 34 (a) the patient has a condition, which shall be specified in the
35 patient's health care record;
- 36 (b) the facilitator by training or experience is qualified to treat
37 the condition;
- 38 (c) the patient is under the facilitator's continuing care for the
39 condition; and
- 40 (d) in the facilitator's professional opinion and review of past
41 treatments, the patient is likely to receive therapeutic or palliative
42 benefit from the primary or adjunctive treatment with medical use of
43 psilocybin for the condition.
- 44 2. The certification shall include: (a) the name, date of birth and
45 address of the patient; (b) a statement that the patient has a condition
46 and the patient is under the facilitator's care for the condition; (c) a
47 statement attesting that all requirements of subdivision one of this
48 section have been satisfied; (d) the date; and (e) the name, address,
49 telephone number, and the signature of the certifying facilitator. The
50 department may require by regulation that the certification shall be on
51 a form provided by the department.
- 52 3. The facilitator shall place a copy of the certification in the
53 patient's health care record.
- 54 4. No facilitator shall issue a certification under this section for
55 themselves.

1 § 3369-cc. Lawful medical use. The use of medical psilocybin by a
2 certified patient for certified medical use, shall be lawful under this
3 title provided that:

4 1. The psilocybin used by a certified patient shall have occurred in a
5 clinical setting, including but not limited to, a facilitator's office
6 or a hospital, under the supervision of a facilitator certified pursuant
7 to section thirty-three hundred sixty-nine-dd of this title. Certified
8 patients who are unable to travel may receive psilocybin treatment in
9 the home. The course developed to certify facilitators by the department
10 shall include regulations and recommendations for creating appropriate
11 settings for psilocybin treatment;

12 2. Facilitators shall receive psilocybin to use through the naturally
13 grown medical psilocybin pilot, pursuant to section thirty-three hundred
14 sixty-nine-jj of this title, upon certification of a patient. Facilita-
15 tors who are able to access any forthcoming Federal Drug Administration
16 approved synthetic psilocybin products shall be permitted to do so.

17 § 3369-dd. Certification of facilitators. Prior to facilitating a
18 psilocybin session, a facilitator must complete a course as determined
19 by the department in regulation.

20 § 3369-ee. Evaluation; research programs; report by department. 1.
21 The department may provide for the analysis and evaluation of the opera-
22 tion of this title. The department may enter into agreements with one or
23 more persons, not-for-profit corporations or other organizations, for
24 the performance of an evaluation of the implementation and effectiveness
25 of this title.

26 2. The department may develop, seek any necessary federal approval
27 for, and carry out research programs relating to medical use of psilocy-
28 bin. Participation in any such research program shall be voluntary on
29 the part of facilitators, patients, and designated caregivers.

30 3. The department shall report every two years, beginning two years
31 after the effective date of this title, to the governor and the legisla-
32 ture on the medical use of psilocybin under this title and make appro-
33 propriate recommendations.

34 § 3369-ff. Relation to other laws. 1. The provisions of this title
35 shall apply, except that where a provision of this title conflicts with
36 another provision of this chapter, this title shall apply.

37 2. Medical psilocybin shall not be deemed to be a "drug" for purposes
38 of article one hundred thirty-seven of the education law.

39 § 3369-gg. Protections for the medical use of psilocybin. 1. Certi-
40 fied patients and practitioners and facilitators shall not be subject to
41 arrest, prosecution, or penalty in any manner, or denied any right or
42 privilege, including but not limited to civil penalty or disciplinary
43 action by a business or occupational or professional licensing board or
44 bureau, solely for the certified medical use of psilocybin, or for any
45 other action or conduct in accordance with this title.

46 2. This subdivision shall not bar the enforcement of a policy prohib-
47 iting an employee from performing his or her employment duties while
48 impaired by a controlled substance. This subdivision shall not require
49 any person or entity to do any act that would put the person or entity
50 in direct violation of federal law or cause it to lose a federal
51 contract or funding.

52 3. The fact that a person is a certified patient and/or acting in
53 accordance with this title, shall not be a consideration in a proceeding
54 pursuant to applicable sections of the domestic relations law, the
55 social services law and the family court act.

1 4. (a) Certification forms and any certified patient information
2 contained within a database shall be deemed exempt from public disclo-
3 sure under sections eighty-seven and eighty-nine of the public officers
4 law. Upon specific request by a certified patient to the department, the
5 department shall verify the requesting patient's status as a valid
6 certified patient to the patient's school or employer or other desig-
7 nated party, to ensure compliance with the protections afforded by this
8 section.

9 (b) The name, contact information, and other information relating to
10 facilitators registered with the department under this title shall be
11 public information and shall be maintained on the department's website
12 accessible to the public in searchable form. However, if a facilitator
13 notifies the department in writing that he or she does not want his or
14 her name and other information disclosed, that facilitator name and
15 other information shall thereafter not be public information or main-
16 tained on the department's website, unless the facilitator cancels the
17 request.

18 5. A person currently under parole, probation or other state or local
19 supervision, or released on bail awaiting trial may not be punished or
20 otherwise penalized for conduct allowed under this title.

21 § 3369-hh. Regulations. The department shall promulgate regulations to
22 implement this title.

23 § 3369-ii. Psilocybin therapy grant program. The department shall
24 establish a program of awarded grants within the amount in the psilocy-
25 bin therapy grant program fund established under section ninety-seven-
26 uuuu of the state finance law for veterans, first responders, and low
27 income individuals to receive monetary assistance for psilocybin therapy
28 pursuant to this title. The department shall promulgate any necessary
29 rules and regulations for the application and distribution of any funds
30 pursuant to this section.

31 § 3369-jj. Naturally grown medical psilocybin pilot. The department
32 of agriculture and markets shall establish and oversee the implementa-
33 tion of a pilot program for psilocybin to be grown in the state to allow
34 for reduced costs in accessing psilocybin for patients via their facili-
35 tators. The department, in conjunction with the department of environ-
36 mental conservation, shall promulgate all necessary rules and regu-
37 lations, as well as a process for approval, governing the safe
38 production of psilocybin, including, but not limited to, environmental
39 and energy standards and restrictions on the use of pesticides.

40 § 3369-kk. Psilocybin therapy advisory board. 1. The psilocybin thera-
41 py advisory board or "advisory board" is established within the depart-
42 ment to advise and issue recommendations on the use of medical psilocy-
43 bin in the state of New York.

44 2. (a) The advisory board shall consist of fourteen voting appointed
45 members, along with the following members serving as non-voting ex-offi-
46 cio members: (i) the commissioner, or his or her designee; and (ii) a
47 representative from the department who is familiar with public health
48 programs and public health activities in the state.

49 (b) The governor shall have eight appointments, the temporary presi-
50 dent of the senate and the speaker of the assembly shall each have three
51 appointments to the board. Advisory board members shall have statewide
52 geographic representation that is balanced and diverse in its composi-
53 tion. Appointed members shall have an expertise in public and behavioral
54 health, substance use disorder treatment, psilocybin-assisted therapy
55 research and/or clinical practice, trauma and mental health, access to

1 care in underserved communities, veteran mental health care, and harm
2 reduction.

3 3. The members shall be appointed to the advisory board to each serve
4 four-year terms and in the event of a vacancy, the vacancy shall be
5 filled in the manner of the original appointment for the remainder of
6 the term. The appointed members and representatives shall receive no
7 compensation for their services but shall be allowed their actual and
8 necessary expenses incurred in the performance of their duties as board
9 members.

10 4. The chairperson of the advisory board and the vice chairperson
11 shall be elected from among the members of the advisory board by the
12 members of such advisory board. The vice chairperson shall represent the
13 advisory board in the absence of the chairperson at all official advi-
14 sory board functions.

15 5. The advisory board shall enact and from time to time may amend
16 bylaws or rules in relation to its meetings and the transaction of its
17 business. The board may also establish committees and subcommittees
18 necessary for the operation of the board. A majority of the total number
19 of voting members which the board would have were there no vacancies,
20 shall constitute a quorum and shall be required for the board to conduct
21 business. All meetings of the advisory board shall be conducted in
22 accordance with the provisions of article seven of the public officers
23 law.

24 6. Within the first two years of the establishment of the advisory
25 board, the board shall meet at least once every calendar month at a time
26 and place determined by the chairperson or a majority of the voting
27 members of the board. After the first two years, the advisory board
28 shall meet at least once every calendar quarter at a time and place
29 determined by the chairperson or a majority of the voting members of the
30 board. The advisory board may also meet at other times and places speci-
31 fied by the call of the chairperson or of a majority of the voting
32 members of the board.

33 7. The advisory board shall have the following duties:

34 (a) Provide advice to the department regarding the provisions of this
35 title and make recommendations on available medical, psychological,
36 scientific studies, research and other information relating to the safe-
37 ty and efficacy of psilocybin in treating mental health conditions,
38 including but not limited to addiction, depression, anxiety disorders
39 and end-of-life psychological distress.

40 (b) Make recommendations to the department on the requirements, spec-
41 ifications and guidelines for providing psilocybin services to a client.

42 (c) Make recommendations to the department on public health and safety
43 standards and industry best practices under this title.

44 (d) Develop a long-term strategic plan for ensuring that psilocybin
45 services will become and remain a safe, accessible and affordable thera-
46 peutic option for all persons eighteen years of age and older in the
47 state for whom psilocybin services may be appropriate.

48 (e) Monitor and study federal laws, regulations and policies regarding
49 psilocybin.

50 (f) Advise on and helping develop public awareness and education
51 campaigns.

52 § 2. The state finance law is amended by adding a new section 97-uuuu
53 to read as follows:

54 § 97-uuuu. Psilocybin therapy grant program fund. 1. There is hereby
55 established in the joint custody of the commissioner of health and the

1 comptroller a fund to be known as the "psilocybin therapy grant program
2 fund".

3 2. The fund shall consist of all monies appropriated for its purpose,
4 and all monies required by this section or any other provision of law to
5 be paid into or credited to such fund. The fund shall not contain any
6 monies which are not intended for the fund.

7 3. Monies shall be payable from the fund on the audit and warrant of
8 the state comptroller on vouchers approved and certified by the commis-
9 sioner of health.

10 § 3. This act shall take effect on the ninetieth day after it shall
11 have become a law. Effective immediately, the addition, amendment
12 and/or repeal of any rule or regulation necessary for the implementation
13 of this act on its effective date are authorized to be made and
14 completed on or before such effective date.