

# STATE OF NEW YORK

3581--A

2023-2024 Regular Sessions

## IN ASSEMBLY

February 3, 2023

Introduced by M. of A. BURKE, LUPARDO, KELLES, DARLING, SIMON, FORREST, ZEBROWSKI, REYES, GONZALEZ-ROJAS, RIVERA, DICKENS, WALLACE, SEAWRIGHT, McDONALD, BRONSON, STIRPE, CLARK, CRUZ, FALL, HEVESI, CONRAD, McDO- NOUGH, DeSTEFANO, MAMDANI, BURDICK, GLICK, PAULIN, BENDETT, SAYEGH, MITAYNES, BORES, GIBBS, BLUMENCRANZ, BURGOS, EPSTEIN, DE LOS SANTOS, WEPRIN, SANTABARBARA, SHRESTHA, RAGA -- read once and referred to the Committee on Health -- 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; and making an appropriation therefor

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

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

### TITLE V-B

#### MEDICAL USE OF PSILOCYBIN

##### Section 3369-aa. Definitions.

3369-bb. Lawful medical use.

3369-cc. Certification of facilitators.

3369-dd. Evaluation; research programs; report by department.

3369-ee. Relation to other laws.

3369-ff. Protections for the medical use of psilocybin.

3369-gg. Regulations.

3369-hh. Psilocybin assisted therapy grant program.

3369-ii. Naturally grown medical psilocybin pilot.

3369-jj. Psilocybin assisted therapy advisory board.

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

1. "Psilocybin" means a naturally occurring psychedelic prodrug compound produced by fungi, including but not limited to members of the

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

LBD07859-02-3

1 genus Psilocybe. Such term shall include psilocin, the substance into  
2 which psilocybin is converted in the human body.

3 2. "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 3. "Certified medical use" includes use of medical psilocybin for a  
7 patient to treat or alleviate a patient's medical condition or symptoms  
8 associated with the patient's medical condition.

9 4. "License" means a written authorization as provided under this  
10 title permitting persons to engage in a specified activity authorized  
11 pursuant to this title.

12 5. "Licensee" means an individual or an entity who has been granted a  
13 license under this title.

14 6. "Medical psilocybin" means psilocybin intended for a certified  
15 medical use, as determined by the department.

16 7. "Facilitator" means a mental health counselor, psychoanalyst,  
17 psychologist, physician, physician assistant, registered professional  
18 nurse, clinical nurse specialist, nurse practitioner, occupational ther-  
19 apist, occupational therapy assistant, licensed clinical social worker,  
20 or an individual with evidence of prior experience and knowledge in the  
21 field of psychedelic assisted therapy who has completed all requirements  
22 under section thirty-three hundred sixty-nine-cc of this title.

23 § 3369-bb. Lawful medical use. The use of medical psilocybin by a  
24 patient for certified medical use, shall be lawful under this title  
25 provided that:

26 1. The psilocybin used by a patient shall have occurred in a clinical  
27 setting, including but not limited to, a facilitator's office or a  
28 hospital, under the supervision of a facilitator certified pursuant to  
29 section thirty-three hundred sixty-nine-cc of this title. Patients who  
30 are unable to travel may receive psilocybin treatment in the home. The  
31 course developed to certify facilitators by the department shall include  
32 regulations and recommendations for creating appropriate settings for  
33 psilocybin treatment;

34 2. Facilitators shall receive psilocybin to use through the naturally  
35 grown medical psilocybin pilot, pursuant to section thirty-three hundred  
36 sixty-nine-ii of this title. Facilitators who are able to access any  
37 forthcoming Federal Food and Drug Administration approved synthetic  
38 psilocybin products or MDMA shall be permitted to do so.

39 § 3369-cc. Certification of facilitators. Prior to facilitating a  
40 psilocybin session, a facilitator shall complete a course as determined  
41 by the department in regulation.

42 § 3369-dd. Evaluation; research programs; report by department. 1.  
43 The department may provide for the analysis and evaluation of the opera-  
44 tion of this title. The department may enter into agreements with one or  
45 more persons, not-for-profit corporations, universities or other organ-  
46 izations, for the performance of an evaluation of the implementation and  
47 effectiveness of this title.

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

52 3. The department shall report every two years, beginning two years  
53 after the effective date of this title, to the governor and the legisla-  
54 ture on the medical use of psilocybin under this title and make appro-  
55 priate recommendations.

1     § 3369-ee. Relation to other laws. 1. The provisions of this title  
2 shall apply, except that where a provision of this title conflicts with  
3 another provision of this chapter, this title shall apply.

4     2. For the purposes of this title, medical psilocybin shall not be  
5 deemed to be a "drug" for purposes of article one hundred thirty-seven  
6 of the education law.

7     § 3369-ff. Protections for the medical use of psilocybin. 1. Patients  
8 and practitioners and facilitators shall not be subject to arrest, pros-  
9 ecution, or penalty in any manner, or denied any right or privilege,  
10 including but not limited to civil penalty or disciplinary action by a  
11 business or occupational or professional licensing board or bureau,  
12 solely for the certified medical use of psilocybin or for any other  
13 action or conduct in accordance with this title.

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

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

24     4. (a) Certification forms and any patient information contained with-  
25 in a database shall be deemed exempt from public disclosure under  
26 sections eighty-seven and eighty-nine of the public officers law. Upon  
27 specific request by a patient to the department, the department shall  
28 verify the requesting patient's status as a valid patient to the  
29 patient's school or employer or other designated party, to ensure  
30 compliance with the protections afforded by this section.

31     (b) The name, contact information, and other information relating to  
32 facilitators registered with the department under this title shall be  
33 public information and shall be maintained on the department's website  
34 accessible to the public in searchable form. However, if a facilitator  
35 notifies the department in writing that he or she does not want his or  
36 her name and other information disclosed, that facilitator's name and  
37 other information shall thereafter not be public information or main-  
38 tained on the department's website, unless the facilitator cancels the  
39 request.

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

43     § 3369-gg. Regulations. The department shall promulgate regulations to  
44 implement this title.

45     § 3369-hh. Psilocybin assisted therapy grant program. 1. The depart-  
46 ment shall establish a psilocybin assisted therapy grant program within  
47 the amount in the psilocybin and MDMA assisted therapy grant program  
48 fund established under section ninety-seven-uuuu of the state finance  
49 law. Such grant program shall provide veterans, first responders,  
50 retired first responders, and low-income individuals, with the funding  
51 necessary to receive psilocybin and/or MDMA assisted therapy. Funding  
52 may be initially applied toward an expanded access program approved by  
53 the federal food and drug administration pursuant to 21 CFR 312 or other  
54 psilocybin and/or MDMA therapies available pursuant to this title. Such  
55 grant program shall be terminated upon the approval of psilocybin and/or

1 MDMA for medical use by the federal drug enforcement administration, or  
2 any successor agency.

3 2. The department shall promulgate any necessary rules and regulations  
4 for the application and distribution of any funds pursuant to this  
5 section.

6 § 3369-ii. Naturally grown medical psilocybin pilot. The department of  
7 agriculture and markets shall establish and oversee the implementation  
8 of a pilot program for psilocybin-containing mushrooms to be grown in  
9 the state. The department shall promulgate all necessary rules and  
10 regulations, regarding medical, therapeutic, or supported use of  
11 naturally grown psilocybin mushrooms. The department, in conjunction  
12 with the department of environmental conservation, shall establish and  
13 implement a process for approval, governing the safe production of  
14 psilocybin, including, but not limited to, environmental and energy  
15 standards and restrictions on the use of pesticides. The department  
16 shall make a good faith effort to work with the federal Department of  
17 Justice and Drug Enforcement Agency to receive public health research  
18 exemption from the Controlled Substances Act under section 872 (e) or  
19 any similar provision. Accredited universities and colleges within the  
20 state may apply to the department to participate in pilot cultivation,  
21 treatment, and research programs.

22 § 3369-jj. Psilocybin assisted therapy advisory board. 1. The psilocy-  
23 bin assisted therapy advisory board or "advisory board" is established  
24 within the department to advise and issue recommendations on the use of  
25 medical psilocybin in the state of New York.

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

31 (b) The governor shall have seven appointments, at least one of which  
32 shall be a member of a federally recognized Native American tribe, the  
33 temporary president of the senate and the speaker of the assembly shall  
34 each have three appointments to the board. Advisory board members shall  
35 have statewide geographic representation that is balanced and diverse in  
36 its composition. Appointed members shall have an expertise in public and  
37 behavioral health, substance use disorder treatment, psilocybin-assisted  
38 therapy research, MDMA-assisted therapy research and/or clinical prac-  
39 tice, trauma and mental health, access to care in underserved communi-  
40 ties, veteran mental health care, and harm reduction.

41 3. The members shall be appointed to the advisory board to each serve  
42 four-year terms and in the event of a vacancy, the vacancy shall be  
43 filled in the manner of the original appointment for the remainder of  
44 the term. The appointed members and representatives shall receive no  
45 compensation for their services but shall be allowed their actual and  
46 necessary expenses incurred in the performance of their duties as board  
47 members.

48 4. The chairperson of the advisory board and the vice chairperson  
49 shall be elected from among the members of the advisory board by the  
50 members of such advisory board. The vice chairperson shall represent the  
51 advisory board in the absence of the chairperson at all official advi-  
52 sory board functions.

53 5. The advisory board shall enact and from time to time may amend  
54 bylaws or rules in relation to its meetings and the transaction of its  
55 business. The board may also establish committees and subcommittees  
56 necessary for the operation of the board. The advisory board is

1 expected to work with established religious, cultural and community-  
2 based psilocybin groups and cultivators on recommendations to the  
3 department regarding guidelines for safe and effective services, safety  
4 standards, industry best practices, code of professional conduct, educa-  
5 tion, training, and examination for facilitators, production, and long  
6 term strategic plans for service. A majority of the total number of  
7 voting members which the board would have were there no vacancies, shall  
8 constitute a quorum and shall be required for the board to conduct busi-  
9 ness. All meetings of the advisory board shall be conducted in accord-  
10 ance with the provisions of article seven of the public officers law.

11 6. (a) Within the first two years of the establishment of the advisory  
12 board, the board shall meet at least once every calendar month at a time  
13 and place determined by the chairperson or a majority of the voting  
14 members of the board. After the first two years, the advisory board  
15 shall meet at least once every calendar quarter at a time and place  
16 determined by the chairperson or a majority of the voting members of the  
17 board. The advisory board may also meet at other times and places speci-  
18 fied by the call of the chairperson or of a majority of the voting  
19 members of the board.

20 (b) After the first year of the program's implementation, there shall  
21 be: (i) a program audit incorporating patient feedback; and (ii) a  
22 state and independent review of efficacy, efficiency, cost, and equity.  
23 The audit will include consideration of whether and how to expand psilo-  
24 cybin access, provided that the pilot program results are successful.

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

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

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

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

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

40 (e) Monitor and study federal laws, regulations and policies regarding  
41 psilocybin.

42 (f) Advise on and helping develop public awareness and education  
43 campaigns.

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

46 § 97-uuuu. Psilocybin and MDMA assisted therapy grant program fund. 1.  
47 There is hereby established in the joint custody of the commissioner of  
48 health and the comptroller a fund to be known as the "psilocybin and  
49 MDMA assisted therapy grant program fund".

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

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

1     § 3. The sum of five million dollars (\$5,000,000), or so much thereof  
2 as may be necessary, is hereby appropriated to the psilocybin and MDMA  
3 assisted therapy or P.A.T grant program fund, established under section  
4 97-uuuu of the state finance law, out of any moneys in the state treas-  
5 ury in the general fund, not otherwise appropriated, and made immediate-  
6 ly available, for the purpose of carrying out the provisions of this  
7 act. Such moneys shall be payable on the audit and warrant of the comp-  
8 troller on vouchers certified or approved by the commissioner of health  
9 in the manner prescribed by law.

10    § 4. This act shall take effect immediately.