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, McDONOUGH, 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.

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

2. "Caring for" means treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition.

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

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

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

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

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

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

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

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

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

§ 3369-dd. Evaluation; research programs; report by department. 1. The department may provide for the analysis and evaluation of the operation of this title. The department may enter into agreements with one or more persons, not-for-profit corporations, universities or other organizations, for the performance of an evaluation of the implementation and effectiveness of this title.

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

3. The department shall report every two years, beginning two years after the effective date of this title, to the governor and the legislature on the medical use of psilocybin under this title and make appropriate recommendations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. The chairperson of the advisory board and the vice chairperson shall be elected from among the members of the advisory board by the members of such advisory board. The vice chairperson shall represent the advisory board in the absence of the chairperson at all official advisory board functions.

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

expected to work with established religious, cultural and community-based psilocybin groups and cultivators on recommendations to the department regarding guidelines for safe and effective services, safety standards, industry best practices, code of professional conduct, education, training, and examination for facilitators, production, and long term strategic plans for service. A majority of the total number of voting members which the board would have were there no vacancies, shall constitute a quorum and shall be required for the board to conduct business. All meetings of the advisory board shall be conducted in accordance with the provisions of article seven of the public officers law.

6. (a) Within the first two years of the establishment of the advisory board, the board shall meet at least once every calendar month at a time and place determined by the chairperson or a majority of the voting members of the board. After the first two years, the advisory board shall meet at least once every calendar quarter at a time and place determined by the chairperson or a majority of the voting members of the board. The advisory board may also meet at other times and places specified by the call of the chairperson or of a majority of the voting members of the board.

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

7. The advisory board shall have the following duties:

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

(b) Make recommendations to the department on the requirements, specifications and guidelines for providing psilocybin services to a client.

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

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

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

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

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

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

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

3. Monies shall be payable from the fund on the audit and warrant of the state comptroller on vouchers approved and certified by the commissioner of health.

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

§ 4. This act shall take effect immediately.