

STATE OF NEW YORK

2142--A

2025-2026 Regular Sessions

IN ASSEMBLY

January 15, 2025

Introduced by M. of A. PAULIN, LUPARDO, HEVESI, McDONALD, WEPRIN, BURDICK -- 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 penal law, in relation to authorizing the use of psilocybin to treat qualified medical conditions

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

Section 1. This act shall be known and may be cited as the "medical psilocybin act".

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

TITLE V-B

MEDICAL PSILOCYBIN ACT

Section 3369-aa. Definitions.

3369-bb. Medical use of psilocybin program.

3369-cc. Registry identification cards.

3369-dd. Exemption from criminal and civil penalties for possession and medical use of psilocybin.

3369-ee. Prohibitions, restrictions and limitations on the use of psilocybin.

3369-ff. Recordkeeping.

3369-gg. Labelling; warnings.

3369-hh. Safety and testing requirements.

3369-ii. Violations.

3369-jj. Reporting.

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

§ 3369-aa. Definitions. As used in this title:

1. "Designated caregiver" means the individual designated by a qualified patient in a registry application. A qualified patient may designate up to two caregivers;

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

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2. "Licensed healthcare provider" means a person who: (a) is licensed as a physician, a psychologist or a nurse practitioner under title eight of the education law; and (b) has completed a two to four hour course as determined by the commissioner in regulations; provided however, a registration shall not be denied without cause. Such course may count toward board certification requirements. To be a licensed healthcare provider under this title, such licensed professional's authorized scope of practice does not need to, but may include, medical diagnosis or treatment of a qualifying health condition or the prescription of medications;

3. "Licensed producer" means a person or business enterprise, including a sole proprietorship, partnership, corporation, limited liability company, or other business enterprise, who or which has a license from the department pursuant to this title to grow and harvest or prepare psilocybin from psilocybin-producing mushrooms, including to compound, convert, process or manufacture psilocybin products directly or indirectly from psilocybin mushrooms, to package or repackage or label or relabel the products, and to transport and deliver psilocybin and psilocybin products;

4. "Permitted medical use" means the quantity of psilocybin, dosing parameters, method of administration, setting, and whether supervised use is required, for an individual qualified patient as determined by a licensed healthcare provider as part of an individualized treatment plan;

5. "Psilocybin" means the naturally occurring psychedelic compound 4-phosphoryloxy-N,N-dimethyltryptamine, also known as 4-PO-DMT, and its pharmacologically active metabolite psilocin, 4-hydroxy-N,N-dimethyltryptamine, found in certain mushrooms, but does not include synthetic or synthetic analogs of psilocybin;

6. "Qualified patient" means a patient whose licensed healthcare provider has judged to be a medically appropriate candidate for the use of medical psilocybin based on being diagnosed with a qualifying condition;

7. "Qualifying condition" includes:

- (a) major treatment-resistant depression;
- (b) post-traumatic stress disorder;
- (c) substance use disorders;
- (d) end-of-life care;
- (e) cluster headaches; and
- (f) other conditions approved by the department;

8. "Qualified supervisor" means an individual who meets training and qualification standards established by the department and is authorized by the department to supervise the use of psilocybin by qualified patients. A qualified supervisor need not be a licensed healthcare provider; and

9. "Supervised use" means the administration of psilocybin in the presence of a licensed healthcare provider, a licensed healthcare provider's authorized staff, or a qualified supervisor.

§ 3369-bb. Medical use of psilocybin program. 1. The "medical use of psilocybin program" or "the program" is hereby created within the department. In developing the program, the department shall establish:

- (a) procedures for the issuance, renewal, suspension, and revocation of licenses, registrations, or permits necessary for the implementation and operation of the program;
- (b) appropriate requirements for licensed producers, licensed healthcare providers and qualified patients;

1 (c) criteria and a process for licensure and registration of psilocy-
2 bin producers;

3 (d) necessary initial and ongoing training for licensed producers,
4 licensed healthcare providers and qualified supervisors;

5 (e) appropriate qualifications, education and training standards for
6 qualified supervisors;

7 (f) treatment protocols, including patient selection criteria, medical
8 service standards, dosage standards and approved settings for adminis-
9 tration of psilocybin to qualified patients;

10 (g) requirements and standards for supervised use that are focused on
11 safety and efficacy;

12 (h) safety protocols for producing psilocybin from mushrooms, trans-
13 porting, storing, handling and dispensing psilocybin to qualified
14 patients, licensed healthcare providers, qualified supervisors, or other
15 individuals authorized by the department;

16 (i) registry identification systems for patients and designated care-
17 givers;

18 (j) other best practices for licensed producers, licensed healthcare
19 providers and qualified supervisors;

20 (k) requirements for data collection to evaluate the program and the
21 use of best practices by licensed producers, licensed healthcare provid-
22 ers, and qualified supervisors; and

23 (l) other requirements, restrictions and limitations deemed necessary
24 by the department.

25 2. The department shall require that either the qualified patient or
26 the licensed healthcare provider who is recommending psilocybin and
27 treating such patient be a New York state resident.

28 3. The department shall monitor licensed producers, licensed health-
29 care providers, and qualified supervisors to ensure compliance with the
30 provisions of this title and the rules and regulations promulgated
31 therefor.

32 4. The department shall consult with the department of mental hygiene
33 in developing best practices, including best settings for administration
34 of psilocybin. Subject to the regulations of the department, a licensed
35 healthcare provider or qualified supervisor shall determine the appro-
36 priate setting on a case-by-case basis for qualified patients.

37 5. The department shall develop and require labels warning consumers
38 of any potential impact on human health resulting from the consumption
39 of psilocybin products that shall be affixed to those products when
40 sold, if such labels are deemed warranted by the department and may
41 establish standardized and/or uniform packaging and labeling require-
42 ments for medical use psilocybin products.

43 6. Psilocybin shall be dispensed in a sealed and properly labeled
44 package. The labeling shall contain: (a) the information required to be
45 included in the receipt provided to the qualified patient by the
46 licensed producer; (b) the packaging date; (c) any applicable date by
47 which the psilocybin should be used; (d) the amount of individual doses
48 contained within; (e) usage instructions; and (f) a warning that the
49 psilocybin must be kept in the original container in which it was
50 dispensed except for the portion removed for immediate consumption.

51 7. Other than as set forth in subdivision eight of this section, a
52 licensed producer may, in accordance with a qualified patient's permit-
53 ted medical use, transport and deliver psilocybin to: (a) a qualified
54 patient; (b) a licensed healthcare provider; (c) a qualified supervisor;
55 or (d) an authorized designated caregiver.

1 8. Psilocybin intended for supervised use as required by the qualified
2 patient's permitted medical use shall only be delivered directly to a
3 licensed healthcare provider, a licensed healthcare provider's author-
4 ized staff, or to a qualified supervisor.

5 9. (a) No licensed producer may sell, deliver, distribute or dispense
6 a quantity of psilocybin larger than, or in a manner inconsistent with,
7 a qualified patient's permitted medical use as allowed under this title.

8 (b) When dispensing psilocybin to a qualified patient, the licensed
9 producer shall not dispense an amount greater than a thirty day supply
10 of the dosage as determined by the licensed healthcare provider,
11 consistent with the qualified patient's permitted medical use, or, if
12 not specified by the licensed healthcare provider, by the department
13 through regulation, which may include qualifying condition-specific
14 standards for dosing, administration, setting, and supervised use.

15 § 3369-cc. Registry identification cards. 1. Upon a determination of
16 qualification of a patient by a licensed healthcare provider to partic-
17 ipate in the program under this title, the department shall issue a
18 registry identification card for such qualified patient. A registry
19 identification card shall expire as provided in this section. The
20 department may specify a form for a registry application, in which case
21 the department shall provide the form on request, reproductions of the
22 form may be used, and the form shall be available for downloading from
23 the department's website.

24 2. To obtain, amend or renew a registry identification card, a quali-
25 fied patient shall file a registry application with the department. The
26 registry application or renewal application shall include:

27 (a) (i) the licensed healthcare provider's determination of the
28 patient's qualification under this title;

29 (ii) the name, address, and date of birth of the patient;

30 (iii) the date of the qualification;

31 (iv) if the patient has a registry identification card based on a
32 current valid certification, the registry identification number and
33 expiration date of that registry identification card;

34 (v) the specified date until which the patient would benefit from
35 psilocybin use, if the certification states such a date;

36 (vi) the name, address, federal registration number, if any, and tele-
37 phone number of the licensed healthcare provider;

38 (vii) any recommendation or limitation by the provider as to the form
39 or forms of psilocybin or dosage for the qualified patient and whether
40 or not supervised use is required; and

41 (viii) other individual identifying information required by the
42 department;

43 (b) in the case of a qualified patient, if the patient designates a
44 designated caregiver, the name, address, and date of birth of the desig-
45 nated caregiver, and other individual identifying information required
46 by the department;

47 (c) in the case of a designated caregiver:

48 (i) the name, address, and date of birth of the designated caregiver;
49 and

50 (ii) if the designated caregiver has a registry identification card,
51 the registry identification number and expiration date of that registry
52 identification card;

53 (d) a statement that a false statement made in the application is
54 punishable under section 210.45 of the penal law;

55 (e) the date of the application and the signature of the qualified
56 patient; and

1 (f) any other requirements determined by the commissioner.

2 3. A registry identification card shall:

3 (a) contain the name of the qualified patient or the designated care-
4 giver;

5 (b) contain the date of issuance and expiration date of the registry
6 identification card;

7 (c) contain a registry identification number for the qualified patient
8 or the designated caregiver, and a registry identification number;

9 (d) contain a photograph of the individual to whom the registry iden-
10 tification card is being issued, which shall be obtained by the depart-
11 ment in a manner specified by the commissioner in regulations; provided,
12 however, that if the department requires qualified patients to submit
13 photographs for this purpose, there shall be a reasonable accommodation
14 of qualified patients who are confined to their homes due to their
15 medical conditions and may therefore have difficulty procuring photo-
16 graphs;

17 (e) be a secure document as determined by the department;

18 (f) plainly state any recommendation or limitation by the licensed
19 healthcare provider as to the form or forms of psilocybin or dosage for
20 the qualified patient; and

21 (g) any other requirements determined by the commissioner.

22 4. The department shall maintain a confidential list of the persons to
23 whom it has issued registry identification cards. Individual identifying
24 information obtained by the department under this title shall be confi-
25 dential and exempt from disclosure under article six of the public offi-
26 cers law. Notwithstanding this subdivision, the department may notify
27 any appropriate law enforcement agency of information relating to any
28 violation or suspected violation of this title.

29 5. The department shall verify to law enforcement personnel in an
30 appropriate case whether a registry identification card is valid.

31 6. If a qualified patient willfully violates any provision of this
32 title as determined by the department, their registry identification
33 card may be suspended or revoked, in addition to any other penalty that
34 may apply.

35 7. The department shall establish a registry system for designated
36 caregivers who may assist qualified patients, including in obtaining and
37 transporting psilocybin, subject to department regulations.

38 8. The department may waive the requirement for a registry identifica-
39 tion card for certain categories of qualified patients, including but
40 not limited to:

41 (a) qualified patients receiving a limited number of supervised admin-
42 istrations;

43 (b) qualified patients receiving care in end-of-life settings; or

44 (c) other categories of qualified patients where the department deter-
45 mines that registry identification cards are not necessary or appropri-
46 ate.

47 § 3369-dd. Exemption from criminal and civil penalties for possession
48 and medical use of psilocybin. 1. (a) A licensed producer shall not be
49 subject to arrest, prosecution or penalty for the manufacture,
50 possession, transportation, delivery or sale of psilocybin which is in
51 accordance with the provisions of this title.

52 (b) A licensed producer, licensed healthcare provider, qualified
53 supervisor, or a qualified patient shall not be subject to arrest, pros-
54 ecution or penalty for possessing or transporting psilocybin consistent
55 with a qualified patient's permitted medical use and in a quantity not

1 more than allowed by department regulations and in accordance with the
2 provisions of this title.

3 (c) A licensed healthcare provider or qualified supervisor shall not
4 be subject to arrest, prosecution or penalty for providing, and/or
5 administering psilocybin in accordance with the regulations promulgated
6 under this title.

7 (d) A qualified patient shall not be subject to arrest, prosecution or
8 penalty for the possession and use of psilocybin for medical purposes in
9 dosages which are in accordance with the regulations promulgated under
10 this title.

11 (e) A qualified patient, designated caregiver, licensed healthcare
12 provider, qualified supervisor, licensed producer, or other individual
13 authorized by the department, shall not be subject to arrest, prose-
14 cution, or penalty in any manner, or denied any right or privilege,
15 including but not limited to civil penalty or disciplinary action by a
16 business or occupational or professional licensing board or bureau,
17 solely for actions and conduct in accordance with this title.

18 2. The provisions of this title shall not apply to federal food and
19 drug administration-approved clinical trials, or to federal food and
20 drug administration-approved products which contain psilocybin.

21 3. A person currently under state or local supervision, including but
22 not limited to probation, parole, release on bail awaiting trial, or who
23 is in the custody or under the supervision of the department of
24 corrections and community supervision shall not be penalized for partic-
25 ipation in the program.

26 § 3369-ee. Prohibitions, restrictions and limitations on the
27 possession and use of psilocybin. 1. Participation in the medical use of
28 psilocybin program by a licensed producer, licensed healthcare provider,
29 qualified supervisor, or qualified patient does not relieve the produc-
30 er, licensed healthcare provider, qualified supervisor or qualified
31 patient from:

32 (a) criminal prosecution or civil penalties for activities not author-
33 ized under this title; or

34 (b) liability for damages or criminal prosecution arising out of the
35 operation of a motor vehicle while under the influence of psilocybin.

36 2. Psilocybin shall only be dispensed by a licensed producer to a
37 qualified patient, a licensed healthcare provider and their authorized
38 staff, a qualified supervisor, or an individual otherwise authorized by
39 the department as allowed by department regulation and consistent with
40 the provisions of this title.

41 3. The amount of psilocybin that may be possessed by, or on behalf of,
42 a qualified patient shall not exceed a thirty day supply, as determined
43 by the qualifying patient's permitted medical use and department rule.

44 4. A person who makes a fraudulent representation to a law enforcement
45 officer about the person's participation in the program to avoid arrest
46 or prosecution for a psilocybin-related offense is guilty of a misdemea-
47 nor.

48 5. For the purposes of this title, psilocybin shall not be deemed to
49 be a "drug" for purposes of article one hundred thirty-seven of the
50 education law and is not intended to be distributed through any pharma-
51 cy.

52 6. Nothing in this title permits or authorizes the promotion of use of
53 psilocybin as a drug, substance, or product intended to diagnose, treat,
54 cure, or prevent any disease or mental health or other health condi-
55 tions.

1 § 3369-ff. Recordkeeping. 1. A licensed producer shall maintain
2 records of all production and sales of psilocybin containing products.
3 Upon request by the department, a licensed producer shall produce such
4 records and permit annual inspections of any facilities utilized by such
5 producer for such purpose.

6 2. The department shall maintain a registry of licensed producers.

7 § 3369-gg. Labelling; warnings. A licensed producer shall clearly
8 label any psilocybin or psilocybin-containing product with the full name
9 of the licensed producer, the producer's office address, a description
10 of contents of the product including the strain and the culture-specific
11 approximate psilocybin equivalent potency; and any warning label
12 required by the department pursuant to section thirty-three hundred
13 sixty-nine-bb of this title.

14 § 3369-hh. Safety and testing requirements. 1. As is necessary to
15 protect the public health and safety the department shall adopt rules
16 and regulations:

17 (a) Establishing standards for testing psilocybin products.

18 (b) Identifying appropriate tests for psilocybin products, depending
19 on the type of psilocybin product and the manner in which the psilocybin
20 product was manufactured, that are necessary to protect the public
21 health and safety, which may include, but not be limited to, tests for:

22 (i) Microbiological contaminants;

23 (ii) Pesticides;

24 (iii) Other contaminants;

25 (iv) Solvents or residual solvents; and

26 (v) Psilocybin concentration.

27 (c) Establishing procedures for determining batch sizes and for sampl-
28 ing psilocybin products.

29 (d) Establishing different minimum standards for different varieties
30 of psilocybin products.

31 2. In addition to the testing requirements established under subdivi-
32 sion one of this section, the department may require psilocybin products
33 to be tested in accordance with any applicable law of this state, or any
34 applicable rule adopted under a law of this state, related to the
35 production and processing of food products or commodities.

36 3. In adopting rules and regulations under this subdivision the
37 department may require a licensed producer to test psilocybin products
38 before selling or transferring the psilocybin products.

39 4. The department may conduct random testing of psilocybin products
40 for the purpose of determining whether a licensee subject to testing is
41 in compliance with this subdivision.

42 § 3369-ii. Violations. 1. Psilocybin licensed producers who are in
43 violation of this title may be penalized by loss of such license permit
44 for a period of two years and, after such penalization period, shall
45 subsequently be entitled to apply for a psilocybin permit.

46 2. The department may revoke the authority of a licensed producer to
47 participate in the program.

48 § 3369-jj. Reporting. The department shall promulgate regulations for
49 the collection of data from licensed producers, licensed healthcare
50 providers, qualified supervisors and qualified patients as a means to
51 evaluate the effectiveness of the medical use of psilocybin. The depart-
52 ment shall annually report its findings to the legislature. Data shall
53 be reported in such a way that any individual qualified patients cannot
54 be identified.

55 § 3369-kk. Protections for the medical use of psilocybin. 1. Being a
56 qualified patient shall be deemed to be having a "disability" under

1 article fifteen of the executive law, section forty-c of the civil
2 rights law, sections 240.00, 485.00, and 485.05 of the penal law, and
3 section 200.50 of the criminal procedure law. This subdivision shall not
4 bar the enforcement of a policy prohibiting an employee from performing
5 their employment duties while impaired by a controlled substance. This
6 subdivision shall not require any person or entity to do any act that
7 would put the person or entity in direct violation of federal law or
8 cause it to lose a federal contract or funding.

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

13 3. (a) Any qualified patient information contained shall be deemed
14 exempt from public disclosure under sections eighty-seven and eighty-
15 nine of the public officers law. Upon specific request by a qualified
16 patient to the department, the department shall verify the requesting
17 patient's status as a valid qualified patient to the patient's school or
18 employer or other designated party, to ensure compliance with the
19 protections afforded by this section.

20 (b) The name, contact information, and other information relating to a
21 licensed healthcare provider's qualifying patients under this title
22 shall be public information and shall be maintained on the department's
23 website accessible to the public in searchable form. However, if a
24 licensed healthcare provider notifies the board in writing that they do
25 not want their name and other information disclosed, that licensed
26 healthcare provider's name and other information shall thereafter not be
27 public information or maintained on the department's website, unless the
28 licensed healthcare provider cancels the request.

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

32 5. Employees who use medical psilocybin shall be afforded the same
33 rights, procedures and protections that are available and applicable to
34 injured workers under the workers' compensation law, or any rules or
35 regulations promulgated thereunder, when such injured workers are
36 prescribed medications that may prohibit, restrict, or require the
37 modification of the performance of their duties.

38 § 3. The penal law is amended by adding a new article 174 to read as
39 follows:

40 ARTICLE 174

41 CRIMINAL DIVERSION OF MEDICAL PSILOCYBIN

42 Section 174.00 Criminal diversion of medical psilocybin; definitions.

43 174.05 Criminal diversion of medical psilocybin; limitations.

44 174.10 Criminal diversion of medical psilocybin in the first
45 degree.

46 174.11 Criminal diversion of medical psilocybin in the second
47 degree.

48 174.15 Criminal retention of medical psilocybin.

49 174.20 Relationship to other controlled substances offenses.

50 § 174.00 Criminal diversion of medical psilocybin; definitions.

51 The following definitions are applicable to this article:

52 1. "Medical psilocybin" means psilocybin as defined in subdivision
53 five of section thirty-three hundred sixty-nine-aa of the public health
54 law which is provided to a qualifying patient pursuant to title five-B
55 of article thirty-three of the public health law.

2. "Licensure" means a license made under section thirty-three hundred sixty-nine-bb of the public health law.

§ 174.05 Criminal diversion of medical psilocybin; limitations.

The provisions of this article shall not apply to:

1. a licensed healthcare provider authorized to recommend and/or administer medical psilocybin under title five-B of article thirty-three of the public health law who acted in good faith in the lawful course of their profession; or

2. a licensed producer as that term is defined in subdivision three of section thirty-three hundred sixty-nine-aa of the public health law who acted in good faith; or

3. a person who acted in good faith seeking treatment for a medical condition or assisting another person to obtain treatment for a medical condition.

§ 174.10 Criminal diversion of medical psilocybin in the first degree.

A person is guilty of criminal diversion of medical psilocybin in the first degree when such person is a licensed healthcare provider or qualified supervisor, as defined in subdivision two of section thirty-three hundred sixty-nine-aa of the public health law, who recommends or administers with knowledge of reasonable grounds to know that (i) the recipient has no medical need for it, or (ii) it is for a purpose other than to treat a qualifying condition as defined in subdivision seven of section thirty-three hundred sixty-nine-aa of the public health law.

Criminal diversion of medical psilocybin in the first degree is a class E felony.

§ 174.11 Criminal diversion of medical psilocybin in the second degree.

A person is guilty of criminal diversion of medical psilocybin in the second degree when such person sells, trades, delivers, or otherwise provides medical psilocybin to another with knowledge or reasonable grounds to know that the recipient is not registered under title five-B of article thirty-three of the public health law.

Criminal diversion of medical psilocybin in the second degree is a class B misdemeanor.

§ 174.15 Criminal retention of medical psilocybin.

A person is guilty of criminal retention of medical psilocybin when, being a qualifying patient as such term is defined in subdivision six of section thirty-three hundred sixty-nine-aa of the public health law, respectively, such person knowingly obtains, possesses, stores or maintains an amount of psilocybin in excess of the amount they are authorized to possess under the provisions of title five-B of article thirty-three of the public health law.

Criminal retention of medical psilocybin is a class A misdemeanor.

§ 174.20 Relationship to other controlled substances offenses.

A person shall not be convicted of both an offense defined in this article and an offense defined in article two hundred twenty of this chapter based on the same act or transaction. The provisions of this article shall be construed to avoid duplicative punishment. A person may be prosecuted under this article or under article two hundred twenty of this chapter, but not both for the same act or transaction.

§ 4. This act shall take effect July 1, 2028. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such date.