

STATE OF NEW YORK

8569

2021-2022 Regular Sessions

IN ASSEMBLY

December 13, 2021

Introduced by M. of A. BURKE -- read once and referred to the Committee on Health

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:

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. Registry identification cards.

9 3369-ee. Registration as a psilocybin service center.

10 3369-ff. Registered organizations.

11 3369-gg. Registering of registered organizations.

12 3369-hh. Reports of registered organizations.

13 3369-ii. Evaluation; research programs; report by department.

14 3369-jj. Psilocybin research license.

15 3369-kk. Relation to other laws.

16 3369-ll. Psilocybin service facilitator license requirements.

17 3369-mm. Protections for the medical use of psilocybin.

18 3369-nn. Regulations.

19 3369-oo. Suspend; terminate.

20 3369-pp. Pricing.

21 3369-qq. Psilocybin services grant program.

22 3369-rr. Psilocybin services advisory board.

23 § 3369-aa. Definitions. For the purposes of this title, the following
24 terms shall have the following meanings:

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

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

5 2. "Psilocybin product" means psilocybin, concentrated psilocybin, and
6 psilocybin-infused products for use by a certified patient.

7 3. "Psilocybin-infused products" means products that have been manu-
8 factured and contain either psilocybin or concentrated psilocybin and
9 other ingredients that are intended for use or consumption.

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

13 5. "Certified medical use" includes the acquisition, cultivation,
14 manufacture, delivery, harvest, possession, preparation, transfer,
15 transportation, or use of medical psilocybin for a certified patient, or
16 paraphernalia relating to the administration of psilocybin to treat or
17 alleviate a certified patient's medical condition or symptoms associated
18 with the patient's medical condition.

19 6. "Certified patient" means a patient who is a resident of New York
20 state or receiving care and treatment in New York state as determined by
21 the board in regulation, and is certified under this chapter.

22 7. "Condition" means having one of the following conditions: cancer,
23 positive status for human immunodeficiency virus or acquired immune
24 deficiency syndrome, amyotrophic lateral sclerosis, Parkinson's disease,
25 multiple sclerosis, damage to the nervous tissue of the spinal cord with
26 objective neurological indication of intractable spasticity, epilepsy,
27 inflammatory bowel disease, neuropathies, Huntington's disease, post-
28 traumatic stress disorder, pain that degrades health and functional
29 capability where the use of medical cannabis is an alternative to opioid
30 use, substance use disorder, Alzheimer's, muscular dystrophy, dystonia,
31 rheumatoid arthritis, autism or any other condition certified by the
32 practitioner.

33 8. "Cultivation" means growing, cloning, harvesting, drying, curing,
34 grading, and trimming of psilocybin plants for sale to certain other
35 categories of psilocybin license- and permit-holders.

36 9. "Psilocybin service center" means a facility that registers with
37 the department to assist one or more certified patients with the
38 purchase, acquisition, possession, use or administration of medical
39 psilocybin.

40 10. "Designated caregiver" means an individual designated by a certi-
41 fied patient in a registry application. A certified patient may desig-
42 nate up to five designated caregivers not counting designated caregiver
43 facilities or designated caregiver facilities' employees.

44 11. "Psilocybin services" means services provided to a certified
45 patient before, during and after the patient's consumption of a psilocy-
46 bin product, including a preparation session and integration session.

47 12. "Psilocybin service center employee" means an employee of a psilo-
48 cybin service center.

49 13. "Form of medical psilocybin" means characteristics of the medical
50 psilocybin recommended or limited for a particular certified patient,
51 including the method of consumption and any particular strain, variety,
52 and quantity or percentage of psilocybin or particular active ingredi-
53 ent, or whole psilocybin.

54 14. "Laboratory testing facility" means any independent laboratory
55 capable of testing psilocybin and psilocybin products for medical-use.

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

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

6 17. "Medical psilocybin" means psilocybin as defined in this section,
7 intended for a certified medical use, as determined by the department.

8 18. "Package" means any container or receptacle used for holding
9 psilocybin or psilocybin products.

10 19. "Practitioner" means a practitioner who is licensed, registered or
11 certified by New York state to prescribe controlled substances within
12 the state. Nothing in this title shall be interpreted so as to give any
13 such person authority to act outside their scope of practice as defined
14 by title eight of the education law. Additionally, nothing in this title
15 shall be interpreted to allow any unlicensed, unregistered, or uncerti-
16 fied person to act in a manner that would require a license, registra-
17 tion, or certification pursuant to title eight of the education law.

18 20. "Processor" means a licensee that extracts concentrated psilocybin
19 and/or compounds, blends, extracts, infuses, or otherwise manufactures
20 concentrated psilocybin or psilocybin products, but not the cultivation
21 of the psilocybin contained in the psilocybin product.

22 21. "Registered organization" means an organization registered under
23 this title.

24 22. "Registry application" means an application properly completed and
25 filed with the department by a certified patient under this title.

26 23. "Registry identification card" means a document that identifies a
27 certified patient or designated caregiver, as provided under this title.

28 24. "Psilocybin service center operator" means a person or entity that
29 operates a psilocybin service center.

30 25. "Psilocybin service facilitator" means a person or entity that is
31 licensed in accordance with this title to administer psilocybin
32 services.

33 26. "Small business" means small business as defined in section one
34 hundred thirty-one of the economic development law and shall apply for
35 purposes of this chapter where any inconsistencies exist.

36 27. "Terminally ill" means an individual has a medical prognosis that
37 the individual's life expectancy is approximately one year or less if
38 the illness runs its normal course.

39 28. "Warehouse" means and includes a place in which psilocybin
40 products are securely housed or stored.

41 29. "Wholesale" means to solicit or receive an order for, to keep or
42 expose for sale, and to keep with intent to sell, made by any licensed
43 person, whether principal, proprietor, agent, or employee of any medi-
44 cal-use psilocybin or psilocybin product, for purposes of resale.

45 30. "Administration session" means a session held at a psilocybin
46 service center at which a certified patient purchases, consumes and
47 experiences the effects of a psilocybin product under the supervision of
48 a psilocybin service facilitator.

49 31. "Integration session" means a meeting between a certified patient
50 and a psilocybin service facilitator that may occur after the patient
51 completes an administration session.

52 32. "Preparation session" means a meeting between a certified patient
53 and a psilocybin service facilitator that must occur before such patient
54 participates in an administration session.

55 33. "Premises" means all public and private enclosed areas, as well as
56 areas outside of a building at a location, other than a person's primary

1 residence, that are used for activities permitted under this title,
2 including manufacturing psilocybin products, operating a psilocybin
3 service center or providing psilocybin services to certified patients.
4 Such definition shall include offices, kitchens, rest rooms and store-
5 rooms.

6 § 3369-bb. Certification of patients. 1. A patient certification may
7 only be issued if:

8 (a) the patient has a condition, which shall be specified in the
9 patient's health care record;

10 (b) the practitioner by training or experience is qualified to treat
11 the condition;

12 (c) the patient is under the practitioner's continuing care for the
13 condition; and

14 (d) in the practitioner's professional opinion and review of past
15 treatments, the patient is likely to receive therapeutic or palliative
16 benefit from the primary or adjunctive treatment with medical use of
17 psilocybin for the condition.

18 2. The certification shall include: (a) the name, date of birth and
19 address of the patient; (b) a statement that the patient has a condition
20 and the patient is under the practitioner's care for the condition; (c)
21 a statement attesting that all requirements of subdivision one of this
22 section have been satisfied; (d) the date; and (e) the name, address,
23 telephone number, and the signature of the certifying practitioner. The
24 department may require by regulation that the certification shall be on
25 a form provided by the department. The practitioner may state in the
26 certification that, in the practitioner's professional opinion, the
27 patient would benefit from medical psilocybin only until a specified
28 date. The practitioner may state in the certification that, in the prac-
29 titioner's professional opinion, the patient is terminally ill and that
30 the certification shall not expire until the patient dies.

31 3. In making a certification, the practitioner may consider the form
32 of medical psilocybin the patient should consume, including the method
33 of consumption and any particular strain, variety, and quantity or
34 percentage of psilocybin or particular active ingredient, and appropri-
35 ate dosage. The practitioner may state in the certification any recom-
36 mendation or limitation the practitioner makes, in his or her profes-
37 sional opinion, concerning the appropriate form or forms of medical
38 psilocybin and dosage.

39 4. Every practitioner shall consult the prescription monitoring
40 program registry prior to making or issuing a certification, for the
41 purpose of reviewing a patient's controlled substance history. For
42 purposes of this section, a practitioner may authorize a designee to
43 consult the prescription monitoring program registry on his or her
44 behalf, provided that such designation is in accordance with section
45 thirty-three hundred forty-three-a of this article.

46 5. The practitioner shall give the certification to the certified
47 patient and place a copy in the patient's health care record.

48 6. No practitioner shall issue a certification under this section for
49 themselves.

50 7. A registry identification card based on a certification shall
51 expire one year after the date the certification is signed by the prac-
52 titioner, except as provided for in subdivision eight of this section.

53 8. (a) If the practitioner states in the certification that, in the
54 practitioner's professional opinion, the patient would benefit from
55 medical psilocybin only until a specified earlier date, then the regis-
56 try identification card shall expire on that date; (b) if the practi-

1 tioner states in the certification that in the practitioner's profes-
2 sional opinion the patient is terminally ill and that the certification
3 shall not expire until the patient dies, then the registry identifica-
4 tion card shall state that the patient is terminally ill and that the
5 registration card shall not expire until the patient dies; (c) if the
6 practitioner re-issues the certification to terminate the certification
7 on an earlier date, then the registry identification card shall expire
8 on that date and shall be promptly destroyed by the certified patient;
9 (d) if the certification so provides, the registry identification card
10 shall state any recommendation or limitation by the practitioner as to
11 the form or forms of medical psilocybin or dosage for the certified
12 patient; and (e) the department shall make regulations to implement this
13 subdivision.

14 9. (a) A certification may be a special certification if, in addition
15 to the other requirements for a certification, the practitioner certi-
16 fies in the certification that the patient's condition is progressive
17 and degenerative or that delay in the patient's certified medical use of
18 psilocybin poses a risk to the patient's life or health.

19 (b) The department shall create the form to be used for a special
20 certification and shall make that form available to be downloaded from
21 the department's website.

22 10. Prior to issuing a certification a practitioner must complete, at
23 a minimum, a two-hour course as determined by the department in regu-
24 lation. For the purposes of this title a person's status as a practi-
25 tioner is deemed to be a "license" for the purposes of section thirty-
26 three hundred ninety of this article and shall be subject to the same
27 revocation process.

28 § 3369-cc. Lawful medical use. The purchase, possession, acquisition,
29 use, delivery, transfer, transportation, or administration of medical
30 psilocybin by a certified patient, designated caregiver, registered
31 organization or the employees of a psilocybin service center, for certi-
32 fied medical use, shall be lawful under this title provided that:

33 1. The psilocybin purchased, possessed, acquired or used by a certi-
34 fied patient shall have occurred at a psilocybin service center under
35 the supervision of a psilocybin service facilitator;

36 2. The psilocybin that may be possessed by a certified patient shall
37 not exceed the dosage determined by the practitioner, consistent with
38 any guidance and regulations issued by the department;

39 3. The form or forms of medical psilocybin that may be purchased,
40 possessed, acquired or used by the certified patient pursuant to a
41 certification shall be in compliance with any recommendation or limita-
42 tion by the practitioner as to the form or forms of medical psilocybin
43 or dosage for the certified patient in the certification; and

44 4. The medical psilocybin shall be kept in the original package in
45 which it was dispensed under this title, except for the portion removed
46 for immediate consumption for certified medical use by the certified
47 patient.

48 § 3369-dd. Registry identification cards. 1. Upon approval of the
49 certification, the department shall issue registry identification cards
50 for certified patients and designated caregivers. A registry identifica-
51 tion card shall expire as provided in this title or as otherwise
52 provided in this section. The department shall begin issuing registry
53 identification cards as soon as practicable after the certifications
54 required by this title are granted. The department may specify a form
55 for a registry application, in which case the department shall provide

1 the form on request, reproductions of the form may be used, and the form
2 shall be available for downloading from the department's website.

3 2. To obtain, amend or renew a registry identification card, a certi-
4 fied patient or designated caregiver shall file a registry application
5 with the department, unless otherwise exempted by the department in
6 regulation. The registry application or renewal application shall
7 include:

8 (a) in the case of a certified patient:

9 (i) the patient's certification, a new written certification shall be
10 provided with a renewal application if required by the department;

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

12 (iii) the date of the certification;

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

16 (v) the specified date until which the patient would benefit from
17 medical psilocybin, if the certification states such a date;

18 (vi) the name, address, and telephone number of the certifying practi-
19 tioner;

20 (vii) any recommendation or limitation by the practitioner as to the
21 form or forms of medical psilocybin or dosage for the certified patient;

22 (viii) if the certified patient designates a designated caregiver, the
23 name, address, and date of birth of the designated caregiver, and other
24 individual identifying information required by the department; and

25 (ix) other individual identifying information required by the depart-
26 ment;

27 (b) in the case of a designated caregiver:

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

29 (ii) if the designated caregiver has a registry identification card,
30 the registry identification number and expiration date of that registry
31 identification card; and

32 (iii) other individual identifying information required by the depart-
33 ment;

34 (c) a statement that a false statement made in the application is
35 punishable under section 210.45 of the penal law;

36 (d) the date of the application and the signature of the certified
37 patient or designated caregiver, as the case may be; and

38 (e) any other requirements determined by the department.

39 3. Where a certified patient is under the age of eighteen or otherwise
40 incapable of consent, the application for a registry identification card
41 shall be made by the person responsible for making health care decisions
42 for the patient. Such designated caregiver shall be: (a) a parent or
43 legal guardian of the certified patient; (b) a person designated by a
44 parent or legal guardian; or (c) an appropriate person approved by the
45 department upon a sufficient showing that no parent or legal guardian is
46 appropriate or available.

47 4. No person may be a designated caregiver if the person is under
48 twenty-one years of age unless a sufficient showing is made to the
49 department that the person should be permitted to serve as a designated
50 caregiver. The requirements for such a showing shall be determined by
51 the department.

52 5. No person may be a designated caregiver for more than four certi-
53 fied patients at one time.

54 6. If a certified patient wishes to change or terminate his or her
55 designated caregiver, for whatever reason, the certified patient shall
56 notify the department as soon as practicable. The department shall issue

1 a notification to the designated caregiver that their registration card
2 is invalid and must be promptly destroyed. The newly designated caregiv-
3 er must comply with all requirements set forth in this section.

4 7. If the certification so provides, the registry identification card
5 shall contain any recommendation or limitation by the practitioner as to
6 the form or forms of medical psilocybin or dosage for the certified
7 patient.

8 8. The department shall issue separate registry identification cards
9 for certified patients and designated caregivers as soon as reasonably
10 practicable after receiving a complete application under this section,
11 unless it determines that the application is incomplete or factually
12 inaccurate, in which case it shall promptly notify the applicant.

13 9. If the application of a certified patient designates an individual
14 as a designated caregiver who is not authorized to be a designated care-
15 giver, that portion of the application shall be denied by the department
16 but that shall not affect the approval of the balance of the applica-
17 tion.

18 10. A registry identification card shall:

19 (a) contain the name of the certified patient or the designated care-
20 giver as the case may be;

21 (b) contain the date of issuance and expiration date of the registry
22 identification card;

23 (c) contain a registry identification number for the certified patient
24 or designated caregiver, as the case may be and a registry identifica-
25 tion number;

26 (d) contain a photograph of the individual to whom the registry iden-
27 tification card is being issued, which shall be obtained by the depart-
28 ment in a manner specified by the department in regulations; provided,
29 however, that if the department requires certified patients to submit
30 photographs for this purpose, there shall be a reasonable accommodation
31 of certified patients who are confined to their homes due to their
32 medical conditions and may therefore have difficulty procuring photo-
33 graphs;

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

35 (f) plainly state any recommendation or limitation by the practitioner
36 as to the form or forms of medical psilocybin or dosage for the certi-
37 fied patient; and

38 (g) any other requirements determined by the department.

39 11. A certified patient or designated caregiver who has been issued a
40 registry identification card shall notify the department of any change
41 in his or her name or address or, with respect to the patient, if he or
42 she ceases to have the condition noted on the certification within ten
43 days of such change. The certified patient's or designated caregiver's
44 registry identification card shall be deemed invalid and shall be
45 promptly destroyed.

46 12. If a certified patient or designated caregiver loses his or her
47 registry identification card, he or she shall notify the department
48 within ten days of losing the card. The department shall issue a new
49 registry identification card as soon as practicable, which may contain a
50 new registry identification number, to the certified patient or desig-
51 nated caregiver, as the case may be.

52 13. The department shall maintain a confidential list of the persons
53 to whom it has issued registry identification cards. Individual identi-
54 fying information obtained by the department under this title shall be
55 confidential and exempt from disclosure under article six of the public
56 officers law.

1 14. The department shall verify to law enforcement personnel in an
2 appropriate case whether a registry identification card is valid and any
3 other relevant information necessary to protect patients' rights to
4 medical psilocybin by confirming compliance with this title.

5 15. If a certified patient or designated caregiver willfully violates
6 any provision of this title as determined by the department, his or her
7 certification and registry identification card may be suspended or
8 revoked. This is in addition to any other penalty that may apply.

9 16. The department shall make regulations for special certifications,
10 which shall include expedited procedures and which may require the
11 applicant to submit additional documentation establishing the clinical
12 basis for the special certification. If the department has not estab-
13 lished and made available a form for a registry application or renewal
14 application, then in the case of a special certification, a registry
15 application or renewal application that otherwise conforms with the
16 requirements of this section shall not require the use of a form.

17 § 3369-ee. Registration as a psilocybin service center. 1. To obtain,
18 amend or renew a registration as a psilocybin service center, the facil-
19 ity shall file a registry application with the department. The registry
20 application or renewal application shall include:

21 (a) the facility's full name and address;

22 (b) operating certificate or license number where appropriate;

23 (c) name, title, and signature of an authorized facility represen-
24 tative;

25 (d) a statement that the facility agrees to secure and ensure proper
26 handling of all medical psilocybin products;

27 (e) an acknowledgement that a false statement in the application is
28 punishable under section 210.45 of the penal law; and

29 (f) any other information that may be required by the department.

30 2. Prior to issuing or renewing a psilocybin service center registra-
31 tion, the department may verify the information submitted by the appli-
32 cant. The applicant shall provide, at the department's request, such
33 information and documentation, including any consents or authorizations
34 that may be necessary for the department to verify the information.

35 3. The department shall approve, deny or determine incomplete or inac-
36 curate an initial or renewal application within thirty days of receipt
37 of the application. If the application is approved within the thirty-day
38 period, the department shall issue a registration as soon as is reason-
39 ably practicable.

40 4. An applicant shall have thirty days from the date of a notification
41 of an incomplete or factually inaccurate application to submit the mate-
42 rials required to complete, revise or substantiate information in the
43 application. If the applicant fails to submit the required materials
44 within such thirty-day time period, the application shall be denied by
45 the department.

46 5. The applicant shall be under a continuing duty to report to the
47 department any change in facts or circumstances reflected in the appli-
48 cation or any newly discovered or occurring fact or circumstance which
49 is required to be included in the application.

50 6. (a) The department shall grant a registration or amendment to a
51 registration under this section if it is satisfied that:

52 (i) the applicant will be able to maintain effective control against
53 diversion of psilocybin;

54 (ii) the applicant will be able to comply with all applicable state
55 laws;

1 (iii) the applicant and its officers are ready, willing and able to
2 properly carry on the activities for which a registration is sought;

3 (iv) the applicant possesses or has the right to use sufficient land,
4 buildings and equipment to properly carry on the activity described in
5 the application;

6 (v) it is in the public interest that such registration be granted,
7 including but not limited to:

8 (A) whether the number of psilocybin service centers in an area will
9 be adequate or excessive to reasonably serve the area;

10 (B) whether the psilocybin service center is a minority- and/or
11 women-owned business enterprise, a service-disabled veteran-owned busi-
12 ness, or from communities disproportionately impacted by the enforcement
13 of psilocybin prohibition;

14 (C) whether the psilocybin service center provides education and
15 outreach to practitioners;

16 (D) whether the psilocybin service center promotes the research and
17 development of medical psilocybin and patient outreach;

18 (E) the affordability of medical psilocybin products offered by the
19 psilocybin service center;

20 (F) whether the psilocybin service center is culturally, linguis-
21 tically, and medically competent to provide services to unserved and
22 underserved areas; and

23 (G) whether the psilocybin service center promotes racial, ethnic, and
24 gender diversity in its workforce;

25 (vi) the applicant and its managing officers are of good moral charac-
26 ter;

27 (vii) the applicant has entered into a labor peace agreement with a
28 bona fide labor organization that is actively engaged in representing or
29 attempting to represent the applicant's employees; and the maintenance
30 of such a labor peace agreement shall be an ongoing material condition
31 of registration; and

32 (viii) the applicant satisfies any other conditions as determined by
33 the department.

34 (b) If the department is not satisfied that the applicant should be
35 issued a registration, the department shall notify the applicant in
36 writing of those factors upon which further evidence is required. Within
37 thirty days of the receipt of such notification, the applicant may
38 submit additional material to the department or demand a hearing, or
39 both.

40 (c) The fee for a registration under this section shall be an amount
41 determined by the department in regulations; provided, however, if the
42 registration is issued for a period greater than two years the fee shall
43 be increased, pro rata, for each additional month of validity.

44 (d) Registrations issued under this section shall be effective only
45 for the psilocybin service center and shall specify:

46 (i) the name and address of the psilocybin service center;

47 (ii) which activities of a psilocybin service center are permitted by
48 the registration;

49 (iii) the land, buildings and facilities that may be used for the
50 permitted activities of the psilocybin service center; and

51 (iv) such other information as the department shall reasonably provide
52 to ensure compliance with this title.

53 (e) Upon application of a psilocybin service center, a registration
54 may be amended to allow the psilocybin service center to relocate within
55 the state or to add or delete permitted psilocybin service center activ-
56 ities or facilities. The fee for such amendment shall be determined by

1 the department in regulation and be based off the administrative burden
2 to process and review the amendment by the department, provided no fee
3 shall be greater than two thousand dollars.

4 7. Registrations issued under this section shall remain valid for two
5 years from the date of issuance, except that in order to facilitate the
6 renewals of such registrations, the department may upon the initial
7 application for a registration, issue some registrations which may
8 remain valid for a period of time greater than two years but not exceed-
9 ing an additional eleven months.

10 8. (a) An application for the renewal of any registration issued under
11 this section shall be filed with the department not more than six months
12 nor less than four months prior to the expiration thereof. A late-filed
13 application for the renewal of a registration may, in the discretion of
14 the department, be treated as an application for an initial license.

15 (b) The application for renewal shall include such information
16 prepared in the manner and detail as the department may require, includ-
17 ing but not limited to:

18 (i) any material change in the circumstances or factors listed in
19 subdivision one of this section; and

20 (ii) every known charge or investigation, pending or concluded during
21 the period of the registration, by any governmental or administrative
22 agency with respect to:

23 (A) each incident or alleged incident involving the theft, loss, or
24 possible diversion of medical psilocybin manufactured or distributed by
25 the applicant; and

26 (B) compliance by the applicant with the laws of the state with
27 respect to the distribution or sale of medical psilocybin, where appli-
28 cable.

29 (c) An applicant for renewal shall be under a continuing duty to
30 report to the department any change in facts or circumstances reflected
31 in the application or any newly discovered or occurring fact or circum-
32 stance which is required to be included in the application and to obtain
33 approval prior to any material change in management, interest or owner-
34 ship.

35 (d) If the department is not satisfied that the psilocybin service
36 center applicant is entitled to a renewal of the registration, the
37 department shall within a reasonably practicable time as determined by
38 the commissioner, serve upon the psilocybin service center or its attor-
39 ney of record in person or by registered or certified mail an order
40 directing the psilocybin service center to show cause why its applica-
41 tion for renewal should not be denied. The order shall specify in detail
42 the respects in which the applicant has not satisfied the department
43 that the registration should be renewed.

44 (e) Within a reasonably practicable time as determined by the depart-
45 ment of such order, the applicant may submit additional material to the
46 department or demand a hearing or both; if a hearing is demanded the
47 department shall fix a date as soon as reasonably practicable.

48 9. (a) The department shall renew a registration unless it determines
49 and finds that:

50 (i) the applicant is unlikely to maintain or be able to maintain
51 effective control against diversion;

52 (ii) the applicant is unlikely to comply with all state laws applica-
53 ble to the activities in which it may engage under the registration;

54 (iii) it is not in the public interest to renew the registration
55 because the number of psilocybin service centers in an area is excessive
56 to reasonably serve the area;

1 (iv) the applicant has either violated or terminated its labor peace
2 agreement; or

3 (v) the applicant has substantively violated the laws of another
4 jurisdiction, in which it operates or have operated a psilocybin license
5 or registration, related to the operation of a psilocybin business.

6 (b) For purposes of this section, proof that a psilocybin service
7 center, during the period of its registration, has failed to maintain
8 effective control against diversion, violated any provision of this
9 title, or has knowingly or negligently failed to comply with applicable
10 state laws relating to the activities in which it engages under the
11 registration, may constitute grounds for suspension, termination or
12 limitation of the psilocybin service center's registration or as deter-
13 mined by the department. The psilocybin service center shall also be
14 under a continuing duty to report to the department any material change
15 in facts or circumstances to the information provided in the psilocybin
16 service center's application.

17 10. The department may suspend or terminate the registration of a
18 psilocybin service center, on grounds and using procedures under this
19 title relating to a license, to the extent consistent with this title.
20 The department shall suspend or terminate the registration in the event
21 that a psilocybin service center violates or terminates the applicable
22 labor peace agreement. Conduct in compliance with this title which may
23 violate conflicting federal law, shall not be grounds to suspend or
24 terminate a registration.

25 11. In coordination with the chief equity officer, the department
26 shall register additional registered psilocybin service centers to
27 provide services to unserved and underserved areas of the state. Such
28 additional registered psilocybin service centers shall be reflective of
29 the demographics of the state, be representative of communities dispro-
30 portionately impacted by psilocybin prohibition, and be culturally,
31 linguistically, and medically competent to serve unserved and under-
32 served areas of the state. The department shall actively promote racial,
33 ethnic, and gender diversity when registering additional registered
34 psilocybin service centers.

35 § 3369-ff. Registered organizations. 1. A registered organization
36 shall be a for-profit business entity or not-for-profit corporation
37 organized for the purpose of acquiring, possessing, manufacturing, sell-
38 ing, delivering, transporting, distributing or dispensing psilocybin to
39 psilocybin service centers for certified medical use.

40 2. The acquiring, possession, manufacture, sale, delivery, transport-
41 ing, distributing or dispensing of medical psilocybin by a registered
42 organization under this title in accordance with its registration under
43 this title or a renewal thereof shall be lawful under this title.

44 3. Each registered organization shall contract with an independent
45 laboratory permitted by the department to test the medical psilocybin
46 produced by the registered organization. The department shall approve
47 the laboratories used by the registered organization, including sampling
48 and testing protocols and standards used by the laboratories, and may
49 require that the registered organization use a particular testing labo-
50 ratory. The department is authorized to issue regulations requiring the
51 laboratory to perform certain tests and services.

52 4. (a) A registered organization may lawfully, in good faith, sell,
53 deliver, distribute or dispense medical psilocybin to a psilocybin
54 service center registered pursuant to this title for use by a certified
55 patient.

1 (b) The proprietor of a registered organization shall file or cause to
2 be filed any receipt and certification information with the department
3 by electronic means on a real-time basis as the department shall require
4 by regulation. When filing receipt and certification information elec-
5 tronically pursuant to this paragraph, the proprietor of the registered
6 organization shall dispose of any electronically recorded prescription
7 information in such manner as the department shall by regulation
8 require.

9 5. No registered organization may sell, deliver, distribute or
10 dispense medical psilocybin directly to a certified patient or desig-
11 nated caregiver.

12 6. When a registered organization sells, delivers, distributes or
13 dispenses medical psilocybin to a psilocybin service center, it shall
14 provide to that facility a safety insert, developed by the registered
15 organization subject to regulations issued by the department and
16 include, but not be limited to, information on:

17 (a) methods for administering medical psilocybin;

18 (b) any potential dangers stemming from the use of medical psilocybin;

19 (c) how to recognize what may be problematic usage of medical psilocy-
20 bin and obtain appropriate services or treatment for problematic usage;
21 and

22 (d) other information as determined by the department.

23 7. Registered organizations shall not be managed by or employ anyone
24 who has been convicted within three years of the date of hire, of any
25 felony related to the functions or duties of operating a business,
26 except that if the department determines that the manager or employee is
27 otherwise suitable to be hired, and hiring the manager or employee would
28 not compromise public safety, the department shall conduct a thorough
29 review of the nature of the crime, conviction, circumstances, and
30 evidence of rehabilitation of the manager or employee, and shall evalu-
31 ate the suitability of the manager or employee based on the evidence
32 found through the review. In determining which offenses are substantial-
33 ly related to the functions or duties of operating a business, the
34 department shall include, but not be limited to, the following:

35 (a) a felony conviction involving fraud, money laundering, forgery and
36 other unlawful conduct related to owning and operating a business; and

37 (b) a felony conviction for hiring, employing or using a minor in
38 transporting, carrying, selling, giving away, preparing for sale, or
39 peddling, any controlled substance, or selling, offering to sell,
40 furnishing, offering to furnish, administering, or giving any controlled
41 substance to a minor.

42 A felony conviction for the sale or possession of drugs, narcotics, or
43 controlled substances is not substantially related. This subdivision
44 shall only apply to managers or employees who come into contact with or
45 handle medical psilocybin.

46 8. Manufacturing of medical psilocybin by a registered organization
47 shall only be done in a secure facility located in New York state, which
48 may include a greenhouse. The department shall promulgate regulations
49 establishing requirements for such facilities.

50 9. Dispensing of medical psilocybin by a registered organization shall
51 only be done in an indoor, enclosed, secure facility located in New York
52 state. The department shall promulgate regulations establishing require-
53 ments for such facilities.

54 10. A registered organization may contract with a person or entity to
55 provide facilities, equipment or services that are ancillary to the
56 registered organization's functions or activities under this title

1 including, but not limited to, shipping, maintenance, construction,
2 repair, and security, provided that the person or entity shall not
3 perform any function or activity directly involving the planting, grow-
4 ing, tending, harvesting, processing, or packaging of psilocybin plants,
5 medical psilocybin, or medical psilocybin products being produced by the
6 registered organization; or any other function directly involving manu-
7 facturing or retailing of medical psilocybin. All laws and regulations
8 applicable to such facilities, equipment, or services shall apply to the
9 contract. The registered organization and other parties to the contract
10 shall each be responsible for compliance with such laws and regulations
11 under the contract. The department may make regulations consistent with
12 this title relating to contracts and parties to contracts under this
13 subdivision.

14 11. A registered organization shall, based on the findings of an inde-
15 pendent laboratory, provide documentation of the quality, safety and
16 clinical strength of the medical psilocybin manufactured or dispensed by
17 the registered organization to the department and to any psilocybin
18 service center to which the medical psilocybin is sold or dispensed.

19 12. Medical psilocybin shall be dispensed to a psilocybin service
20 center in a sealed and properly labeled package. The labeling shall
21 contain: (a) the packaging date; (b) any applicable date by which the
22 medical psilocybin should be used; (c) a warning stating, "This product
23 is for medicinal use only. Women should not consume during pregnancy or
24 while breastfeeding except on the advice of the certifying health care
25 practitioner, and in the case of breastfeeding mothers, including the
26 infant's pediatrician. This product might impair the ability to drive.
27 Keep out of reach of children."; (d) the amount of individual doses
28 contained within; and (e) a warning that the medical psilocybin must be
29 kept in the original container in which it was dispensed.

30 13. The department is authorized to make rules and regulations
31 restricting the advertising and marketing of medical psilocybin.

32 14. A registered organization shall operate in accordance with minimum
33 operating and recordkeeping requirements determined by the department in
34 regulation.

35 § 3369-gg. Registering of registered organizations. 1. (a) An appli-
36 cant for registration as a registered organization under section thir-
37 ty-three hundred sixty-nine-ff of this title shall include such informa-
38 tion prepared in such manner and detail as the department may require,
39 including but not limited to:

40 (i) a description of the activities in which it intends to engage as a
41 registered organization;

42 (ii) that the applicant:

43 (A) is of good moral character;

44 (B) possesses or has the right to use sufficient land, buildings, and
45 other premises, which shall be specified in the application, and equip-
46 ment to properly carry on the activity described in the application, or
47 in the alternative posts a bond of not less than two million dollars;

48 (C) is able to maintain effective security and control to prevent
49 diversion, abuse, and other illegal conduct relating to the psilocybin;
50 and

51 (D) is able to comply with all applicable state laws and regulations
52 relating to the activities in which it intends to engage under the
53 registration;

54 (iii) that the applicant has entered into a labor peace agreement with
55 a bona fide labor organization that is actively engaged in representing
56 or attempting to represent the applicant's employees and the maintenance

1 of such a labor peace agreement shall be an ongoing material condition
2 of certification;

3 (iv) the applicant's status as a for-profit business entity or not-
4 for-profit corporation; and

5 (v) the application shall include the name, residence address and
6 title of each of the officers and directors and the name and residence
7 address of any person or entity that is a member of the applicant. Each
8 such person, if an individual, or lawful representative if a legal enti-
9 ty, shall submit an affidavit with the application setting forth:

10 (A) any position of management, interest or ownership during the
11 preceding ten years of a ten per centum or greater interest in any other
12 psilocybin business, or applicant, located in or outside this state,
13 manufacturing or distributing drugs including indirect management,
14 interest, or ownership of parent companies, subsidiaries, or affiliates;

15 (B) whether such person or any such business has been convicted of a
16 felony or had a registration or license suspended or revoked in any
17 administrative or judicial proceeding, and if applicable, the history of
18 violations or administrative penalties with respect to any license to
19 cultivate, manufacture, distribute or sell medical psilocybin; and

20 (C) such other information as the department may reasonably require.

21 2. The applicant shall be under a continuing duty to report to the
22 department any change in facts or circumstances reflected in the appli-
23 cation or any newly discovered or occurring fact or circumstance which
24 is required to be included in the application.

25 3. (a) The department shall grant a registration or amendment to a
26 registration under this section if they are satisfied that:

27 (i) the applicant will be able to maintain effective control against
28 diversion of psilocybin;

29 (ii) the applicant will be able to comply with all applicable state
30 laws;

31 (iii) the applicant and its officers are ready, willing and able to
32 properly carry on the manufacturing or distributing activity for which a
33 registration is sought;

34 (iv) the applicant possesses or has the right to use sufficient land,
35 buildings and equipment to properly carry on the activity described in
36 the application;

37 (v) it is in the public interest that such registration be granted,
38 including but not limited to:

39 (A) whether the number of registered organizations in an area will be
40 adequate or excessive to reasonably serve the area;

41 (B) whether the registered organization is a minority and/or woman
42 owned business enterprise, a service-disabled veteran-owned business, or
43 from communities disproportionately impacted by the enforcement of psilo-
44 cybin prohibition;

45 (C) whether the registered organization provides education and
46 outreach to practitioners;

47 (D) whether the registered organization promotes the research and
48 development of medical psilocybin and patient outreach;

49 (E) the affordability of medical psilocybin products offered by the
50 registered organization;

51 (F) whether the registered organization is culturally, linguistically,
52 and medically competent to provide services to unserved and underserved
53 areas; and

54 (G) whether the registered organization promotes racial, ethnic, and
55 gender diversity in their workforce;

1 (vi) the applicant and its managing officers are of good moral charac-
2 ter;

3 (vii) the applicant has entered into a labor peace agreement with a
4 bona fide labor organization that is actively engaged in representing or
5 attempting to represent the applicant's employees; and the maintenance
6 of such a labor peace agreement shall be an ongoing material condition
7 of registration; and

8 (viii) the applicant satisfies any other conditions as determined by
9 the department.

10 (b) If the department is not satisfied that the applicant should be
11 issued a registration, the department shall notify the applicant in
12 writing of those factors upon which further evidence is required. Within
13 thirty days of the receipt of such notification, the applicant may
14 submit additional material to the department or demand a hearing, or
15 both.

16 (c) The fee for a registration under this section shall be an amount
17 determined by the department in regulations; provided, however, if the
18 registration is issued for a period greater than two years the fee shall
19 be increased, pro rata, for each additional month of validity.

20 (d) Registrations issued under this section shall be effective only
21 for the registered organization and shall specify:

22 (i) the name and address of the registered organization;

23 (ii) which activities of a registered organization are permitted by
24 the registration;

25 (iii) the land, buildings and facilities that may be used for the
26 permitted activities of the registered organization; and

27 (iv) such other information as the department shall reasonably provide
28 to assure compliance with this title.

29 (e) Upon application of a registered organization, a registration may
30 be amended to allow the registered organization to relocate within the
31 state or to add or delete permitted registered organization activities
32 or facilities. The fee for such amendment shall be determined by the
33 department in regulation and be based off the administrative burden to
34 process and review the amendment by the department, provided no fee
35 shall be greater than two thousand dollars.

36 4. A registration issued under this section shall be valid for two
37 years from the date of issue, except that in order to facilitate the
38 renewals of such registrations, the department may upon the initial
39 application for a registration, issue some registrations which may
40 remain valid for a period of time greater than two years but not exceed-
41 ing an additional eleven months.

42 5. (a) An application for the renewal of any registration issued under
43 this section shall be filed with the department not more than six months
44 nor less than four months prior to the expiration thereof. A late-filed
45 application for the renewal of a registration may, in the discretion of
46 the department, be treated as an application for an initial license.

47 (b) The application for renewal shall include such information
48 prepared in the manner and detail as the department may require, includ-
49 ing but not limited to:

50 (i) any material change in the circumstances or factors listed in
51 subdivision one of this section; and

52 (ii) every known charge or investigation, pending or concluded during
53 the period of the registration, by any governmental or administrative
54 agency with respect to:

1 (A) each incident or alleged incident involving the theft, loss, or
2 possible diversion of medical psilocybin manufactured or distributed by
3 the applicant; and

4 (B) compliance by the applicant with the laws of the state with
5 respect to the cultivation, manufacture, distribution, or sale of
6 medical psilocybin or adult-use psilocybin, where applicable.

7 (c) An applicant for renewal shall be under a continuing duty to
8 report to the department any change in facts or circumstances reflected
9 in the application or any newly discovered or occurring fact or circum-
10 stance which is required to be included in the application and to obtain
11 approval prior to any material change in management, interest or owner-
12 ship.

13 (d) If the department is not satisfied that the registered organiza-
14 tion applicant is entitled to a renewal of the registration, the depart-
15 ment shall within a reasonably practicable time as determined by the
16 executive director, serve upon the registered organization or its attor-
17 ney of record in person or by registered or certified mail an order
18 directing the registered organization to show cause why its application
19 for renewal should not be denied. The order shall specify in detail the
20 respects in which the applicant has not satisfied the department that
21 the registration should be renewed.

22 (e) Within a reasonably practicable time as determined by the depart-
23 ment of such order, the applicant may submit additional material to the
24 department or demand a hearing or both; if a hearing is demanded the
25 department shall fix a date as soon as reasonably practicable.

26 6. (a) The department shall renew a registration unless it determines
27 and finds that:

28 (i) the applicant is unlikely to maintain or be able to maintain
29 effective control against diversion;

30 (ii) the applicant is unlikely to comply with all state laws applica-
31 ble to the activities in which it may engage under the registration;

32 (iii) it is not in the public interest to renew the registration
33 because the number of registered organizations in an area is excessive
34 to reasonably serve the area;

35 (iv) the applicant has either violated or terminated its labor peace
36 agreement; or

37 (v) the applicant has substantively violated the laws of another
38 jurisdiction, in which they operate or have operated a psilocybin
39 license or registration, related to the operation of a psilocybin busi-
40 ness.

41 (b) For purposes of this section, proof that a registered organiza-
42 tion, during the period of its registration, has failed to maintain
43 effective control against diversion, violates any provision of this
44 title, or has knowingly or negligently failed to comply with applicable
45 state laws relating to the activities in which it engages under the
46 registration, may constitute grounds for suspension, termination or
47 limitation of the registered organization's registration or as deter-
48 mined by the department. The registered organization shall also be under
49 a continuing duty to report to the department any material change or
50 fact or circumstance to the information provided in the registered
51 organization's application.

52 7. The department may suspend or terminate the registration of a
53 registered organization, on grounds and using procedures under this
54 title relating to a license, to the extent consistent with this title.
55 The department shall suspend or terminate the registration in the event
56 that a registered organization violates or terminates the applicable

1 labor peace agreement. Conduct in compliance with this title which may
2 violate conflicting federal law, shall not be grounds to suspend or
3 terminate a registration.

4 8. A registered organization that manufactures medical psilocybin may
5 have no more than four sites wholly owned and operated by such regis-
6 tered organization. Such registered organization may have an additional
7 four sites; provided, however, that the first two additional sites shall
8 be located in underserved or unserved geographic locations, as deter-
9 mined by the department. The department shall ensure that such regis-
10 tered organizations and sites are geographically distributed across the
11 state and that their ownership reflects the demographics of the state.

12 9. In coordination with the chief equity officer the department shall
13 register additional registered organizations to provide services to
14 unserved and underserved areas of the state. Such additional registered
15 organizations shall be reflective of the demographics of the state, be
16 representative of communities disproportionately impacted by psilocybin
17 prohibition, and be culturally, linguistically, and medically competent
18 to serve unserved and underserved areas of the state. The department
19 shall actively promote racial, ethnic, and gender diversity when regis-
20 tering additional registered organizations.

21 § 3369-hh. Reports of registered organizations. 1. The department
22 shall, by regulation, require each registered organization to file
23 reports by the registered organization during a particular period. The
24 department shall determine the information to be reported and the forms,
25 time, and manner of the reporting.

26 2. The department shall, by regulation, require each registered organ-
27 ization to adopt and maintain security, tracking, recordkeeping, record
28 retention and surveillance systems, relating to all medical psilocybin
29 at every stage of acquiring, possession, manufacture, sale, delivery,
30 transporting, distributing, or dispensing by the registered organiza-
31 tion, subject to regulations of the department.

32 § 3369-ii. Evaluation; research programs; report by department. 1.
33 The department may provide for the analysis and evaluation of the opera-
34 tion of this title. The department may enter into agreements with one or
35 more persons, not-for-profit corporations or other organizations, for
36 the performance of an evaluation of the implementation and effectiveness
37 of this title.

38 2. The department may develop, seek any necessary federal approval
39 for, and carry out research programs relating to medical use of psilocy-
40 bin. Participation in any such research program shall be voluntary on
41 the part of practitioners, patients, and designated caregivers.

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

46 § 3369-jj. Psilocybin research license. 1. The department shall estab-
47 lish a psilocybin research license that permits a licensee to produce,
48 process, purchase and/or possess psilocybin for the following limited
49 research purposes:

- 50 (a) to test chemical potency and composition levels;
51 (b) to conduct clinical investigations of psilocybin-derived drug
52 products;
53 (c) to conduct research on the efficacy and safety of administering
54 psilocybin as part of medical treatment; and
55 (d) to conduct genomic or agricultural research.

1 2. As part of the application process for a psilocybin research
2 license, an applicant must submit to the department a description of the
3 research that is intended to be conducted as well as the amount of
4 psilocybin to be grown or purchased. The department shall review an
5 applicant's research project and determine whether it meets the require-
6 ments of subdivision one of this section. In addition, the department
7 shall assess the application based on the following criteria:

8 (a) project quality, study design, value, and impact;

9 (b) whether the applicant has the appropriate personnel, expertise,
10 facilities and infrastructure, funding, and human, animal, or other
11 approvals in place to successfully conduct the project; and

12 (c) whether the amount of psilocybin to be grown or purchased by the
13 applicant is consistent with the project's scope and goals. If the
14 department determines that the research project does not meet the
15 requirements of subdivision one of this section, the application must be
16 denied.

17 3. A psilocybin research licensee may only sell psilocybin grown or
18 within its operation to other psilocybin research licensees. The depart-
19 ment may revoke a psilocybin research license for violations of this
20 section.

21 4. A psilocybin research licensee may contract with an institution of
22 higher education, including but not limited to a hospital within the
23 state university of New York, to perform research in conjunction with
24 such institution. All research projects, entered into under this section
25 must be approved by the department and meet the requirements of subdivi-
26 sion one of this section.

27 5. In establishing a psilocybin research license, the department may
28 adopt regulations on the following:

29 (a) application requirements;

30 (b) psilocybin research license renewal requirements, including wheth-
31 er additional research projects may be added or considered;

32 (c) conditions for license revocation;

33 (d) security measures to ensure psilocybin is not diverted to purposes
34 other than research;

35 (e) amount of plants, useable psilocybin, psilocybin concentrates, or
36 psilocybin-infused products a licensee may have on its premises;

37 (f) licensee reporting requirements;

38 (g) conditions under which psilocybin grown by licensed psilocybin
39 producers and other product types from licensed psilocybin processors
40 may be donated to psilocybin research licensees; and

41 (h) any additional requirements deemed necessary by the department.

42 6. A psilocybin research license issued pursuant to this section must
43 be issued in the name of the applicant and specify the location at which
44 the psilocybin researcher intends to operate, which must be within the
45 state of New York.

46 7. The application fee for a psilocybin research license shall be
47 determined by the department on an annual basis and may be based on the
48 size, scope and duration of the research proposed.

49 8. Each psilocybin research licensee shall issue an annual report to
50 the department. The department shall review such report and make a
51 determination as to whether the research project continues to meet the
52 research qualifications under this section.

53 § 3369-kk. Relation to other laws. 1. The provisions of this title
54 shall apply, except that where a provision of this title conflicts with
55 another provision of this chapter, this title shall apply.

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

3 § 3369-ll. Psilocybin service facilitator license requirements. 1. An
4 applicant for a psilocybin service facilitator license shall meet the
5 following requirements:

6 (a) Have a high school diploma or equivalent education;

7 (b) Any additional education or training requirements established by
8 the department, except that the department shall not require a degree
9 from an institution of higher education;

10 (c) Any examination requirements established by the department, except
11 that the department may provide for waivers of examination requirements
12 in cases it deems appropriate. The department shall offer any required
13 examination at least twice annually. The department may appoint a person
14 to conduct or supervise examinations of applicants. An applicant may
15 retake any failed section of the examination in accordance with rules
16 adopted by the department; and

17 (d) Any other training, education, skill or fitness requirements
18 adopted by the department, such as:

19 (i) Facilitation skills that are affirming, nonjudgmental and nondi-
20 rective; and

21 (ii) Support skills for clients during an administration session,
22 including specialized skills relating to client safety and clients who
23 may have mental health conditions, ability to establish a proper envi-
24 ronment in which psilocybin services occur and social and cultural
25 skills.

26 2. The department shall establish a process to approve training cours-
27 es for psilocybin service facilitators. To obtain approval of a course,
28 the person providing the course shall submit an outline of instruction
29 to the department and to the department of education that includes the
30 course topics, total hours of instruction, hours of lectures in theory
31 and hours of instruction in application of practical skills.

32 3. The department shall establish a code of professional conduct,
33 including a code of ethics, for psilocybin service facilitators. The
34 department shall establish standards of practice and professional
35 responsibility for psilocybin service facilitators.

36 4. A psilocybin service facilitator licensee may engage in the follow-
37 ing activities in accordance with rules adopted by the department:

38 (a) Deliver psilocybin products to premises for which a license has
39 been issued under this title;

40 (b) Receive psilocybin products from a registered organization or
41 another psilocybin service center licensee; and

42 (c) Sell psilocybin products to a certified patient on the premises
43 for which the license has been issued.

44 § 3369-mm. Protections for the medical use of psilocybin. 1. Certi-
45 fied patients, designated caregivers, psilocybin service centers and
46 employees of psilocybin service centers, practitioners, registered
47 organizations and the employees of registered organizations, and psilo-
48 cybin researchers shall not be subject to arrest, prosecution, or penal-
49 ty in any manner, or denied any right or privilege, including but not
50 limited to civil penalty or disciplinary action by a business or occupa-
51 tional or professional licensing board or bureau, solely for the certi-
52 fied medical use or manufacture of psilocybin, or for any other action
53 or conduct in accordance with this title.

54 2. Being a certified patient shall be deemed to be having a "disabili-
55 ty" under article fifteen of the executive law, section forty-c of the
56 civil rights law and sections 240.00, 485.00, and 485.05 of the penal

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

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

11 4. (a) Certification applications, certification forms, any certified
12 patient information contained within a database, and copies of registry
13 identification cards shall be deemed exempt from public disclosure under
14 sections eighty-seven and eighty-nine of the public officers law. Upon
15 specific request by a certified patient to the department, the depart-
16 ment shall verify the requesting patient's status as a valid certified
17 patient to the patient's school or employer or other designated party,
18 to ensure compliance with the protections afforded by this section.

19 (b) The name, contact information, and other information relating to
20 practitioners registered with the department under this title shall be
21 public information and shall be maintained on the department's website
22 accessible to the public in searchable form. However, if a practitioner
23 notifies the department in writing that he or she does not want his or
24 her name and other information disclosed, that practitioner's name and
25 other information shall thereafter not be public information or main-
26 tained on the department's website, unless the practitioner cancels the
27 request.

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

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

37 § 3369-nn. Regulations. The department shall promulgate regulations to
38 implement this title.

39 § 3369-oo. Suspend; terminate. Based upon the recommendation of the
40 department, executive director and/or the superintendent of state police
41 that there is a risk to the public health or safety, the governor may
42 immediately suspend or terminate all licenses issued to registered
43 organizations.

44 § 3369-pp. Pricing. Registered organizations shall submit documenta-
45 tion to the executive director of any change in pricing per dose for any
46 medical psilocybin product within fifteen days of such change. Prior
47 approval by the executive director shall not be required for any such
48 change; provided however that the department is authorized to modify the
49 price per dose for any medical psilocybin product if necessary to main-
50 tain public access to appropriate medication.

51 § 3369-qq. Psilocybin services grant program. The department shall
52 establish a program of awarded grants within the amount in the psilocy-
53 bin services grant program fund established under section ninety-seven-
54 uuuu of the state finance law for veterans and first responders to
55 receive monetary assistance for psilocybin services pursuant to this
56 title. The department shall promulgate any necessary rules and regu-

1 lations for the application and distribution of any funds pursuant to
2 this section.

3 § 3369-rr. Psilocybin services advisory board. 1. The psilocybin
4 services advisory board or "advisory board" is established within the
5 department to advise and issue recommendations on the use of medical
6 psilocybin in the state of New York.

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

12 (b) The governor shall have eight appointments, the temporary presi-
13 dent of the senate and the speaker of the assembly shall each have three
14 appointments to the board. Advisory board members shall have statewide
15 geographic representation that is balanced and diverse in its composi-
16 tion. Appointed members shall have an expertise in public and behavioral
17 health, substance use disorder treatment, effective rehabilitative
18 treatment for adults and juveniles, homelessness and housing, economic
19 development, environmental conservation, job training and placement,
20 criminal justice, and drug policy. Further, the advisory board shall
21 include residents from communities most impacted by psilocybin prohibi-
22 tion, people with prior drug convictions, the formerly incarcerated, and
23 representatives from the farming industry, psilocybin industry, and
24 organizations serving communities impacted by past federal and state
25 drug policies.

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

33 4. The chairperson of the advisory board and the vice chairperson
34 shall be elected from among the members of the advisory board by the
35 members of such advisory board. The vice chairperson shall represent the
36 advisory board in the absence of the chairperson at all official advi-
37 sory board functions.

38 5. The advisory board shall enact and from time to time may amend
39 bylaws or rules in relation to its meetings and the transaction of its
40 business. The board may also establish committees and subcommittees
41 necessary for the operation of the board. A majority of the total number
42 of voting members which the board would have were there no vacancies,
43 shall constitute a quorum and shall be required for the board to conduct
44 business. All meetings of the advisory board shall be conducted in
45 accordance with the provisions of article seven of the public officers
46 law.

47 6. Within the first two years of the establishment of the advisory
48 board, the board shall meet at least once every two calendar months at a
49 time and place determined by the chairperson or a majority of the voting
50 members of the board. After the first two years, the advisory board
51 shall meet at least once every calendar quarter at a time and place
52 determined by the chairperson or a majority of the voting members of the
53 board. The advisory board may also meet at other times and places speci-
54 fied by the call of the chairperson or of a majority of the voting
55 members of the board.

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

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

7 (b) Make recommendations to the department on the requirements, spec-
8 ifications and guidelines for providing psilocybin services to a client,
9 including:

10 (i) The requirements, specifications and guidelines for holding and
11 verifying the completion of a preparation session, an administration
12 session and an integration session; and

13 (ii) The contents of the certified patient information form that a
14 certified patient must complete and sign before the patient participates
15 in an administration session, giving particular consideration to:

16 (A) The information that should be solicited from the patient to
17 determine whether such patient should participate in the administration
18 session, including information that may identify risk factors and
19 contraindications;

20 (B) The information that should be solicited from the patient to
21 assist the psilocybin service center operator and the psilocybin service
22 facilitator in meeting any public health and safety standards and indus-
23 try best practices during the administration session; and

24 (C) The health and safety warnings and other disclosures that should
25 be made to the patient before such patient participates in the adminis-
26 tration session.

27 (c) Make recommendations to the department on public health and safety
28 standards and industry best practices for each type of licensee under
29 this title.

30 (d) Make recommendations to the department on the formulation of a
31 code of professional conduct for psilocybin service facilitators, giving
32 particular consideration to a code of ethics.

33 (e) Make recommendations to the department on the education and train-
34 ing that psilocybin service facilitators must complete, including but
35 not limited to whether such education and training should be available
36 through online resources. Giving particular consideration to:

37 (i) Facilitation skills that are affirming, non-judgmental and non-di-
38 rective;

39 (ii) Support skills for clients during an administration session,
40 including specialized skills for client safety and clients who may have
41 a mental health condition;

42 (iii) The environment in which psilocybin services should occur; and

43 (iv) Social and cultural considerations.

44 (f) Make recommendations to the department on the examinations that
45 psilocybin service facilitators must pass.

46 (g) Make recommendations to the department on public health and safe-
47 ty standards and industry best practices for holding and completing an
48 administration session, including:

49 (i) Whether group administration sessions should be available;

50 (ii) Whether certified patients should be able to access common or
51 outside areas on the premises of the psilocybin service center at which
52 the administration session is held;

53 (iii) The circumstances under which an administration session is
54 considered complete; and

55 (iv) The transportation needs of the client after the completion of
56 the administration session.

1 (h) In consultation with the department of agriculture and markets and
2 the department of environmental conservation, promulgate necessary rules
3 and regulations governing the safe production of psilocybin, including
4 environmental and energy standards and restrictions on the use of pesti-
5 cides and best practices for water and energy conservation.

6 (i) Develop a long-term strategic plan for ensuring that psilocybin
7 services will become and remain a safe, accessible and affordable thera-
8 peutic option for all persons twenty-one years of age and older in the
9 state for whom psilocybin services may be appropriate.

10 (j) Monitor and study federal laws, regulations and policies regarding
11 psilocybin.

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

14 § 97-uuuu. Psilocybin services grant program fund. 1. There is hereby
15 established in the joint custody of the commissioner of health and the
16 comptroller a fund to be known as the "psilocybin services grant program
17 fund".

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

22 3. Monies of the fund, when allocated, shall be available pursuant to
23 section thirty-three hundred sixty-nine-qq of the public health law.

24 4. Monies shall be payable from the fund on the audit and warrant of
25 the state comptroller on vouchers approved and certified by the commis-
26 sioner of health.

27 § 3. The sum of two million dollars (\$2,000,000), or so much thereof
28 as may be necessary, is hereby appropriated to the department of health
29 out of any moneys in the state treasury in the general fund to the cred-
30 it of the psilocybin services grant program, not otherwise appropriated,
31 and made immediately available, for the purpose of carrying out the
32 provisions of this act. Such moneys shall be payable on the audit and
33 warrant of the comptroller on vouchers certified or approved by the
34 commissioner of health in the manner prescribed by law.

35 § 4. This act shall take effect on the ninetieth day after it shall
36 have become a law.