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:

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

TITLE V-B

MEDICAL USE OF PSILOCYBIN

Section 3369-aa. Definitions.
3369-bb. Certification of patients.
3369-cc. Lawful medical use.
3369-dd. Registry identification cards.
3369-ee. Registration as a psilocybin service center.
3369-ff. Registered organizations.
3369-gg. Registering of registered organizations.
3369-hh. Reports of registered organizations.
3369-ii. Evaluation; research programs; report by department.
3369-jj. Psilocybin research license.
3369-kk. Relation to other laws.
3369-ll. Psilocybin service facilitator license requirements.
3369-mm. Protections for the medical use of psilocybin.
3369-nn. Regulations.
3369-oo. Suspend; terminate.
3369-pp. Pricing.
3369-qq. Psilocybin services grant program.
3369-rr. Psilocybin services advisory board.

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

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

LBD11894-04-1

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

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

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

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

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

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

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

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

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

10. "Designated caregiver" means an individual designated by a certified patient in a registry application. A certified patient may designate up to five designated caregivers not counting designated caregiver facilities or designated caregiver facilities' employees.

11. "Psilocybin services" means services provided to a certified patient before, during and after the patient's consumption of a psilocybin product, including a preparation session and integration session.

12. "Psilocybin service center employee" means an employee of a psilocybin service center.

13. "Form of medical psilocybin" means characteristics of the medical psilocybin recommended or limited for a particular certified patient, including the method of consumption and any particular strain, variety, and quantity or percentage of psilocybin or particular active ingredient, or whole psilocybin.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. In making a certification, the practitioner may consider the form of medical psilocybin the patient should consume, including the method of consumption and any particular strain, variety, and quantity or percentage of psilocybin or particular active ingredient, and appropriate dosage. The practitioner may state in the certification any recommendation or limitation the practitioner makes, in his or her professional opinion, concerning the appropriate form or forms of medical psilocybin and dosage.

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

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

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

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

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

tioner states in the certification that in the practitioner's professional opinion the patient is terminally ill and that the certification shall not expire until the patient dies, then the registry identification card shall state that the patient is terminally ill and that the registration card shall not expire until the patient dies; (c) if the practitioner re-issues the certification to terminate the certification on an earlier date, then the registry identification card shall expire on that date and shall be promptly destroyed by the certified patient; (d) if the certification so provides, the registry identification card shall state any recommendation or limitation by the practitioner as to the form or forms of medical psilocybin or dosage for the certified patient; and (e) the department shall make regulations to implement this subdivision.

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

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

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

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

1. The psilocybin purchased, possessed, acquired or used by a certified patient shall have occurred at a psilocybin service center under the supervision of a psilocybin service facilitator;

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

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

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

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

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

2. To obtain, amend or renew a registry identification card, a certified patient or designated caregiver shall file a registry application with the department, unless otherwise exempted by the department in regulation. The registry application or renewal application shall include:

(a) in the case of a certified patient:

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

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

(iii) the date of the certification;

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

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

(vi) the name, address, and telephone number of the certifying practitioner;

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

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

(ix) other individual identifying information required by the department;

(b) in the case of a designated caregiver:

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

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

(iii) other individual identifying information required by the department;

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

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

(e) any other requirements determined by the department.

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

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

5. No person may be a designated caregiver for more than four certified patients at one time.

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

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

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

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

9. If the application of a certified patient designates an individual as a designated caregiver who is not authorized to be a designated caregiver, that portion of the application shall be denied by the department but that shall not affect the approval of the balance of the application.

10. A registry identification card shall:

(a) contain the name of the certified patient or the designated caregiver as the case may be;

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

(c) contain a registry identification number for the certified patient or designated caregiver, as the case may be and a registry identification number;

(d) contain a photograph of the individual to whom the registry identification card is being issued, which shall be obtained by the department in a manner specified by the department in regulations; provided, however, that if the department requires certified patients to submit photographs for this purpose, there shall be a reasonable accommodation of certified patients who are confined to their homes due to their medical conditions and may therefore have difficulty procuring photographs;

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

(f) plainly state any recommendation or limitation by the practitioner as to the form or forms of medical psilocybin or dosage for the certified patient; and

(g) any other requirements determined by the department.

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

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

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

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

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

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

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

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

(b) operating certificate or license number where appropriate;

(c) name, title, and signature of an authorized facility representative;

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

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

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

2. Prior to issuing or renewing a psilocybin service center registration, the department may verify the information submitted by the applicant. The applicant shall provide, at the department's request, such information and documentation, including any consents or authorizations that may be necessary for the department to verify the information.

3. The department shall approve, deny or determine incomplete or inaccurate an initial or renewal application within thirty days of receipt of the application. If the application is approved within the thirty-day period, the department shall issue a registration as soon as is reasonably practicable.

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

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

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

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

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

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

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

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

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

(B) whether the psilocybin service center is a minority- and/or women-owned business enterprise, a service-disabled veteran-owned business, or from communities disproportionally impacted by the enforcement of psilocybin prohibition;

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

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

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

(F) whether the psilocybin service center is culturally, linguistically, and medically competent to provide services to unserved and underserved areas; and

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

(vi) the applicant and its managing officers are of good moral character;

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) The application for renewal shall include such information prepared in the manner and detail as the department may require, including but not limited to:

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

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

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

(B) compliance by the applicant with the laws of the state with respect to the distribution or sale of medical psilocybin, where applicable.

(c) An applicant for renewal shall be under a continuing duty to report to the department any change in facts or circumstances reflected in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application and to obtain approval prior to any material change in management, interest or ownership.

(d) If the department is not satisfied that the psilocybin service center applicant is entitled to a renewal of the registration, the department shall within a reasonably practicable time as determined by the commissioner, serve upon the psilocybin service center or its attorney of record in person or by registered or certified mail an order directing the psilocybin service center to show cause why its application for renewal should not be denied. The order shall specify in detail the respects in which the applicant has not satisfied the department that the registration should be renewed.

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

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

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

(ii) the applicant is unlikely to comply with all state laws applicable to the activities in which it may engage under the registration;

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

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

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

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

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

11. In coordination with the chief equity officer, the department shall register additional registered psilocybin service centers to provide services to unserved and underserved areas of the state. Such additional registered psilocybin service centers shall be reflective of the demographics of the state, be representative of communities disproportionately impacted by psilocybin prohibition, and be culturally, linguistically, and medically competent to serve unserved and underserved areas of the state. The department shall actively promote racial, ethnic, and gender diversity when registering additional registered psilocybin service centers.

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

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

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

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

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

5. No registered organization may sell, deliver, distribute or dispense medical psilocybin directly to a certified patient or designated caregiver.

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

(a) methods for administering medical psilocybin;

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

(c) how to recognize what may be problematic usage of medical psilocybin and obtain appropriate services or treatment for problematic usage; and

(d) other information as determined by the department.

7. Registered organizations shall not be managed by or employ anyone who has been convicted within three years of the date of hire, of any felony related to the functions or duties of operating a business, except that if the department determines that the manager or employee is otherwise suitable to be hired, and hiring the manager or employee would not compromise public safety, the department shall conduct a thorough review of the nature of the crime, conviction, circumstances, and evidence of rehabilitation of the manager or employee, and shall evaluate the suitability of the manager or employee based on the evidence found through the review. In determining which offenses are substantially related to the functions or duties of operating a business, the department shall include, but not be limited to, the following:

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

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

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

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

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

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

including, but not limited to, shipping, maintenance, construction, repair, and security, provided that the person or entity shall not perform any function or activity directly involving the planting, growing, tending, harvesting, processing, or packaging of psilocybin plants, medical psilocybin, or medical psilocybin products being produced by the registered organization; or any other function directly involving manufacturing or retailing of medical psilocybin. All laws and regulations applicable to such facilities, equipment, or services shall apply to the contract. The registered organization and other parties to the contract shall each be responsible for compliance with such laws and regulations under the contract. The department may make regulations consistent with this title relating to contracts and parties to contracts under this subdivision.

11. A registered organization shall, based on the findings of an independent laboratory, provide documentation of the quality, safety and clinical strength of the medical psilocybin manufactured or dispensed by the registered organization to the department and to any psilocybin service center to which the medical psilocybin is sold or dispensed.

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

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

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

§ 3369-gg. Registering of registered organizations. 1. (a) An applicant for registration as a registered organization under section thirty-three hundred sixty-nine-ff of this title shall include such information prepared in such manner and detail as the department may require, including but not limited to:

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

(ii) that the applicant:

(A) is of good moral character;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) whether the registered organization is a minority and/or woman owned business enterprise, a service-disabled veteran-owned business, or from communities disproportionally impacted by the enforcement of psilocybin prohibition;

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

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

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

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

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

(vi) the applicant and its managing officers are of good moral character;

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

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

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

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

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

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

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

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

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

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

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

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

(b) The application for renewal shall include such information prepared in the manner and detail as the department may require, including but not limited to:

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

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

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

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

(c) An applicant for renewal shall be under a continuing duty to report to the department any change in facts or circumstances reflected in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application and to obtain approval prior to any material change in management, interest or ownership.

(d) If the department is not satisfied that the registered organization applicant is entitled to a renewal of the registration, the department shall within a reasonably practicable time as determined by the executive director, serve upon the registered organization or its attorney of record in person or by registered or certified mail an order directing the registered organization to show cause why its application for renewal should not be denied. The order shall specify in detail the respects in which the applicant has not satisfied the department that the registration should be renewed.

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

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

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

(ii) the applicant is unlikely to comply with all state laws applicable to the activities in which it may engage under the registration;

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

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

(v) the applicant has substantively violated the laws of another jurisdiction, in which they operate or have operated a psilocybin license or registration, related to the operation of a psilocybin business.

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

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

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

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

9. In coordination with the chief equity officer the department shall register additional registered organizations to provide services to unserved and underserved areas of the state. Such additional registered organizations shall be reflective of the demographics of the state, be representative of communities disproportionately impacted by psilocybin prohibition, and be culturally, linguistically, and medically competent to serve unserved and underserved areas of the state. The department shall actively promote racial, ethnic, and gender diversity when registering additional registered organizations.

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

2. The department shall, by regulation, require each registered organization to adopt and maintain security, tracking, recordkeeping, record retention and surveillance systems, relating to all medical psilocybin at every stage of acquiring, possession, manufacture, sale, delivery, transporting, distributing, or dispensing by the registered organization, subject to regulations of the department.

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

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

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

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

(a) to test chemical potency and composition levels;

(b) to conduct clinical investigations of psilocybin-derived drug products;

(c) to conduct research on the efficacy and safety of administering psilocybin as part of medical treatment; and

(d) to conduct genomic or agricultural research.

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

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

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

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

3. A psilocybin research licensee may only sell psilocybin grown or within its operation to other psilocybin research licensees. The department may revoke a psilocybin research license for violations of this section.

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

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

(a) application requirements;

(b) psilocybin research license renewal requirements, including whether additional research projects may be added or considered;

(c) conditions for license revocation;

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

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

(f) licensee reporting requirements;

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

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

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

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

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

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

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

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

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

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

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

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

(i) Facilitation skills that are affirming, nonjudgmental and nondirective; and

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

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

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

4. A psilocybin service facilitator licensee may engage in the following activities in accordance with rules adopted by the department:

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

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

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

§ 3369-mm. Protections for the medical use of psilocybin. 1. Certified patients, designated caregivers, psilocybin service centers and employees of psilocybin service centers, practitioners, registered organizations and the employees of registered organizations, and psilocybin researchers shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for the certified medical use or manufacture of psilocybin, or for any other action or conduct in accordance with this title.

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

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

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

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

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

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

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

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

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

§ 3369-pp. Pricing. Registered organizations shall submit documentation to the executive director of any change in pricing per dose for any medical psilocybin product within fifteen days of such change. Prior approval by the executive director shall not be required for any such change; provided however that the department is authorized to modify the price per dose for any medical psilocybin product if necessary to maintain public access to appropriate medication.

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

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

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

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

(b) The governor shall have eight appointments, the temporary president of the senate and the speaker of the assembly shall each have three appointments to the board. Advisory board members shall have statewide geographic representation that is balanced and diverse in its composition. Appointed members shall have an expertise in public and behavioral health, substance use disorder treatment, effective rehabilitative treatment for adults and juveniles, homelessness and housing, economic development, environmental conservation, job training and placement, criminal justice, and drug policy. Further, the advisory board shall include residents from communities most impacted by psilocybin prohibition, people with prior drug convictions, the formerly incarcerated, and representatives from the farming industry, psilocybin industry, and organizations serving communities impacted by past federal and state drug policies.

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

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

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

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

7. The advisory board shall have the following duties:

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

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

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

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

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

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

(C) The health and safety warnings and other disclosures that should be made to the patient before such patient participates in the administration session.

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

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

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

(i) Facilitation skills that are affirming, non-judgmental and non-directive;

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

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

(iv) Social and cultural considerations.

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

(g) Make recommendations to the department on public health and safety standards and industry best practices for holding and completing an administration session, including:

(i) Whether group administration sessions should be available;

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

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

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

(h) In consultation with the department of agriculture and markets and the department of environmental conservation, promulgate necessary rules and regulations governing the safe production of psilocybin, including environmental and energy standards and restrictions on the use of pesticides and best practices for water and energy conservation.

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

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

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

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

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

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

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

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

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