SENATE COMMITTEE SUBSTITUTE FOR

SENATE, No, 2283

STATE OF NEW JERSEY

221st LEGISLATURE

ADOPTED JUNE 6, 2024

Sponsored by:
Senator NICHOLAS P. SCUTARI
District 22 (Somerset and Union)
Senator JOSEPH F. VITALE
District 19 (Middlesex)

Co-Sponsored by:
Senators Schepisi, Zwicker, Cruz-Perez, O'Scanlon and Burgess

SYNOPSIS

"Psilocybin Behavioral Health Access and Services Act"; authorizes production and use of psilocybin to promote health and wellness.

CURRENT VERSION OF TEXT

Substitute as adopted by the Senate Health, Human Services and Senior Citizens Committee.

(Sponsorship Updated As Of: 6/13/2024)

AN ACT concerning the production and use of psilocybin for certain purposes, supplementing Title 24 of the Revised Statutes, and amending Title 45 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. (New section) This act shall be known and may be cited as the "Psilocybin Behavioral Health Access and Services Act."

2. (New section) The Legislature finds and declares that:

a. New Jersey has a high prevalence of adults living with behavioral health conditions.

b. Studies conducted by nationally and internationally recognized medical institutions indicate that psilocybin has shown efficacy, tolerability, and safety in the treatment of a variety of behavioral health conditions, including, but not limited to, clinical dependence disorders, depression, anxiety disorders, and end-of-life psychological distress.

c. The United States Food and Drug Administration has determined that preliminary clinical evidence indicates psilocybin may demonstrate substantial improvement over available therapies for treatment-resistant depression, and has granted a breakthrough therapy designation for a treatment that uses psilocybin as a therapy for treatment-resistant depression.

d. It is the intent of the Legislature to facilitate the establishment of safe, legal, and affordable psilocybin service centers to provide residents of New Jersey who are 21 years of age or older with opportunities for supported psilocybin experiences to alleviate distress, provide preventative behavioral health care, and foster wellness and personal growth.

e. In establishing this act, the Legislature seeks to improve the physical, mental, and social well-being of all residents of New Jersey, and to prevent and reduce the prevalence of behavioral health disorders in adults, by providing for supported adult use of psilocybin under the supervision of trained and licensed psilocybin service facilitators.

f. The Legislature further seeks to develop a long-term Statewide strategic plan for ensuring that psilocybin services become and remain a safe, accessible, and affordable treatment option for people age 21 and older in New Jersey for whom behavioral health treatment and preventative behavioral health care using psilocybin is appropriate.

g. It is necessary and appropriate to develop a comprehensive regulatory scheme to ensure that psilocybin can be accessed in safe,

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined <u>thus</u> is new matter.

controlled environments that are designed to foster improvements in behavioral health for adult patients, including establishing requirements for the licensure and regulation of psilocybin product manufacturers and psilocybin service providers, as well as requirements to restrict access to psilocybin to adults age 21 and older and to prevent the unlawful diversion of psilocybin in the State.

3. (New section) As used in this act:

"18-month program development period" means the period beginning on the effective date of this act and ending 18 months thereafter.

"Administration session" means a session at which a patient consumes and experiences the effects of a psilocybin product under the supervision of a psilocybin service facilitator.

"Adverse employment action" means refusing to hire or employ an individual, barring or discharging an individual from employment, requiring an individual to retire from employment, or discriminating against an individual in compensation or in any terms, conditions, or privileges of employment.

"Adverse event" means an event that the board determines is a negative consequence of receiving psilocybin services that results in unintended injury or illness, which may or may not have been preventable.

"Behavioral health care provider" means a psychiatrist, psychiatric advanced practice nurse, psychologist, clinical social worker, marriage and family therapist, any other mental health or substance use disorder treatment provider licensed pursuant to Title 45 of the Revised Statutes, or a practitioner otherwise authorized to provide behavioral health care services in the State.

"Board" means the Psilocybin Advisory Board established pursuant to section 4 of this act.

"Commissioner" means the Commissioner of Health.

"Department" means the Department of Health.

"Distressed area" means an area that: is categorized as a distressed area by the New Jersey Department of Labor and Workforce Development; or is a State legislative district in which 50 percent or more of the children in the district participate in the federal free lunch program or in which 20 percent or more of the households in the district receive assistance under the federal supplemental nutrition assistance program.

"Health care practitioner" means a physician, advanced practice nurse, physician assistant, psychologist, clinical social worker, or professional counselor licensed or certified pursuant to Title 45 of the Revised Statutes who is the health care practitioner responsible for the ongoing treatment of a patient's qualifying medical condition, the symptoms of that condition, or the symptoms associated with the treatment of that condition, provided, however,

that the ongoing treatment shall not be limited to the provision of psilocybin services to a patient solely for that purpose.

"Integration therapy session" means the mandatory therapy session between a patient and behavioral health care provider, in collaboration with the psilocybin service facilitator when appropriate and necessary, that occurs after the patient completes an administration session, in which therapy session the provider shall provide any follow-up services and additional referrals as may be appropriate for the patient's ongoing treatment needs and within the provider's scope of practice.

"Licensee" means a person who holds a psilocybin product manufacturer license, a psilocybin service center operator license, a psilocybin testing laboratory license, or a psilocybin service facilitator license issued pursuant to this act.

"Manufacture" means the manufacture, planting, cultivation, growing, harvesting, production, preparation, propagation, compounding, conversion, or processing of a psilocybin product, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the psilocybin product or labeling or relabeling of its container.

"Patient" means a resident of the State who is 21 years of age or older and has been referred for psilocybin services by a health care practitioner.

"Preparation session" means an in-person or remote meeting between a patient and a psilocybin service facilitator that is required as a prerequisite to an administration session, in which meeting a psilocybin service facilitator shall: verify a patient's age and if the patient has received a referral for psilocybin services from a health care practitioner; obtain, in collaboration with the patient's health care practitioner or behavioral health care provider to the extent possible, any necessary information to complete a psilocybin services safety screening tool and patient information form for the patient; provide the patient with any health and safety warnings and other necessary disclosures; obtain informed consent from the patient to proceed with an administration session; and help the patient establish goals of care, including the identification of any clinical metrics relevant to tracking progress in the patient's goals.

"Psilocybin" means psilocybin or psilocin.

"Psilocybin product manufacturer" means a person licensed to manufacture psilocybin products pursuant to this act.

"Psilocybin product" means psilocybin-producing fungi and mixtures or substances containing a detectable amount of psilocybin.

"Psilocybin service center" means an establishment at which administration sessions are held and other psilocybin services may be provided.

"Psilocybin service center operator" means a person licensed to operate a psilocybin service center pursuant to this act.

"Psilocybin service facilitator" means an individual licensed to facilitate the provision of psilocybin services pursuant to this act.

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

"Psilocybin services safety screening tool" means an instrument used for the systematic evaluation of the potential risks or hazards for an individual receiving psilocybin services.

"Qualifying medical condition" means any medical condition or its treatment that would qualify a patient to receive psilocybin services as determined by the board.

4. (New section) a. There is established in the Department of Health the Psilocybin Behavioral Health Access and Services Advisory Board.

b. The board shall comprise 15 members, as follows:

(1) the Commissioner of Health, the Deputy Commissioner for Public Health Services, the Adjutant General, and the Attorney General, or their designees, who shall serve as ex officio, nonvoting members;

(2) a representative from the department who is familiar with public health programs and public health activities in New Jersey and a designee of the Public Health Council in the Department of Health, who shall serve at the pleasure of the commissioner as nonvoting members; and

(3) nine public members, to be appointed by the Governor with preference given to members who have experience with psychedelic-assisted therapy, which members shall include:

(a) a person with expertise in substance use disorders;

(b) a representative of a community-based entity that provides public health services directly to the public;

(c) a psychiatrist licensed pursuant to Title 45 of the Revised Statutes, who has professional experience engaging in the diagnosis and treatment of behavioral, mental, and emotional health conditions including, but not limited to, substance use disorders;

(d) a physician licensed pursuant to Title 45 of the Revised Statutes;

(e) a psychologist licensed pursuant to the "Practicing Psychology Licensing Act," P.L.1966, c.282 (C.45:14B-1 et seq.) who has professional experience engaging in the diagnosis and treatment of behavioral, mental, and emotional health conditions including, but not limited to, substance use disorders;

(f) an individual working in academia with expertise in public health policy;

(g) a person with professional experience conducting scientific research regarding the use of psychedelic compounds in clinical therapy;

(h) a pharmacist licensed pursuant to Title 45 of the Revised Statutes who specializes in psychological medicine; and

(i) a person with experience with health care access.

c. The public members of the board shall serve for a term of four years, provided that, of the members first appointed, two shall serve for a term of two years, two shall serve for a term of three years, and three shall serve for a term of four years. Public members shall be eligible for reappointment to the board. Vacancies in the board shall be filled in the same manner as is provided for the initial appointment for the remainder of the unexpired term.

d. The Governor shall appoint the public members to the board no later than 60 days after the effective date of this act. The board shall organize upon the appointment of the public members and shall select a chairperson and a vice-chairperson from among the membership. The chairperson shall appoint a secretary, who need not be a member of the board.

e. A majority of the public members of the board shall constitute a quorum for the purpose of conducting official board business. The official adoption of advice or recommendations by the board shall require the approval of a majority of the public members.

f. During the 18-month program development period, the board shall meet at least once every calendar month, at a time and place designated by the chairperson. Following the end of the 18-month program development period, the board shall meet at least quarterly at a time and place designated by the chairperson. The board shall meet at any time at the call of the chairperson or at the call of a majority of the public members.

g. The members of the board shall serve without compensation but may be reimbursed for reasonable expenses incurred in the performance of their official duties, within the limits of funds made available to the board for this purpose.

h. The board may establish committees and subcommittees as may be necessary for the board's operation. The department shall provide such stenographic, clerical, and other administrative assistants and such professional staff as the board requires to carry out its work. The board shall be entitled to call to its assistance and avail itself of the services of the employees of any State, county, or municipal department, board, bureau, commission, or agency as it may require and as may be available for its purposes.

5. (New section) a. The purpose of the board established pursuant to section 4 of this act shall be to provide advice and recommendations to the department, upon request or upon the

board's own initiative, concerning the implementation of this act, including providing recommendations to the department concerning:

(1) educating the public about the use of psilocybin in behavioral health care;

(2) available medical, psychological, and scientific studies, social scientific research, and other information relating the safety of psilocybin and any other psychedelic substances, as determined by the board, and their efficacy in ameliorating behavioral health conditions, including, but not limited to, clinical dependence disorders, depression, anxiety disorders, and end-of-life psychological distress, and the potential for psilocybin and any other psychedelic substances to promote community, address trauma, and enhance physical and mental wellness;

(3) the requirements, specifications, and guidelines for providing psilocybin services to a patient, including:

(a) requirements, specifications, and guidelines for holding and documenting the completion of preparation sessions, administration sessions, and integration therapy sessions;

(b) requirements, specifications, and guidelines for holding and documenting the completion of group administration sessions and establishing a limit on the total number of patients who may participate in a group administration session that is supervised by one psilocybin service facilitator;

(c) the contents of the psilocybin services safety screening tool and patient information form that a patient will be required to complete and sign before the patient will be authorized to participate in an administration session, including:

(i) the information that should be solicited from the patient or the patient's health care practitioner or behavioral health care provider to determine whether the patient should participate in the administration session, including information that may identify potential risk factors and contraindications;

(ii) the information that should be solicited from the patient or the patient's health care practitioner or behavioral health care provider to assist the psilocybin service center and the psilocybin service facilitator in meeting any public health and safety standards and industry best practices during the administration session; and

(iii) the health and safety warnings and other disclosures that should be made to the patient before the patient participates in the administration session;

(d) guidelines and best practices for assessing the type, nature, and severity of a risk factor or contraindication identified in a patient information form, and determining whether the risk factor or contraindication:

(i) can be accommodated or mitigated in a manner that will allow the patient to proceed with an administration session; or

(ii) is of a type, nature, or severity that would make it unsafe for the patient to proceed with an administration session;

(e) the list of medical conditions and the symptoms of those medical conditions that would qualify a patient to receive psilocybin services pursuant to this act;

(f) dosage guidelines for patients, which guidelines the board may periodically review and update as appropriate and psilocybin service facilitators shall use to determine the appropriate dose of psilocybin product a patient may consume during an administration session; and

(g) the types and severity of adverse events that constitute a serious adverse event and that each psilocybin service center shall report to the department;

(4) public health and safety standards and industry best practices for psilocybin product manufacturers, psilocybin service centers, psilocybin testing facilities, and psilocybin service facilitators, including, but not limited to, the implementation of security and safety measures to ensure psilocybin products are stored in a safe and secure manner that prevents theft, diversion, adulteration, and access by unauthorized individuals;

(5) the formulation of a code of professional conduct for psilocybin service facilitators, with particular consideration to developing a code of ethics;

(6) the education and training requirements for psilocybin service facilitators, with particular consideration of:

(a) training in facilitation skills that are affirming, nonjudgmental, culturally competent, and nondirective;

(b) providing support to patients during an administration session, including training in specialized skills for patient safety and patients who may have a behavioral health disorder;

(c) the environment in which psilocybin services should be provided; and

(d) social and cultural considerations;

(7) the examinations that psilocybin service facilitators will be required to successfully complete as a condition of licensure;

(8) public health and safety standards and industry best practices for holding and completing an administration session, including:

(a) the circumstances under which administration sessions should be available;

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

(c) the circumstances under which an administration session is considered complete; and

(d) the transportation needs of the patient after the completion of the administration session, including standards and restrictions for when an administration session may be terminated after the administration of a psilocybin product to a patient, along with

appropriate procedures to ensure the safety of the patient following termination of the administration session;

(9) the qualification criteria and amount to be charged in license application and issuance fees for licenses authorized under this act, as well as the qualification criteria and amount to be charged in application and issuance fees for psilocybin worker permits;

(10) requirements and restrictions for advertising psilocybin services;

(11) establishing a tracking system for psilocybin products and the reporting of adverse events that may occur during the provision of psilocybin services;

(12) requirements concerning the transportation and delivery of psilocybin products between psilocybin product manufacturers psilocybin service centers, and psilocybin testing laboratories;

(13) requirements for the social opportunity program established pursuant to section 14 of this act and the equitable access program established pursuant to section 15 of this act that promote social equity and accessibility;

(14) development of a long-term strategic plan for ensuring that psilocybin services will become and remain a safe, accessible, and affordable wellness option for all persons 21 years of age or older in this State for whom psilocybin may be appropriate;

(15) determining whether psilocybin services provided under this act should be expanded to include the provision of in-home psilocybin services and whether the State should consider the use of any other psychedelic substances to promote health and wellness; and

(16) monitoring and studying federal laws, regulations, and policies regarding psilocybin.

b. The board shall vote upon and submit recommendations to the department according to a schedule agreed upon by the department and the board related to:

(1) the requirement for the department to adopt rules and regulations to implement and administer this act; and

(2) the development of a long-term plan for ensuring that psilocybin services will become and remain a safe, accessible, and affordable wellness option for all persons 21 years of age or older in New Jersey for whom psilocybin may be appropriate. Advice and recommendations shall be made in consideration of federal laws, regulations, and policies concerning psilocybin.

6. (New section) a. The department shall have the following duties, powers, and functions:

(1) to review and make publicly available on its Internet website available medical, psychological, and scientific studies, research, and other information relating to the safety and efficacy of psilocybin in treating mental health conditions, including, but not limited to, clinical dependence disorders, depression, anxiety

disorders, and end-of-life psychological distress, and the potential for psilocybin to promote community, address trauma, and enhance physical and mental wellness;

(2) after the 18-month program development period:

(a) to regulate the manufacturing, testing, transportation, delivery, sale, and purchase of psilocybin products and the provision of psilocybin services in this State in accordance with the provisions of this act;

(b) to issue, renew, suspend, revoke, or refuse to issue or renew psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, and psilocybin service facilitator licenses and psilocybin worker permits;

(c) to approve and regulate psilocybin service facilitator training programs; and

(d) to regulate the use of psilocybin products and psilocybin services for other purposes as the department deems necessary or appropriate;

(3) to adopt, amend, and repeal rules and regulations, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), as necessary to implement the provisions of this act; and

(4) to exercise all powers incidental, convenient, or necessary to enable the department to implement and administer the requirements of this act or any other New Jersey law that charges the department with a duty, function, or power related to psilocybin products and psilocybin services, which powers shall include, but shall not be limited to:

(a) issuing subpoenas;

(b) compelling the attendance of witnesses;

(c) administering oaths;

(d) certifying official acts;

(e) taking depositions as provided by law;

(f) establishing reasonable fees, which fees shall not exceed the amount necessary to administer the provisions of this act; and

(g) compelling the production of books, payrolls, accounts, papers, records, documents, and testimony.

b. The department shall not require that a psilocybin product be manufactured by means of chemical synthesis, prohibit the use of naturally grown mushrooms that meet quality and safety standards, or mandate the use of patented products or procedures.

c. The department shall require a patient to be diagnosed with, or exhibit the symptoms of, a qualifying medical condition and to receive a referral from a health care practitioner for psilocybin services, as a prerequisite to being provided psilocybin services.

d. Commencing six months after the effective date of this act, the department shall post on its Internet website available medical, psychological, and scientific studies, research, and other information relating to the safety and efficacy of psilocybin in ameliorating behavioral health conditions, including, but not limited

to, clinical dependence disorders, depression, anxiety disorders, and end-of-life psychological distress. The department shall periodically update the information posted on its Internet website pursuant to this subsection as may be necessary to ensure the information is current and accurate.

e. No later than 24 months after the effective date of this act, the department shall establish the necessary forms and commence the process of accepting applications for and approving psilocybin service facilitator training programs.

f. No later than 24 months after the effective date of this act, the department shall establish the necessary forms and commence the process of accepting applications for issuance of psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, and psilocybin service facilitator licenses and psilocybin worker permits.

7. (New section) a. A health care practitioner shall not be required to be listed publicly in any psilocybin practitioner registry as a condition of referring patients for psilocybin services.

b. No referral for psilocybin services may be issued by a health care practitioner to the practitioner's own self or to a member of the practitioner's immediate family.

c. A health care practitioner may initially refer any patient for psilocybin services using telemedicine or telehealth, provided that the use of telemedicine or telehealth, rather than an in-person visit, is consistent with the standard of care required for assessment and treatment of the patient's condition. Following the initial referral, the practitioner may provide continued referral for psilocybin services via telemedicine or telehealth if the practitioner determines that an in-person visit is not required, consistent with the standard of care. The practitioner may require in-office consultations if additional consultations are necessary to continue to refer the patient to receive psilocybin services.

As used in this subsection, "telehealth" and "telemedicine" shall have the same meaning as is provided in section 1 of P.L.2017, c.117 (C.45:1-61).

8. (New section) a. Except as provided in subsection b. of this section, no health care practitioner who has referred a patient for psilocybin services pursuant to this act within the past 90 days, and no member of such health care practitioner's immediate family, shall be an interest holder in, or receive any form of direct or indirect compensation from, any psilocybin product manufacturer, psilocybin service center, psilocybin service center operator, psilocybin testing laboratory, or employee thereof.

b. Nothing in subsection a. of this section shall be construed to prevent a health care practitioner from serving on the governing board of a psilocybin product manufacturer, psilocybin service

center, or psilocybin testing laboratory, or from receiving a reasonable stipend for such service, provided that:

(1) the stipend does not exceed the stipend paid to any other member of the governing board for serving on the board; and

(2) the amount of the stipend is not based on patient volumes at any psilocybin service center or on the number of referrals for psilocybin services by the health care practitioner pursuant to this act.

c. A health care practitioner, or an immediate family member of a health care practitioner, who applies to be an owner, director, officer, or employee of a psilocybin product manufacturer, psilocybin service center, or psilocybin testing laboratory, or who otherwise seeks to be an interest holder in, or receive any form of direct or indirect compensation from, a psilocybin product manufacturer, psilocybin service center, or psilocybin testing laboratory, shall certify that the health care practitioner has not referred a patient for psilocybin services pursuant to this act within the 90 days immediately preceding the date of the application.

d. A person who violates subsection a. of this section shall be guilty of a crime of the fourth degree.

9. (New section) a. A health care practitioner shall provide a written referral for psilocybin services for a patient to present to a psilocybin service center to receive psilocybin services.

b. A patient shall present documentation of the patient's referral to receive psilocybin services at the time the patient requests psilocybin services. The psilocybin service center shall verify the referral with the patient’s health care practitioner. A health care practitioner may provide a copy of a written referral by electronic or other means, including, but not limited to, telemedicine and telehealth, as determined by the department, directly to a psilocybin service center on behalf of a patient. Psilocybin services pursuant to any written referral shall be provided within one year of the date that the referral was written, or the referral is void.

c. Upon completing an administration session with a patient, the psilocybin service center shall transmit to the patient's health care practitioner information concerning the amount and type of psilocybin product that was consumed by the patient.

10. (New section) a. An applicant for a license or permit or renewal of a license or permit issued pursuant to this act shall submit the application in a form and manner as shall be specified by the department by regulation, which application shall include, at a minimum, the name and address of the applicant and any other information as the department may require. In the case of an applicant for issuance or renewal of a psilocybin product manufacturer license, a psilocybin service center operator license, or a psilocybin testing laboratory license, the application shall

additionally identify the proposed location of the premises that is to be operated under the license.

b. The department shall promptly review and approve or deny any application for licensure as a psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, or psilocybin service facilitator or for a psilocybin worker permit submitted pursuant to this act.

c. The department may reject an application that is not submitted in a form and manner required by the department. An applicant whose application is rejected pursuant to this subsection shall not be prohibited from submitting subsequent applications for licensure or a permit, or for renewal of a license or permit, to the department.

d. Except as provided in subsection c. of this section, an appeal of a decision to suspend, revoke, or refuse to renew a license or permit issued under this act shall be subject to the requirements for contested cases set forth in the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.).

e. No license or permit shall be issued pursuant to this act to any applicant who is younger than 21 years of age.

f. The department may refuse to issue or renew a license or permit or may issue a restricted license or permit to an applicant upon finding that the applicant:

(1) has not completed the requirements for issuance or renewal of the license or permit;

(2) has made false statements to the department;

(3) in the case of an applicant for a psilocybin product manufacturer license, a psilocybin service center operator license, or a psilocybin laboratory testing license, demonstrates a lack of capacity or incompetency to carry on the management of the facility that is the subject of the application;

(4) has been convicted of violating a federal law, State law, or local ordinance, if the conviction is substantially related to the fitness and ability of the applicant to lawfully carry out activities authorized or required under the license or permit;

(5) has an unsatisfactory record of compliance with the requirements of this act;

(6) in the case of an applicant for a psilocybin product manufacturer license, a psilocybin service center operator license, or a psilocybin testing laboratory license, fails to submit documentation demonstrating:

(a) that the applicant will have final control of the premises both within six months after the application is submitted and upon approval of the application, which documentation may include, but shall not be limited to, a lease agreement, contract for sale, title, deed, or similar documentation; and

(b) if the applicant will lease the premises, certification from the landlord that the landlord is aware that the tenant's use of the

premises will involve activities related to the production, processing, or administration of psilocybin products or the provision of psilocybin services, as applicable;

(7) in the case of an applicant for a psilocybin product manufacturer license, a psilocybin service center operator license, or a psilocybin testing laboratory license, has not demonstrated financial responsibility sufficient to adequately meet the requirements of the facility that is the subject of the application; or

(8) for other good cause as determined by the department.

g. The application and issuance fees for a new or renewed psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, or psilocybin service facilitator license or a psilocybin worker permit shall not exceed the administrative costs to the department of processing the application and administering the provisions of this act.

h. A license or permit issued pursuant to this act shall be valid for one year.

i. The department may not issue any psilocybin product manufacturer, psilocybin service center, psilocybin testing laboratory, or psilocybin service facilitator license, or any psilocybin worker permit, during the 18-month development period.

11. (New section) a. For the purposes of this section, the term "applicant" shall include any owner, director, officer, or employee of, and any significantly involved person in, a psilocybin product manufacturer, psilocybin service center operator, or psilocybin testing laboratory, as well as any applicant for issuance of a psilocybin service facilitator license or a psilocybin worker permit.

b. The department shall require each applicant for licensure as a psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, or psilocybin service facilitator, and each applicant for a psilocybin worker permit, to undergo a criminal history record background check. The department shall be authorized to exchange fingerprint data with and receive criminal history record background information from the Division of State Police and the Federal Bureau of Investigation, consistent with the provisions of applicable State and federal laws, rules, and regulations. The Division of State Police shall forward criminal history record background information to the department in a timely manner when requested pursuant to the provisions of this section.

c. An applicant who is required to undergo a criminal history record background check pursuant to this section shall submit to being fingerprinted in accordance with applicable State and federal laws, rules, and regulations. No check of criminal history record background information shall be performed pursuant to this section unless the applicant has furnished the applicant's written consent to that check. An applicant who is required to undergo a criminal

history record background check pursuant to this section who refuses to consent to, or cooperate in, the securing of a check of criminal history record background information shall not be considered for licensure as a psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, or psilocybin service facilitator or for issuance of a psilocybin worker permit. An applicant shall bear the cost for the criminal history record background check, including all costs of administering and processing the check.

d. The department shall not approve an applicant for licensure as a psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, or psilocybin service facilitator or for a psilocybin worker permit if the criminal history record background information of the applicant reveals a disqualifying conviction as set forth in subsection e. of this section.

e. A person who has been convicted of a crime of the first, second, or third degree under New Jersey law or of a crime involving any controlled dangerous substance or controlled substance analog as set forth in chapter 35 of Title 2C of the New Jersey Statutes except paragraph (11) or (12) of subsection b. of N.J.S.2C:35-5, paragraph (13) of subsection b. of N.J.S.2C:35-5 involving psilocybin, or paragraph (3), (4), or (5) of subsection a. of N.J.S.2C:35-10, or any similar law of the United States or any other state shall not be issued a psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, or psilocybin service facilitator license or a psilocybin worker permit, unless such conviction occurred after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) and was for a violation of federal law relating to possession or sale of cannabis for conduct that is authorized under P.L.2009, c.307 (C.24:6I-1 et al.), P.L.2015, c.158 (C.18A:40-12.22 et al.), or P.L.2021, c.16 (C.24:6I-31 et al.).

f. Upon receipt of the criminal history record background information from the Division of State Police and the Federal Bureau of Investigation, the department shall provide written notification to the applicant of the applicant's qualification or disqualification for licensure as a psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, or psilocybin service facilitator, or for issuance of a psilocybin worker permit, as applicable. If the applicant is disqualified because of a disqualifying conviction pursuant to the provisions of this section, the conviction that constitutes the basis for the disqualification shall be identified in the written notice.

g. The Division of State Police shall promptly notify the department in the event that an individual who was the subject of a criminal history record background check conducted pursuant to this section is convicted of a crime or offense in this State after the date the background check was performed. Upon receipt of that

notification, the department shall make a determination regarding the continued eligibility for licensure as a psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, or psilocybin service facilitator or to hold a psilocybin worker permit, as applicable.

h. Notwithstanding the provisions of subsection e. of this section to the contrary, the department may offer provisional authority for an applicant to be licensed as a psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, or psilocybin service facilitator, or to be issued a psilocybin worker permit, for a period not to exceed three months if the applicant submits to the department a sworn statement attesting that the applicant has not been convicted of any disqualifying conviction pursuant to this section.

i. Notwithstanding the provisions of subsection e. of this section to the contrary, no applicant for licensure as a psilocybin product manufacturer, psilocybin service center operator, psilocybin testing laboratory, or psilocybin service facilitator, or for a psilocybin worker permit, shall be disqualified on the basis of any conviction disclosed by a criminal history record background check conducted pursuant to this section if the individual has affirmatively demonstrated to the department clear and convincing evidence of rehabilitation. In determining whether clear and convincing evidence of rehabilitation has been demonstrated, the department shall consider the following factors:

(1) the nature and responsibility of the position that the convicted individual would hold, has held, or currently holds;

(2) the nature and seriousness of the crime or offense;

(3) the circumstances under which the crime or offense occurred;

(4) the date of the crime or offense;

(5) the age of the individual when the crime or offense was committed;

(6) whether the crime or offense was an isolated or repeated incident;

(7) any social conditions which may have contributed to the commission of the crime or offense; and

(8) any evidence of rehabilitation, including good conduct in prison or in the community, counseling or psychiatric treatment received, acquisition of additional academic or vocational schooling, successful participation in correctional work-release programs, or the recommendation of those who have had the individual under their supervision.

12. (New section) a. The department shall not issue any license to a psilocybin product manufacturer, psilocybin service center operator, or psilocybin testing laboratory if the premises of the psilocybin product manufacturer, psilocybin service center, or

psilocybin testing laboratory are not clearly described and defined in the application.

b. No application for a psilocybin product manufacturer or psilocybin service center operator license shall be approved unless it includes a description of the proposed location for the applicant's site, including:

(1) the proposed location, the surrounding area, and the suitability or advantages of the proposed location, along with a floor plan and optional renderings or architectural or engineering plans; and

(2) the submission of zoning approvals for the proposed location, which shall consist of a letter or affidavit from appropriate municipal officials that the location will conform to municipal zoning requirements allowing for the production of psilocybin products, the provision of psilocybin services, or both, as applicable.

13. (New section) The department may require a licensed psilocybin product manufacturer, psilocybin service center operator, or psilocybin testing laboratory, or an applicant for a psilocybin product manufacturer, psilocybin service center operator, or psilocybin testing laboratory license, to submit to the department a sworn statement identifying the name and address of each person holding a financial interest in the licensee or the applicant for licensure, and the nature and extent of the financial interest held by each person holding a financial interest in the licensee or the applicant for licensure.

14. (New section) a. The department shall establish and administer a social opportunity program to assist individuals who qualify as social opportunity applicants and who otherwise meet the requirements for issuance of a psilocybin product manufacturer, psilocybin service center, psilocybin service facilitator, or psilocybin testing laboratory license pursuant to this act.

b. An applicant for a psilocybin product manufacturer, psilocybin service center, or psilocybin testing laboratory license shall be eligible for participation in the social opportunity program if:

(1) at least 51 percent of the applicant is owned or controlled by individuals who have lived in a distressed area for five of the past 10 years;

(2) the applicant is an entity:

(a) that has more than 10 full-time employees; and

(b) has more than half of its employees currently residing in a distressed area; or

(3) the applicant is an entity that meets any other eligibility criteria for the social opportunity program as may be established by the department.

c. An applicant for a psilocybin service facilitator license shall be eligible for participation in the social equity program if the applicant has a primary residence in a distressed area for five of the past 10 years, has demonstrated economic need, and meets any other eligibility criteria for the social opportunity program as may be established by the department.

d. For the purposes of implementing the social opportunity program, the department shall:

(1) identify geographic areas that are distressed areas;

(2) establish other appropriate criteria to identify social opportunity applicants;

(3) provide technical assistance to social opportunity applicants, either through direct assistance or by methods that may include establishing a partnership network of entities available to support social opportunity applicants;

(4) provide reduced licensure application, renewal, and issuance fees for social opportunity applicants; and

(5) if applicable, create eligibility for social opportunity applicants to receive points towards a license application score.

15. (New section) a. The department shall establish and administer an equitable access program to provide assistance with the cost of receiving psilocybin services assist to any individual, who:

(1) has a primary residence in a distressed area, as identified by the department pursuant to paragraph (1) of subsection d. of section 14 of this act, for five of the past 10 years;

(2) has demonstrated economic need; and

(3) meets any other eligibility criteria for the equitable access program as may be established by the department.

b. The department shall adopt eligibility criteria for providing financial assistance to individuals under the equitable access program established pursuant to subsection a. of this section. An individual who wishes to receive financial assistance from the program shall submit an application in a form and manner to be determined by the department.

16. (New section) a. A person may hold multiple psilocybin service center operator licenses and may hold both a psilocybin product manufacturer license and one or more psilocybin service center operator licenses, which licenses may be issued for the same or for different premises, provided that no individual may have a financial interest in:

(1) more than one psilocybin product manufacturer; or

(2) more than five psilocybin service centers.

17. (New section) a. No person who is younger than 21 years of age shall be employed at any psilocybin product manufacturer,

psilocybin service center, or psilocybin testing laboratory. The department may require a licensee to furnish proof that all employees of the licensee are 21 years of age or older, and may require any person for whom proof of age is unavailable to leave the licensed premises until such time as the person presents acceptable proof of age. Failure to provide proof of age for an employee within a reasonable period of time shall constitute prima facie evidence that the licensee knowingly employed the person in violation of the requirements of this subsection.

b. No individual may engage in any activities involving the manufacture, processing, transportation, delivery, testing, sale, or administration of psilocybin products, provide psilocybin services, or engage in other activities related to the manufacture, processing, transportation, delivery, testing, sale, or administration of psilocybin products or the provision of psilocybin services, unless the individual holds a current, valid psilocybin worker permit issued by the department.

c. Each psilocybin product manufacturer, psilocybin service center, and psilocybin testing laboratory shall ensure that each employee of the psilocybin product manufacturer, psilocybin service center, or psilocybin testing laboratory, as applicable, including any psilocybin service facilitator employed by the licensee, possesses a current, valid psilocybin worker permit.

d. An application for a psilocybin worker permit shall be submitted in a form and manner as required by the department. A psilocybin worker permit shall be valid for one year and shall be subject to renewal. The department shall establish reasonable application and issuance fees for psilocybin worker permits, which fees shall not exceed the cost to the department of processing the permit application and issuing the permit.

e. The department may require applicants for a psilocybin worker permit to complete a course provided and approved by the department as a condition of issuance of the permit, which course may include training in:

(1) verifying a patient’s age;

(2) verifying a patient’s information and referral to receive psilocybin services;

(3) conducting a psilocybin services safety screening for a patient to receive psilocybin services, in collaboration with the patient’s health care practitioner and behavioral healthcare provider to the extent possible and as necessary;

(4) providing the patient with any health and safety warnings and other necessary disclosures, and obtaining informed consent prior to conducting an administration session for the patient;

(5) determining the amount of psilocybin product an individual is to consume during an administration session based on the dosage guidelines established by the board and any of the patient’s potential risk factors and contraindications;

(6) detecting signs of patient intoxication;

(7) safe and sanitary handling of psilocybin products;

(8) best practices for sanitation and for the safe production, processing, transportation, and storage of psilocybin products;

(9) confidentiality requirements;

(10) the requirements of this act, as they bear on the applicant's duties; and

(11) any other topics the department determines to be appropriate.

f. (1) The department may charge, or authorize a course provider to charge, a reasonable fee, not to exceed $250, for a course described in subsection e. of this section.

(2) The department shall not require an individual to attend a course described in subsection e. of this section more than one time, except in cases where the individual's psilocybin worker permit has been suspended or revoked by the department, in which case the department may require the individual to complete the course as a condition of removing the suspension or issuing a new psilocybin worker permit to the individual.

g. The department may require a person issued both a psilocybin product manufacturer license and a psilocybin service center license for the same premises to require the premises be segregated into separate areas for conducting the activities authorized under each license, as may be necessary to protect the public health and safety.

18. (New section) a. The department shall designate specific psilocybin manufacturing activities that shall be authorized for psilocybin product manufacturers, and a psilocybin product manufacturer shall not engage in a psilocybin manufacturing activity unless the manufacturer holds an endorsement authorizing the manufacturer to engage in that specific activity. A psilocybin product manufacturer shall not be limited in the number of endorsements the manufacturer holds at one time, and a psilocybin product manufacturer may request approval from the department for additional endorsements at any time. The department shall approve a request for an additional endorsement unless the department determines that the psilocybin product manufacturer will be unable to meet the requirements for the requested endorsement. Denial of a request for an additional endorsement shall not preclude a manufacturer from submitting a subsequent request for approval of the same or any other endorsement.

b. The department may restrict the quantity or volume of psilocybin annually produced by a psilocybin product manufacturer, which may include establishing specific, lower quantity or volume limits for psilocybin product manufacturers issued a microbusiness license pursuant to subsection d. of this section. In establishing quantity or volume restrictions pursuant to this subsection, the

department shall take into consideration the demand for psilocybin services in the State, the number of entities issued psilocybin product manufacturer licenses and the number of applicants for psilocybin product manufacturer licenses, and the number of each type of endorsement held by psilocybin product manufacturers, as well as the geographic distribution of licensees, applicants, and endorsements throughout the State.

c. In no case shall psilocybin manufacturing activities be conducted in an outdoor area.

d. (1) The department shall establish a psilocybin product manufacturer microbusiness license, for which the maximum fee assessed by the department for issuance or renewal of the license shall be no more than half the fee applicable to full psilocybin product manufacturer license. A license issued to a microbusiness shall be valid for one year and may be renewed annually.

(2) A microbusiness shall meet the following requirements:

(a) at least 51 percent of the owners, directors, officers, and employees of the microbusiness shall be residents of the municipality in which the microbusiness is or will be located, or a municipality bordering the municipality in which the microbusiness is or will be located;

(b) the microbusiness shall employ no more than 10 employees at one time, inclusive of any owners, officers, and directors of the microbusiness; and

(c) the entire microbusiness facility shall occupy an area of no more than 2,500 square feet.

19. (New section) a. A psilocybin service center shall not constitute a health care facility licensed pursuant to P.L.1971, c.163 (C.26:2H-1 et seq.).

b. (1) Except as provided in paragraphs (2) and (3) of this subsection, a psilocybin service center shall not be approved for any location that is entirely zoned for residential use or that is within 1,000 feet of an elementary or secondary school.

(2) (a) A psilocybin service center may be approved for a location that is within 1,000 feet of an elementary or secondary school if the psilocybin service center is not located within 500 feet of an elementary or secondary school and the center does not use any signage that is attractive to minors.

(b) As used in this paragraph, “attractive to minors” means a design that includes: cartoons; a design, brand, or name that resembles a non-psilocybin consumer product of the type that is typically marketed to minors; symbols or celebrities that are commonly used to market products to minors; images of minors; or words that refer to products that are commonly associated with minors or marketed by minors.

(3) An existing psilocybin service center shall not be required to relocate in the event an elementary or secondary school is newly

constructed within 1,000 feet of the psilocybin service center for such time as the psilocybin service center continues to hold a valid license issued by the department. The department may not revoke the license of a psilocybin service center solely on the grounds that an elementary or secondary school is newly constructed within 1,000 feet of the psilocybin service center.

c. Psilocybin service center operators shall take steps to prevent noisy, lewd, disorderly, and disruptive conduct on the licensee's premises, and shall ensure the premises are maintained in a safe and sanitary condition.

20. (New section) Psilocybin product manufacturers, psilocybin service centers, and psilocybin service facilitators shall not advertise any psilocybin products to the public, provided that nothing in this subsection shall be construed to prohibit:

(1) a psilocybin service center from furnishing information concerning psilocybin products that are available from the psilocybin service center to patients within the interior premises of the psilocybin service center or during the course of a preparation session;

(2) a psilocybin product manufacturer from providing information concerning the manufacturer's products to psilocybin service centers and psilocybin service facilitators; or

(3) a psilocybin service center or psilocybin service facilitator from advertising psilocybin services to a health care practitioner in this State.

21. (New section) a. Each applicant for a psilocybin service facilitator license shall submit documentation proving that the applicant:

(1) is 21 years of age or older;

(2) has a high school diploma or its equivalent;

(3) has completed the education and training requirements established by the department for licensure as a psilocybin service facilitator;

(4) has successfully completed any examination as may be required by the department; and

(5) has met any other requirements for licensure established by the department.

b. In no case shall an applicant for licensure as a psilocybin service facilitator be required to hold a degree issued by an institution of higher education.

c. A psilocybin service facilitator may be an employee, manager, officer, investor, partner, member, shareholder, or direct or indirect owner of one or more psilocybin service centers.

d. A psilocybin service facilitator shall be authorized to provide psilocybin facilitation services at or through more than one psilocybin service center.

22. (New section) a. Psilocybin service centers and psilocybin service facilitators shall verify each patient's referral to receive psilocybin services and the age of each patient, prior to providing any psilocybin service to the patient or selling or furnishing a psilocybin product to the patient. Information collected for the purposes of verifying the patient's referral to receive psilocybin services and the patient's age shall not be retained by a psilocybin service center or psilocybin service facilitator, and shall not be used by the psilocybin service center or psilocybin service facilitator for any purpose other than verifying the information. In no case shall a psilocybin service center or a psilocybin service facilitator sell or furnish a psilocybin product to any person who is under 21 years of age.

b. A preparation session and an integration therapy session may be held in person at a psilocybin service center or other appropriate location, or remotely using any appropriate form of communication technology as may be authorized by the department by regulation. An administration session shall be held at a psilocybin service center.

c. A psilocybin service center or psilocybin service facilitator may refuse to provide psilocybin services to any person for any reason, provided that a psilocybin service center or psilocybin service facilitator shall not cease to provide psilocybin services during an administration session after the patient has consumed a psilocybin product, except under circumstances as may be authorized by the department and in conformance with any guidelines and best practices as the department may establish for ceasing the provision of psilocybin services during an administration session.

d. In no case shall a psilocybin service center or a psilocybin service facilitator sell or furnish a psilocybin product to any person who is visibly intoxicated.

e. A psilocybin service facilitator who is supervising an administrative session shall not consume or be under the influence of a psilocybin product during the administrative session.

f. A psilocybin service facilitator shall be responsible for:

(1) ensuring the patient completes a preparation session prior to initiating an administration session;

(2) ensuring the patient is furnished with verbal notice and a written copy of the warnings and other disclosures required by the department during the preparation session;

(3) determining whether the patient is precluded from receiving services by department rule;

(4) prior to initiating an administration session, ensuring the patient completes and signs a psilocybin services safety screening safety tool and patient information form;

(5) determining the amount of psilocybin product an individual is to consume during an administration session based on the dosage

guidelines established by the board and any of the patient's potential risk factors and contraindications;

(6) prior to initiating an administration session, ensuring the patient provides informed consent to receive psilocybin services;

(7) transmitting any completed patient information, psilocybin services safety screening tool, or informed consent forms to the psilocybin service center prior to initiating the administration session;

(8) documenting the completion of all preparation, administration, and integration therapy sessions and reporting any adverse events that may have occurred in the provision of psilocybin services;

(9) ensuring the patient completes an integration therapy session following the completion of an administration session and providing any assistance to the behavioral health care provider conducting the integration therapy session, as necessary and appropriate; and

(10) providing follow-up services to the patient within 72 hours after the patient completes an administration session.

g. Each psilocybin service center shall either employ a physician licensed in this State to serve as the center's medical director or contract with an emergency medical services provider, approved by the department, to ensure that emergency medical services are available to patients at the psilocybin service center during the center's hours of operations. A psilocybin service center medical director shall be responsible for responding to any medical emergencies within the center and shall be available during the center's hours of operation. The medical director shall not be involved in the provision of psilocybin services. Nothing in this act shall be construed to permit or authorize acts by a medical director prohibited by State and federal law.

h. Each psilocybin service center shall establish standard operating procedures for adverse event reporting, which shall include, but not be limited to:

(1) taking any necessary action to ensure the safety of the patient, including, but not limited to, contacting an emergency medical service provider or behavioral health crisis response service provider to respond to a medical or behavioral health emergency;

(2) collecting the data and information necessary to track adverse events and to investigate serious adverse events;

(3) reporting a serious adverse event to the department within 48 hours of becoming aware of the adverse event, in a manner to be determined by the department; and

(4) investigating a serious adverse event, if necessary, to determine possible causes of the adverse event.

i. To the extent possible, each psilocybin service center shall collect various outcomes data and information from patients and

psilocybin service center employees, including, but not limited to, information concerning:

(1) whether employees felt adequately trained to perform their role;

(2) whether patients met their goals of care;

(3) whether patients will be seeking any further psilocybin services;

(4) whether patients received any necessary follow-up services; and

(5) any relevant demographic information as determined by the department.

j. (1) Each psilocybin service center shall annually report to the department:

(a) the total number of patients who were provided psilocybin services during the preceding year and the number of repeat patients served, by dosage, medical condition, and the type of health care practitioner who provided the patient a referral for psilocybin services;

(b) the total number of group administration sessions provided and the average number of patients participating in each group administration session;

(c) the average cost of psilocybin services per patient;

(d) to the extent possible, demographic information about the patients who received psilocybin services, which information may include age, race, sex, socioeconomic status, and county of residence;

(e) the purposes for which patients requested psilocybin services, including the number of requests received for each type of behavioral health condition or other purpose for which psilocybin services were requested;

(f) the number of patients who completed a preparation session but not an administration session;

(g) the total number of patients who completed an integration therapy session;

(h) any adverse events involving a patient during the provision of psilocybin services;

(i) assessments of patient satisfaction with the psilocybin services provided and employee satisfaction with any training provided; and

(j) any other information concerning the provision of psilocybin services as deemed necessary by the department.

(2) The department shall make the information reported pursuant to paragraph (1) of this subsection publicly available in a deidentified and aggregate form.

(3) Nothing in this subsection shall be construed to require any psilocybin service center to disclose to the department any personal identifying information or health information about any individual patient.

23. (New section) No psilocybin service center, psilocybin service facilitator, or other employee of a psilocybin service center may disclose any information about any patient that may be used to identify the patient, any confidential health or medical information about a patient, or any communications between a patient and the psilocybin service center, psilocybin service facilitator, or employee of the psilocybin service center, unless:

a. the patient, or a person authorized to act on the patient's behalf, provides written consent authorizing the disclosure;

b. disclosure is required to prevent an imminent act that will result in serious physical harm to the patient or to any other person or to monitor patient safety;

c. disclosure is required to report an act of neglect of a minor or an act of physical, sexual, or emotional abuse of a minor;

d. as may be required by the department in the course of an investigation involving alleged violations of the provisions of this act by the psilocybin service center, psilocybin service facilitator, or employee of the psilocybin service center; or

e. the information or communication is de-identified and aggregated and used by the department for program evaluation.

24. (New section) a. A psilocybin product manufacturer may not deliver psilocybin products to any location or entity other than a psilocybin product manufacturer, psilocybin service center, or psilocybin testing laboratory. A psilocybin product manufacturer shall not receive psilocybin products from any entity other than a psilocybin product manufacturer or, as provided in paragraph (2) of subsection b. of this section, a psilocybin service center.

b. (1) Except as provided in paragraph (2) of this subsection, a psilocybin service center shall not sell, furnish, or deliver psilocybin products to any entity other than a patient, a psilocybin service center, or a psilocybin testing laboratory. A psilocybin service center shall not receive psilocybin products from any entity other than a psilocybin product manufacturer or a psilocybin service center.

(2) The department shall establish requirements concerning the return of psilocybin products by a psilocybin service center to a psilocybin product manufacturer, which requirements shall, at a minimum, identify the circumstances under which the psilocybin products may be returned, establish measures to ensure the security and integrity of returned products, and establish requirements to mitigate the risks of adulteration and diversion.

c. Psilocybin product manufacturers shall be responsible for ensuring the accurate labeling of all psilocybin products produced and distributed by the manufacturer, which labels shall accurately and comprehensively describe the contents of the product, including, as appropriate, product ingredients, allergen warnings, an expiration or sell by date if needed to ensure product safety and

efficacy, as well as anticipated activation time, potency, the size of an individual serving, the total number of servings in the packaged product, and any other information as may be required by the department by regulation. The product labeling shall include a clear statement that the product contains psilocybin, which is a psychoactive substance that can produce intoxication when consumed, that the product should be kept out of the reach of people under 21 years of age, and that the product should not be consumed except under the supervision of a psilocybin service facilitator.

d. Psilocybin products purchased by a patient from, or sold to a patient by, a psilocybin service center or psilocybin service facilitator shall be consumed by the patient on the premises of the psilocybin service center. Psilocybin products shall not be consumed by a patient except under the supervision of a psilocybin service facilitator.

e. In order to prevent diversion, accidental ingestion, and accidental injury, the department shall establish requirements for the disposal of partially consumed, unused, adulterated, expired, and mislabeled psilocybin products.

f. The department shall have the authority to waive the provisions of subsections a. and b. of this section as may be necessary to implement the provisions of this act.

25. (New section) a. The department may require a psilocybin product manufacturer to test psilocybin products before selling or transferring the psilocybin products to another psilocybin product manufacturer or to a psilocybin service center.

b. The department may conduct random testing of psilocybin products for the purpose of determining whether a licensee is in compliance with the requirements of this act.

c. The department may not require a psilocybin product to undergo the same test more than once unless the psilocybin product is processed into a different type of psilocybin product or the condition of the psilocybin product has fundamentally changed.

d. The testing of psilocybin products shall be restricted to laboratories licensed pursuant to this act.

26. (New section) a. For the purpose of tracking the manufacture and administration of psilocybin products and the transfer of psilocybin products between licensed premises, the department shall develop a system to track the manufacture and administration of psilocybin products and the transfer of psilocybin products between licensed premises.

b. In implementing the requirements of subsection a. of this section, the department shall ensure the selected tracking methodology is designed to: prevent the diversion of psilocybin products to other states; prevent the substitution of and tampering

with psilocybin products; ensure accurate accounting of the production, processing, and sale of psilocybin products; ensure that the results of laboratory tests of psilocybin products are accurately reported; and ensure compliance with the requirements of this act.

c. The tracking system implemented by the department pursuant to subsection a. of this section shall, at a minimum, be capable of tracking:

(1) the manufacture of psilocybin products;

(2) the sale of psilocybin products by a psilocybin service center operator to a patient;

(3) the sale, purchase, transfer, and delivery of psilocybin products between licensees;

(4) individual product batches that may be mislabeled, adulterated, or present health or safety risks to patients; and

(5) any other information that the department determines is reasonably necessary to implement the requirements of this act.

27. (New section) a. The department may purchase, possess, seize, transfer to a licensee, or dispose of psilocybin products as is necessary for the department to ensure compliance with, and enforce the provisions of, this act.

b. The department may, upon providing the licensee with 72 hours' notice, make an examination of the books of a licensed psilocybin product manufacturer, psilocybin service center, or psilocybin testing laboratory for the purpose of determining compliance with the requirements of this act. The department may, at any time, conduct an inspection of the premises of a licensed psilocybin product manufacturer, psilocybin service center, or psilocybin testing laboratory for the purpose of determining compliance with the requirements of this act.

c. The department shall allow, but shall not require, the books of a licensee to be maintained on the licensed premises.

d. The department may require licensees to maintain general liability insurance, in an amount the department determines is reasonably affordable and available, for the purpose of protecting the licensee against damages resulting from a cause of action related to activities authorized under the license held by the licensee.

e. The department may immediately restrict, suspend, or refuse to renew a license issued pursuant to this act if:

(1) the department finds probable cause exists that a licensee purchased or received a psilocybin product from an unlicensed source or a licensee has sold, stored, or transferred a psilocybin product in a manner that is not permitted under the license held by the licensee;

(2) the department determines that a person who has a financial interest in a licensee or an applicant for licensure pursuant to this act committed or failed to commit an act that would constitute

grounds for the department to refuse to issue, or to suspend, revoke, or refuse to renew, the license if the person with the financial interest were a licensee or applicant for licensure;

(3) the department finds the licensee made any false representation or statement to the department in the licensee's application for licensure or renewal of a license;

(4) the department finds the licensee made any false representation or statement to the department to conceal a violation of this act or to otherwise avoid disciplinary action against the licensee;

(5) in the case of a psilocybin product manufacturer or a psilocybin service center operator, the licensee is insolvent, incompetent, or physically unable to manage the operations of the licensed entity;

(6) in the case of a psilocybin product manufacturer or a psilocybin service center operator, the licensee is cited by the department three or more times within a 12-month period for selling or offering for sale mislabeled or adulterated psilocybin products, or for selling or furnishing a psilocybin product to a person who is younger than 21 years of age or who is not a patient of the licensee;

(7) following issuance of the license, the licensee is convicted of, adjudicated guilty to, or pleads guilty to a disqualifying conviction, as defined in subsection e. of section 11 of this act; or

(8) the department determines that allowing the individual to hold or retain a license issued under this act would present a risk to the public health and safety.

f. An entity whose application for renewal of a license is denied or whose license is restricted, suspended, or revoked pursuant to subsection e. of this section shall be entitled to a hearing before the department concerning the department's action. The department shall issue a final order or decision following the hearing, which final order or decision may be appealed to the Appellate Division of the Superior Court.

g. Notwithstanding the lapse, suspension, or revocation of a license or permit issued pursuant to this act, the department may:

(1) proceed with any investigation of, or any action or disciplinary proceeding against, the person who held the license or permit, as applicable; and

(2) revise or render void an order suspending or revoking the license or permit, as applicable.

h. In cases involving the proposed denial of a license or permit issued pursuant to this act, the applicant for licensure or a permit may not withdraw the licensure or permit application that is proposed for denial.

28. (New section) a. A psilocybin product manufacturer, psilocybin service center, psilocybin testing laboratory, psilocybin service facilitator, employee of a psilocybin product manufacturer,

psilocybin service center, or psilocybin testing laboratory, or a psilocybin service facilitator or patient, who engages in conduct authorized under this act shall be immune from criminal liability under chapter 35 and chapter 36 of Title 2C of the New Jersey Statutes.

b. It shall be unlawful to take any adverse employment action against an employee who receives psilocybin services pursuant to this act, unless the employee is visibly impaired while at work, and an employer may not test an employee for the presence of psilocybin in the employee's system unless the employee exhibits clear, observable symptoms of impairment.

c. Conduct permitted by this act shall not, by itself, constitute child abuse or neglect or constitute a basis to deny parenting time with a child without a finding of actual threat to the health or welfare of a child based on relevant factors.

d. Conduct permitted by this act shall not, by itself, constitute a basis to deny eligibility for any public assistance program.

e. Treatment for behavioral health, mental health, or substance use disorders, or other health care a patient is otherwise eligible to receive, shall not be denied on the basis that the care or treatment is covered in conjunction with psilocybin services or that psilocybin is prohibited by federal law.

f. No contract shall be held to be unenforceable on the basis that psilocybin is prohibited by federal law.

g. A holder of a professional or occupational license, certification, or registration shall not be subject to professional discipline or loss of a professional license or certification for providing advice or services related to psilocybin or for applications for licensure under this act.

29. (New section) a. The governing body of a county or municipality may adopt, by ordinance, reasonable regulations on the operation of psilocybin product manufacturers and psilocybin service centers located within that county or municipality.

b. No county or municipality shall be authorized to establish any taxes or fees on the manufacture or sale of psilocybin products or the provision of psilocybin services.

30. (New section) a. The department shall, by regulation:

(1) establish requirements concerning the form, manner, and fees to apply for initial and renewal licenses for psilocybin product manufacturers, psilocybin service center operators, psilocybin testing laboratories and psilocybin service facilitators, as well as the fees to apply for initial and renewed psilocybin worker permits, which fees shall not exceed the administrative costs to the department of processing licensure applications and administering the provisions of this act;

(2) establish the eligibility criteria for licensure as a psilocybin product manufacturer, psilocybin service center, psilocybin testing laboratory, and psilocybin service facilitator and for issuance of psilocybin worker permits;

(3) establish eligibility criteria to qualify for the social opportunity program established pursuant to section 14 of this act and the equitable access program established pursuant to section 15 of this act, as well as the standards and requirements for the administration of those programs;

(4) establish criteria for designating areas as distressed areas for the purposes of section 14 of this act;

(5) establish best practices for psilocybin product manufacturers, psilocybin service centers, psilocybin testing laboratories, and psilocybin service facilitators;

(6) establish health and safety standards for psilocybin product manufacturers, psilocybin service centers, psilocybin testing laboratories, and psilocybin service facilitators;

(7) establish the qualification, training, education, and fitness standards for licensure as a psilocybin service facilitator, with particular consideration of:

(a) facilitation skills that are affirming, nonjudgmental, culturally competent, and nondirective;

(b) support skills for patients during an administration session, including specialized skills for patient safety and patients who may have a behavioral health disorder;

(c) the environment in which psilocybin services should occur; and

(d) social and cultural considerations;

(8) establish the standards for approval of one or more psilocybin service facilitator training courses, which shall include:

(a) requirements for training course providers to submit to the department an outline of instruction that identifies the approved courses, the total number of hours of instruction, the number of hours of instruction in theory, and the number of hours of instruction in application of practical skills;

(b) requirements for psilocybin service facilitator training courses to be modular, thereby allowing the offer of both comprehensive training programs and partial training programs, allowing a candidate to piece together a training curriculum from among the modules offered by different training programs; and

(c) allowing the core curriculum in psilocybin service facilitator training to be completed in person or through distance education, provided that the practical portion of the curriculum is completed in person;

(9) establish or approve, a psilocybin service facilitator examination, which examination shall be offered at least twice per year;

(10) establish a code of professional conduct and a code of ethics for psilocybin service facilitators;

(11) establish requirements for the contents, completion, and retention of the psilocybin services safety screening tool and patient information forms, which forms shall:

(a) solicit the information necessary for a psilocybin service center operator and a psilocybin service facilitator to determine whether an administration session is appropriate for the patient, including information identifying patient risk factors and contraindications; and

(b) solicit the information necessary for the psilocybin service center operator and the psilocybin service facilitator to meet applicable public health and safety standards and industry best practices during the administration session;

(12) establish requirements concerning the warnings and disclosures to be furnished to patients during a preparation session;

(13) establish requirements which a health care practitioner shall be required to meet in order provide a patient with a referral for psilocybin services under this act;

(14) establish procedures to verify and document that a patient has completed a preparation session prior to initiating an administration session, as well as to document that a patient has completed an administration session and an integration therapy session;

(15) establish standards and protocols concerning the circumstances under which a psilocybin service center or psilocybin service facilitator may cease to provide psilocybin services to a patient after the patient has ingested a psilocybin product, which standards and protocols shall include mandatory procedures to be followed as are necessary to ensure the health and safety of the patient;

(16) establish requirements for licensees to maintain general liability insurance, if the department deems the maintenance of general liability insurance to be necessary and appropriate;

(17) establish requirements for labeling psilocybin products, including, as appropriate, requirements for the psilocybin product label to list all product ingredients, the source of the product, the age of the product, allergen warnings, and an expiration or sell by date if necessary to ensure the safety or efficacy of the product, as well as anticipated activation time, potency, the number of servings in the product and the size of an individual serving, and any other requirements as may be appropriate for specific types of psilocybin products;

(18) establish requirements for psilocybin product packaging, which requirements:

(a) may include different packaging requirements for different types of psilocybin products;

(b) shall seek to minimize the impact of psilocybin product packaging on the environment; and

(c) may require the psilocybin product packaging to include child-resistant safety features;

(19) in consultation with the Department of Agriculture:

(a) develop standards for testing psilocybin products;

(b) identify appropriate tests for psilocybin products, depending on the type of psilocybin product and the manner in which the psilocybin product is manufactured, including, but not limited to, tests for:

(i) microbiological contaminants;

(ii) pesticides;

(iii) other contaminants;

(iv) solvents or residual solvents; and

(v) psilocybin concentration;

(c) establishing procedures for determining batch sizes and for sampling psilocybin products; and

(d) establishing minimum quality and safety standards specific to different types of psilocybin products;

(20) establish penalties for licensees that sell or offer for sale psilocybin products that include a misleading or deceptive label, that include a label that fails to accurately describe the contents of the psilocybin product, or that are packaged in a manner that is not consistent with psilocybin product packaging requirements;

(21) establish penalties for licensees that sell or offer for sale adulterated psilocybin products, as well as protocols for identifying, tracking the source of, and removing from the marketplace, adulterated psilocybin products;

(22) establish standards for when the department will require psilocybin product manufacturers to submit proposed psilocybin product labels and proposed psilocybin product packaging to the department for approval prior to the label or packaging being put into use, as well as reasonable fees for conducting psilocybin product label and packaging approval reviews, which fees shall not exceed the cost to the department of conducting the review;

(23) establish restrictions on the maximum concentration of psilocybin that is permitted in a single serving of a psilocybin product and the maximum number of servings that is permitted in a psilocybin product package;

(24) establish requirements for reporting to the department adverse events occurring during the provisions of psilocybin services, including a description of any factors that likely contributed to the adverse event;

(25) establish procedures for tracking and investigating adverse event reports;

(26) establish requirements and restrictions concerning the advertising of psilocybin services by psilocybin service centers and psilocybin service facilitators; and

(27) establish the categories and types of data that each type of licensee will be required to collect and report to the department.

b. In adopting rules and regulations pursuant to this section, the department shall consider the cost of the proposed regulation and how it will affect the cost of psilocybin products for patients.

c. The department shall not adopt rules and regulations that are more restrictive than is reasonably necessary to protect the public health and safety.

31. (New section) Nothing in this act shall be construed to:

a. require a government medical assistance program or private health insurer to reimburse a person for costs associated with the use of psilocybin products;

b. prohibit a recipient of a federal grant or an applicant for a federal grant from prohibiting the manufacture, delivery, possession, or use of psilocybin products to the extent necessary to satisfy federal requirements for the grant;

c. prohibit a party to a federal contract or a person applying to be a party to a federal contract from prohibiting the manufacture, delivery, possession, or use of psilocybin products to the extent necessary to comply with the terms and conditions of the contract or to satisfy federal requirements for the contract;

d. obstruct the enforcement of federal law; or

e. deem psilocybin services to constitute a medical diagnosis or medical treatment.

32. (New section) a. No later than 18 months after the effective date of this act, the Psilocybin Behavioral Health Services Advisory Board shall prepare and submit a report to the Department of Health, the Governor, and, pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1), the Legislature, outlining its findings and recommendations to the department concerning the implementation of this act.

b. Commencing one year after the end of the 18-month program development period, and annually thereafter, the Commissioner of Health shall prepare, submit to the Governor and, pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1), the Legislature, and make available on the Internet website of the Department of Health, a report concerning the department's implementation and administration of this act. The report shall include, at a minimum: the total number of psilocybin product manufacturer, psilocybin service center, psilocybin testing laboratory, and psilocybin service facilitator licenses and the total number of psilocybin worker permits issued pursuant to this act, to the extent possible, by region, county, age, race, sex, and socioeconomic status; the total number of psilocybin facilitator training programs approved; the total number of patients served during the preceding one-year period and the number of those

patients who previously received psilocybin services; the purposes for which patients requested psilocybin services, including the types of behavioral health conditions and the nature of any other purposes for which psilocybin services were requested; any adverse events reported during the preceding one-year period; the number of psilocybin products tested during the preceding one-year period; any incidents during the preceding one-year period involving, and any disciplinary actions taken in response to, the sale, distribution, or administration of adulterated, mislabeled, or deceptively labeled psilocybin products; recommendations for legislation or other action related to the implementation or administration of this act; and any other information or recommendations as the commissioner deems necessary and appropriate.

33. (New section) A professional counselor licensed pursuant to Title 45 of the Revised Statutes may refer patients for psilocybin services pursuant to P.L. , c. (C.) (pending before the Legislature as this bill) provided that the professional counselor complies with the requirements for referring patients for psilocybin services established pursuant to P.L. , c. (C.) (pending before the Legislature as this bill).

34. (New section) A physician licensed pursuant to Title 45 of the Revised Statutes may refer patients for psilocybin services pursuant to P.L. , c. (C.) (pending before the Legislature as this bill) provided that the physician complies with the requirements for referring patients for psilocybin services established pursuant to P.L. , c. (C.) (pending before the Legislature as this bill).

35. Section 7 of P.L.1991, c.378 (C.45:9-27.16) is amended to read as follows:

7. a. A physician assistant may perform the following procedures:

(1) Approaching a patient to elicit a detailed and accurate history, perform an appropriate physical examination, identify problems, record information, and interpret and present information to the supervising physician;

(2) Suturing and caring for wounds including removing sutures and clips and changing dressings, except for facial wounds, traumatic wounds requiring suturing in layers, and infected wounds;

(3) Providing patient counseling services and patient education consistent with directions of the supervising physician;

(4) Assisting a physician in an inpatient setting by conducting patient rounds, recording patient progress notes, determining and implementing therapeutic plans jointly with the supervising physician, and compiling and recording pertinent narrative case summaries;

(5) Assisting a physician in the delivery of services to patients requiring continuing care in a private home, nursing home, extended care facility, or other setting, including the review and monitoring of treatment and therapy plans; and (6) Referring patients to, and promoting their awareness of, health care facilities and other appropriate agencies and resources in the community.

(7) (Deleted by amendment, P.L.2015, c.224)

b. A physician assistant may perform the following procedures only when directed, ordered, or prescribed by the supervising physician, or when performance of the procedure is delegated to the physician assistant by the supervising physician as authorized under subsection d. of this section:

(1) Performing non-invasive laboratory procedures and related studies or assisting duly licensed personnel in the performance of invasive laboratory procedures and related studies;

(2) Giving injections, administering medications, and requesting diagnostic studies;

(3) Suturing and caring for facial wounds, traumatic wounds requiring suturing in layers, and infected wounds;

(4) Writing prescriptions or ordering medications in an inpatient or outpatient setting in accordance with section 10 of P.L.1991, c.378 (C.45:9-27.19);

(5) Prescribing the use of patient restraints; **[**and**]**

(6) Authorizing qualifying patients for the medical use of cannabis and issuing written instructions for medical cannabis to registered qualifying patients pursuant to P.L.2009, c.307 (C.24:6I-1 et al.)<u>; and</u>

<u>(7) Referring patients for psilocybin services pursuant to P.L. , c. (C.) (pending before the Legislature as this bill)</u>.

c. A physician assistant may assist a supervising surgeon in the operating room when a qualified assistant physician is not required by the board and a second assistant is deemed necessary by the supervising surgeon.

d. A physician assistant may perform medical services beyond those explicitly authorized in this section, when such services are delegated by a supervising physician with whom the physician assistant has signed a delegation agreement pursuant to section 8 of P.L.1991, c.378 (C.45:9-27.17). The procedures delegated to a physician assistant shall be limited to those customary to the supervising physician's specialty and within the supervising physician's and the physician assistant's competence and training.

e. Notwithstanding subsection d. of this section, a physician assistant shall not be authorized to measure the powers or range of human vision, determine the accommodation and refractive states of the human eye, or fit, prescribe, or adapt lenses, prisms, or frames for the aid thereof. Nothing in this subsection shall be construed to prohibit a physician assistant from performing a routine visual

screening.
(cf: P.L.2019, c.153, s.45)

36. Section 10 of P.L.1991, c.378 (C.45:9-27.19) is amended to read as follows:

10. A physician assistant may order, prescribe, dispense, and administer medications and medical devices **[**and**]**, issue written instructions to registered qualifying patients for medical cannabis, and refer patients for psilocybin services to the extent delegated by a supervising physician.

a. Controlled dangerous substances may only be ordered or prescribed if:

(1) a supervising physician has authorized a physician assistant to order or prescribe Schedule II, III, IV, or V controlled dangerous substances in order to:

(a) continue or reissue an order or prescription for a controlled dangerous substance issued by the supervising physician;

(b) otherwise adjust the dosage of an order or prescription for a controlled dangerous substance originally ordered or prescribed by the supervising physician, provided there is prior consultation with the supervising physician;

(c) initiate an order or prescription for a controlled dangerous substance for a patient, provided there is prior consultation with the supervising physician if the order or prescription is not pursuant to subparagraph (d) of this paragraph; or

(d) initiate an order or prescription for a controlled dangerous substance as part of a treatment plan for a patient with a terminal illness, which for the purposes of this subparagraph means a medical condition that results in a patient's life expectancy being 12 months or less as determined by the supervising physician;

(2) the physician assistant has registered with, and obtained authorization to order or prescribe controlled dangerous substances from, the federal Drug Enforcement Administration and any other appropriate State and federal agencies; and

(3) the physician assistant complies with all requirements which the board shall establish by regulation for the ordering, prescription, or administration of controlled dangerous substances, all applicable educational program requirements, and continuing professional education programs approved pursuant to section 16 of P.L.1991, c.378 (C.45:9-27.25).

b. (Deleted by amendment, P.L.2015, c.224)

c. (Deleted by amendment, P.L.2015, c.224)

d. In the case of an order or prescription for a controlled dangerous substance or written instructions for medical cannabis, the physician assistant shall print on the order or prescription or the written instructions the physician assistant's Drug Enforcement Administration registration number.

e. The dispensing of medication or a medical device by a physician assistant shall comply with relevant federal and State regulations, and shall occur only if: (1) pharmacy services are not reasonably available; (2) it is in the best interest of the patient; or (3) the physician assistant is rendering emergency medical assistance.

f. A physician assistant may request, receive, and sign for prescription drug samples and may distribute those samples to patients.

g. A physician assistant may issue written instructions to a registered qualifying patient for medical cannabis pursuant to section 10 of P.L.2009, c.307 (C.24:6I-10) only if:

(1) a supervising physician has authorized the physician assistant to issue written instructions to registered qualifying patients;

(2) the physician assistant verifies the patient's status as a registered qualifying patient; and

(3) the physician assistant complies with the requirements for issuing written instructions for medical cannabis established pursuant to P.L.2009, c.307 (C.24:6I-1 et al.).

h. A physician assistant may provide referrals to a patient for psilocybin services pursuant to section 9 of P.L. , c. (C.) (pending before the Legislature as this bill) only if:

(1) a supervising physician has authorized the physician assistant to provide referrals to patients; and

(2) the physician assistant complies with the requirements for referring patients for psilocybin services established pursuant to P.L. , c. (C.) (pending before the Legislature as this bill).

(cf: P.L.2019, c.153, s.46)

37. Section 10 of P.L.1991, c.377 (C.45:11-49) is amended to read as follows:

10. a. In addition to all other tasks which a registered professional nurse may, by law, perform, an advanced practice nurse may manage preventive care services and diagnose and manage deviations from wellness and long-term illnesses, consistent with the needs of the patient and within the scope of practice of the advanced practice nurse, by:

(1) initiating laboratory and other diagnostic tests;

(2) prescribing or ordering medications and devices, as authorized by subsections b. and c. of this section; and

(3) prescribing or ordering treatments, including referrals to other licensed health care professionals, and performing specific procedures in accordance with the provisions of this subsection.

b. An advanced practice nurse may order medications and devices in the inpatient setting, subject to the following conditions:

(1) the collaborating physician and advanced practice nurse shall address in the joint protocols whether prior consultation with

the collaborating physician is required to initiate an order for a controlled dangerous substance;

(2) the order is written in accordance with standing orders or joint protocols developed in agreement between a collaborating physician and the advanced practice nurse, or pursuant to the specific direction of a physician;

(3) the advanced practice nurse authorizes the order by signing the nurse's own name, printing the name and certification number, and printing the collaborating physician's name;

(4) the physician is present or readily available through electronic communications;

(5) the charts and records of the patients treated by the advanced practice nurse are reviewed by the collaborating physician and the advanced practice nurse within the period of time specified by rules adopted by the Commissioner of Health pursuant to section 14 of P.L.1991, c.377 (C.45:11-52);

(6) the joint protocols developed by the collaborating physician and the advanced practice nurse are reviewed, updated, and signed at least annually by both parties; and

(7) the advanced practice nurse has completed six contact hours of continuing professional education in pharmacology related to controlled substances, including pharmacologic therapy, addiction prevention and management, and issues concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion, in accordance with regulations adopted by the New Jersey Board of Nursing. The six contact hours shall be in addition to New Jersey Board of Nursing pharmacology education requirements for advanced practice nurses related to initial certification and recertification of an advanced practice nurse as set forth in N.J.A.C.13:37-7.2.

c. An advanced practice nurse may prescribe medications and devices in all other medically appropriate settings, subject to the following conditions:

(1) the collaborating physician and advanced practice nurse shall address in the joint protocols whether prior consultation with the collaborating physician is required to initiate a prescription for a controlled dangerous substance;

(2) the prescription is written in accordance with standing orders or joint protocols developed in agreement between a collaborating physician and the advanced practice nurse, or pursuant to the specific direction of a physician;

(3) the advanced practice nurse writes the prescription on a New Jersey Prescription Blank pursuant to P.L.2003, c.280 (C.45:14-40 et seq.), signs the nurse's own name to the prescription and prints the nurse's name and certification number;

(4) the prescription is dated and includes the name of the patient and the name, address, and telephone number of the collaborating physician;

(5) the physician is present or readily available through electronic communications;

(6) the charts and records of the patients treated by the advanced practice nurse are periodically reviewed by the collaborating physician and the advanced practice nurse;

(7) the joint protocols developed by the collaborating physician and the advanced practice nurse are reviewed, updated, and signed at least annually by both parties; and

(8) the advanced practice nurse has completed six contact hours of continuing professional education in pharmacology related to controlled substances, including pharmacologic therapy, addiction prevention and management, and issues concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion, in accordance with regulations adopted by the New Jersey Board of Nursing. The six contact hours shall be in addition to New Jersey Board of Nursing pharmacology education requirements for advanced practice nurses related to initial certification and recertification of an advanced practice nurse as set forth in N.J.A.C.13:37-7.2.

d. The joint protocols employed pursuant to subsections b. and c. of this section shall conform with standards adopted by the Director of the Division of Consumer Affairs pursuant to section 12 of P.L.1991, c.377 (C.45:11-51) or section 10 of P.L.1999, c.85 (C.45:11-49.2), as applicable.

e. (Deleted by amendment, P.L.2004, c.122.)

f. An attending advanced practice nurse may determine and certify the cause of death of the nurse's patient and execute the death certification pursuant to R.S.26:6-8 if no collaborating physician is available to do so and the nurse is the patient's primary caregiver.

g. An advanced practice nurse may authorize qualifying patients for the medical use of cannabis and issue written instructions for medical cannabis to registered qualifying patients, subject to the following conditions:

(1) the collaborating physician and advanced practice nurse shall address in the joint protocols whether prior consultation with the collaborating physician is required to authorize a qualifying patient for the medical use of cannabis or issue written instructions for medical cannabis;

(2) the authorization for the medical use of cannabis or issuance of written instructions for cannabis is in accordance with standing orders or joint protocols developed in agreement between a collaborating physician and the advanced practice nurse, or pursuant to the specific direction of a physician;

(3) the advanced practice nurse signs the nurse's own name to the authorization or written instruction and prints the nurse's name and certification number;

(4) the authorization or written instruction is dated and includes the name of the qualifying patient and the name, address, and telephone number of the collaborating physician;

(5) the physician is present or readily available through electronic communications;

(6) the charts and records of qualifying patients treated by the advanced practice nurse are periodically reviewed by the collaborating physician and the advanced practice nurse;

(7) the joint protocols developed by the collaborating physician and the advanced practice nurse are reviewed, updated, and signed at least annually by both parties; and

(8) the advanced practice nurse complies with the requirements for authorizing qualifying patients for the medical use of cannabis and for issuing written instructions for medical cannabis established pursuant to P.L.2009, c.307 (C.24:6I-1 et al.).

h. An advanced practice nurse may provide referrals to patients for psilocybin services, subject to the following conditions:

(1) the collaborating physician and advanced practice nurse shall address in the joint protocols whether prior consultation with the collaborating physician is required to refer a patient for psilocybin services;

(2) the referral for psilocybin services is in accordance with standing orders or joint protocols developed in agreement between a collaborating physician and the advanced practice nurse, or pursuant to the specific direction of a physician;

(3) the advanced practice nurse signs the nurse's own name to the referral and prints the nurse's name and certification number;

(4) the referral is dated and includes the name of the patient and the name, address, and telephone number of the collaborating physician;

(5) the physician is present or readily available through electronic communications;

(6) the charts and records of patients treated by the advanced practice nurse are periodically reviewed by the collaborating physician and the advanced practice nurse;

(7) the joint protocols developed by the collaborating physician and the advanced practice nurse are reviewed, updated, and signed at least annually by both parties; and

(8) the advanced practice nurse complies with the requirements for referring patients for psilocybin services established pursuant to P.L. , c. (C.) (pending before the Legislature as this bill).

(cf: P.L.2019, c.153, s.47)

38. (New section) A psychologist licensed pursuant to Title 45 of the Revised Statutes may refer patients for psilocybin services

pursuant to P.L. , c. (C.) (pending before the Legislature as this bill) provided that the psychologist complies with the requirements for referring patients for psilocybin services established pursuant to P.L. , c. (C.) (pending before the Legislature as this bill).

39. (New section) A clinical social worker licensed pursuant to Title 45 of the Revised Statutes may refer patients for psilocybin services pursuant to P.L. , c. (C.) (pending before the Legislature as this bill) provided that the clinical social worker complies with the requirements for referring patients for psilocybin services established pursuant to P.L. , c. (C.) (pending before the Legislature as this bill).

40. This act shall take effect the first day of the fourth month next following the date of enactment, except that the Governor and the Commissioner of Health may take any anticipatory administrative action in advance as shall be necessary for the implementation of this act.`