SENATE, No. 2283

STATE OF NEW JERSEY

221st LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2024 SESSION

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

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SYNOPSIS

"Psilocybin Behavioral Health Access and Services Act"; authorizes production and use of psilocybin to promote health and wellness; decriminalizes, and expunges past offenses involving, psilocybin production, possession, use, and distribution.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.

(Sponsorship Updated As Of: 6/3/2024)

AN ACT concerning the production and use of psilocybin for certain purposes, decriminalizing and expunging past convictions for certain psilocybin-related conduct, and supplementing Title 24 of the Revised Statutes and Title 2C of the New Jersey Statutes.

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

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

2. 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, 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. 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 client 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.

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

“Client” means an individual 21 years of age or older who is provided psilocybin services in this State.

“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.

“Integration session” means the optional meeting between a client and a psilocybin service facilitator that may occur after the client completes an administration session.

“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.

"Preparation session" means an in-person or remote meeting between a client and a psilocybin service facilitator that is required as a prerequisite to an administration session.

"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 client before, during, and after the client's consumption of a psilocybin product, including the mandatory preparation session, the administration session, and the optional integration session.

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

b. The board shall comprise 18 members, as follows:

(1) the Commissioner of Health, the Deputy Commissioner for Public Health Services, 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;

(3) a representative from the Cannabis Regulatory Commission who has expertise in the tracking of cannabis items, who shall serve at the pleasure of the commission as a nonvoting member; and

(4) 12 public members, to be appointed by the Governor, which members shall include:

(a) a person with expertise in clinical dependence;

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

(c) 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;

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

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

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

(g) a professional mycologist, a person with expertise in ethnobotany, or a person with expertise in psychopharmacology;

(h) a person with experience with issues confronting veterans;

(i) a person with expertise in the traditional, cultural, and religious uses of psilocybin;

(j) a first responder with experience and expertise with emergency medical services;

(k) a person with experience with harm reduction and drug policy; and

(l) a person with experience with racial and economic equity and 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. 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 its 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 to promote community, address trauma, and enhance physical and mental wellness;

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

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

(b) the contents of the client information form that a client will be required to complete and sign before the client will be authorized to participate in an administration session, including:

(i) the information that should be solicited from the client to determine whether the client 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 client 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 client before the client participates in the administration session; and

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

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

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

(4) public health and safety standards and industry best practices for psilocybin product manufacturers, psilocybin service centers, psilocybin testing facilities, and psilocybin service facilitators;

(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 clients during an administration session, including training in specialized skills for client safety and clients 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 clients 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 client 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 client, along with appropriate procedures to ensure the safety of the client 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) standards for when in-home administration sessions may be permitted, as well as protocols, guidelines, and best practices for conducting in-home administration sessions;

(12) establishing a new tracking system for psilocybin products or using the cannabis tracking system established pursuant to section 29 of P.L.2019, c.153 (C.24:6I-22) to track psilocybin products;

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

(14) requirements for the social opportunity program established pursuant to section 11 of this act that promote social equity and accessibility;

(15) 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; 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;

(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. 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 additional 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 not require a client to be diagnosed with or have any particular medical or mental health condition as a prerequisite to being provided psilocybin services.

d. If recommended by the advisory board, the department may exclude individuals, or categories of individuals, from receiving psilocybin services, which exclusion may be based on preexisting diagnoses, identified risk factors, or contraindications.

e. 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.

f. No later than six 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.

g. No later than 18 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. 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.

8. 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 or psilocybin 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.), P.L.2021, c.16 (C.24:6I-31 et al.), or P.L. , c. (C.) (pending before the Legislature as this bill).

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.

9. 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.

10. 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.

11. 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.

e. The department shall establish and administer an equitable access program to assist qualified economically disadvantaged individuals with the cost of receiving psilocybin services.

12. 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.

b. 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.

13. 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 or approved by the department as a condition of issuance of the permit, which course may include training in:

(1) verifying client ages;

(2) detecting signs of client intoxication;

(3) safe and sanitary handling of psilocybin products;

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

(5) confidentiality requirements;

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

(7) 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.

14. 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.

15. 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 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 department determines that there is a physical or geographic barrier capable of preventing children from traversing the premises of the psilocybin service center.

(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.

16. a. Psilocybin product manufacturers and psilocybin service centers shall not advertise any psilocybin products to the public,

provided that nothing in this paragraph 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 clients within the interior premises of the psilocybin service center or during the course of a preparation session; or

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

b. Psilocybin service centers and psilocybin service facilitators may advertise psilocybin services, provided such advertisements do not:

(1) appeal to minors;

(2) promote excessive use of psilocybin;

(3) promote illegal activity;

(4) violate the code of professional conduct for psilocybin service facilitators; or

(5) otherwise present a significant risk to public health and safety.

17. 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.

18. a. Psilocybin service centers and psilocybin service facilitators shall verify the age of a client prior to providing any psilocybin service to the client or selling or furnishing a psilocybin product to the client. Information collected for the purposes of verifying a client is 21 years of age or older 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 client's age.

b. (1) A preparation session and an integration 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.

(2) Except as provided in paragraph (3) of this section, an administration session shall be held at a psilocybin service center.

(3) A psilocybin service facilitator shall be authorized to provide psilocybin services in a private residence if, for medical reasons, the client is unable to travel to the psilocybin service center. The psilocybin service center shall document the basis upon which an in-home administration session is authorized pursuant to this paragraph. In no case shall in-home psilocybin services be provided to a client who is located outside New Jersey.

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 client 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 client completes a preparation session prior to initiating an administration session;

(2) ensuring the client 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 client is precluded from receiving services by department rule;

(4) prior to initiating an administration session, ensuring the client completes and signs a client information form;

(5) transmitting completed client information forms to the psilocybin service center prior to initiating the administration session;

(6) documenting the completion of all preparation, administration, and integration sessions, as well as the provision of all required warnings and disclosures to the client; and

(7) ensuring the client is offered the opportunity to participate in an integration session following completion of an administration session.

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

(a) the total number of clients who were provided psilocybin services during the preceding year, including the number of repeat clients served;

(b) the purposes for which clients 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;

(c) the number of clients who completed a preparation session but not an administration session;

(d) the total number of clients who elected to complete an integration session;

(e) the total number of in-house administration sessions performed;

(f) any adverse events involving a client during an administration session; and

(g) assessments of client satisfaction with the psilocybin services provided.

(2) The department shall make the information reported pursuant to paragraph (1) of this section publicly available, provided that nothing in this paragraph shall be construed to authorize the disclosure by the department of any personal identifying information or health information about any individual client.

(3) Nothing in paragraph (1) of 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 client.

19. No psilocybin service center, psilocybin service facilitator, or other employee of a psilocybin service center may disclose any information about any client that may be used to identify the client, any confidential health or medical information about a client, or any communications between a client and the psilocybin service center, psilocybin service facilitator, or employee of the psilocybin service center, unless:

a. the client, or a person authorized to act on the client'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 client or to any other person;

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; or

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.

20. 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 client, 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 client from, or sold to a client by, a psilocybin service center or psilocybin service facilitator shall be consumed by the client on the premises of the psilocybin service center, except in the case of a home visit authorized pursuant to paragraph (3) of subsection b. of section 18 of this act, in which case the psilocybin product shall be consumed by the client at the location in which the administration session is held, and the psilocybin service facilitator returns any unconsumed

portion of the psilocybin product to the psilocybin service center. Psilocybin products shall not be consumed by a client 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.

21. 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.

22. 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 either:

(1) develop a system to track the manufacture and administration of psilocybin products and the transfer of psilocybin products between licensed premises; or

(2) enter into an agreement with the Cannabis Regulatory Commission authorizing the department to use the system developed and maintained pursuant to section 29 of P.L.2019, c.153 (C.24:6I-22) 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 client;

(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 clients; and

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

23. 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 client 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 8 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.

24. 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 client, 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 client 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.

25. 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.

26. a. The department shall establish, by regulation:

(1) 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) 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) eligibility criteria to qualify for the social opportunity program established pursuant to section 11 of this act, as well as the standards and requirements for administration of the social opportunity program;

(4) criteria for designating areas as distressed areas for the purposes of section 11 of this act;

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

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

(7) 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 clients during an administration session, including specialized skills for client safety and clients who may have a behavioral health disorder;

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

(d) social and cultural considerations;

(8) establishing 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) establishing or approving a psilocybin service facilitator examination, which examination shall be offered at least twice per year;

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

(11) requirements for the contents, completion, and retention of client 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 client, including information identifying client 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) requirements concerning the warnings and disclosures to be furnished to clients during a preparation session;

(13) procedures to verify and document that a client has completed a preparation session prior to initiating an administration session, as well as to document that a client has completed an administration session and, if applicable, a integration session;

(14) standards and protocols concerning the circumstances under which a psilocybin service center or psilocybin service facilitator may cease to provide psilocybin services to a client after the client 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 client;

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

(16) 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;

(17) 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;

(18) in consultation with the Cannabis Regulatory Commission and the Department of Agriculture:

(a) developing standards for testing psilocybin products;

(b) identifying 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;

(19) 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;

(20) 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;

(21) 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;

(22) 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;

(23) the criteria for determining whether a client qualifies for an in-home administration session pursuant to paragraph (3) of subsection b. of section 18 of this act, and the procedures, requirements, and best practices for in-home administration sessions;

(24) requirements for reporting to the department adverse events occurring during an administration session, including a description of any factors that likely contributed to the adverse event;

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

(26) 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 clients.

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

27. 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.

28. 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; the total number of psilocybin facilitator training programs approved; the total number of clients served during the preceding one-year period and the number of those clients who previously received psilocybin services; the purposes for which clients requested psilocybin services, including the types of behavioral health conditions and the nature of any other purposes for which psilocybin services were requested; the number of in-home administration sessions provided during the preceding one-year period; 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.

29. a. Except as otherwise provided in this act, the acts enumerated in subsection b. of this section shall not:

(1) be deemed unlawful or considered an offense under State law or the laws of any county or municipal governing body;

(2) constitute the basis to assess against any person a civil penalty, a civil sanction, or professional or administrative discipline;

(3) constitute the basis for detention, search, or arrest of any person; or

(4) constitute the basis to deny a person any right or privilege, or to seize or forfeit the assets of any person under State law or the laws of any county or municipal governing body, provided the person is at least 21 years of age.

b. (1) Possessing, storing, using, ingesting, inhaling, processing, transporting, delivering without consideration, or distributing without consideration four grams or less of psilocybin.

(2) Growing, cultivating, or processing plants or fungi capable of producing psilocybin for personal use and possessing the psilocybin produced if the plants and fungi are kept on the grounds of a private home or residence and are kept secure from access by persons under 21 years of age.

(3) Assisting another person who is 21 years of age or older, or allowing property to be used, in the course of engaging in any of the actions or conduct permitted under paragraphs (1) or (2) of this subsection.

30. a. A person currently serving a sentence for a conviction, whether by trial or by plea of guilty or nolo contendere, who would not have been guilty of the offense or who would have been guilty of a lesser offense under this act had it been in effect at the time of the offense, may file a petition for resentencing, reversal of conviction and dismissal of case, or modification of judgment and sentence before the trial court that entered the judgment of conviction in the person's case to request resentencing, modification, or reversal in accordance with this act.

b. Upon receiving a petition submitted pursuant to subsection a. of this section, the court shall presume the petitioner satisfies the criteria in subsection a. of this section and shall, without delay, resentence, reverse the conviction as legally invalid, or modify the judgment and sentence, unless the State opposes the petition or alleges that granting the petition would pose an unreasonable risk of danger to an identifiable individual's safety.

c. In the event that the State opposes a petition submitted pursuant to subsection a. of this section or alleges that granting the petition would pose an unreasonable risk of danger to an identifiable individual's safety, the petitioner shall be entitled to a hearing on the record, including the opportunity to question witnesses and present evidence supporting the granting of an order

for resentencing, reversal and dismissal, or modification of the judgment and sentence. The State shall bear the burden of proving, by clear and convincing evidence, that the petitioner does not satisfy the criteria in subsection a. of this section or that granting the petition would pose an unreasonable risk of danger to an identifiable individual if alleged. Unless the State sustains its burden, the court shall resentence, reverse the conviction as legally invalid and dismiss the case, or modify the judgment and sentence. Any outstanding fines, court costs, and fees imposed in connection with the conviction at issue shall be waived.

d. Any person brought before the court upon an application to revoke a suspended sentence for a conviction that would not have been an offense or would have been a lesser offense had this act been in effect at the time of the offense shall have the person's sentence vacated or modified in accordance with the provisions of this act. Any person brought before the court upon an application to accelerate a deferred sentence for charges that would not have been an offense or would have been a lesser offense had this act been in effect at the time of the offense shall have the charges brought against the person vacated or modified in accordance with the provisions of this act. Any outstanding fines, court costs, and fees imposed in connection with the conviction at issue shall be waived.

e. Under no circumstance shall a resentencing, reversal and dismissal, modification, revocation, or acceleration granted pursuant to this section result in the imposition of a supervision or imprisonment term longer than the original sentence, or the reinstatement of charges dismissed pursuant to a negotiated plea agreement, or require the payment of any additional fines or fees beyond those authorized by this act.

f. A person who has completed a sentence for a conviction, whether by trial or plea of guilty or nolo contendere, who would not have been guilty of the offense or who would have been guilty of a lesser offense under this act had it been in effect at the time of the offense, may file a petition before the trial court that entered the judgment of conviction in the person's case to have the conviction dismissed, expunged, and vacated as legally invalid or redesignated as a civil infraction in accordance with this act.

g. The court shall presume that an applicant who submits a petition pursuant to subsection f. of this section satisfies the criteria in subsection f. of this section unless the State opposes the application and proves by clear and convincing evidence that the petitioner does not satisfy the criteria in subsection f. of this section. If the petitioner satisfies the criteria in subsection f. of this section, the court shall redesignate the conviction as a civil infraction or dismiss, expunge, and vacate the conviction as legally invalid in accordance with this act. Any outstanding fines, court costs, and fees imposed in connection with the conviction at issue shall be waived.

h. Unless requested by the applicant, no hearing is necessary to grant or deny an application filed under subsection f. of this section.

i. Any conviction for a crime or criminal offense that is modified, resentenced, or redesignated as a civil infraction pursuant to subsection a., subsection d., or subsection f. of this section shall be considered a civil infraction for all purposes.

j. If the court that originally sentenced the petitioner is not available, the presiding judge shall designate another judge to rule on the petition or application.

k. Nothing in this section shall be construed to diminish or abrogate any rights or remedies otherwise available to the petitioner or applicant who submits a petition pursuant to this section.

l. The provisions of this section shall apply equally to juvenile cases if the juvenile would have been guilty of a lesser offense under this act.

31. 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.

STATEMENT

This bill, designated the "Psilocybin Behavioral Health Access and Services Act," establishes a framework for the regulated production and use of psilocybin in connection with behavioral health care and preventative behavioral health treatment, decriminalizes the production, dispensing, and use of psilocybin by persons over 21 years of age, and expunges past and pending offenses for conduct involving psilocybin that is authorized under the bill.

<u>Psilocybin Behavioral Health Access and Services Advisory Board</u>

The bill establishes in the Department of Health (DOH) the Psilocybin Behavioral Health Access and Services Advisory Board. The board will comprise 18 members, including:

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

2) a representative from the DOH 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 will serve at the pleasure of the commissioner as nonvoting members;

3) a representative from the Cannabis Regulatory Commission who has expertise in the tracking of cannabis items, who will serve at the pleasure of the commission as a nonvoting member; and

4) 12 public members, to be appointed by the Governor, which members are to include individuals with expertise in areas related to behavioral health care; public health; clinical research related to the use of psychedelic compounds in clinical therapy; mycology, ethnobotany, or psychopharmacology; issues confronting veterans; the traditional, cultural, and religious uses of psilocybin; emergency medical services; harm reduction and drug policy; and racial and economic equity and health care access.

The public members of the board will serve for a term of four years, with staggered terms of appointment for the members first appointed, and will be eligible for reappointment. The Governor will be required to appoint the public members no later than 60 days after the effective date of the bill. The board will organize upon the appointment of the public members and select a chairperson and a vice-chairperson from among the membership. The chairperson will appoint a secretary, who need not be a member of the board. The members of the board will 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.

During an 18-month program development period established under the bill, the board will be required to 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 will meet at least quarterly at a time and place designated by the chairperson. The board will additionally meet at any time at the call of the chairperson or at the call of a majority of the public members. The board will be authorized to establish committees and subcommittees as are necessary for the board's operation.

The purpose of the board will be to provide advice and recommendations to the DOH, upon request or upon the board's own initiative, concerning the implementation of the bill, including providing recommendations to the department concerning:

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

2) available studies and research concerning the safety of psilocybin and its efficacy in ameliorating behavioral health conditions, as well as the potential for psilocybin to promote community, address trauma, and enhance physical and mental wellness;

3) the requirements, specifications, and guidelines for providing psilocybin services to a client, including requirements specific to documenting services, screening clients for potential health or safety issues, and providing clients with certain information;

4) public health and safety standards and industry best practices for psilocybin businesses and psilocybin service facilitators;

5) the formulation of a code of professional conduct for psilocybin service facilitators;

6) the education and training requirements for psilocybin service facilitators;

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 a psilocybin administration session, including;

9) the qualification criteria and amount to be charged in license application and issuance fees;

10) requirements and restrictions for advertising psilocybin services;

11) standards, protocols, and best practices for in-home psilocybin administration sessions;

12) requirements for tracking psilocybin products;

13) requirements concerning the transportation and delivery of psilocybin products between psilocybin businesses;

14) requirements for the social opportunity program established under the bill to promote social equity and accessibility;

15) development of a long-term strategic plan for ensuring that psilocybin services are a safe, accessible, and affordable wellness option; and

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

The board will vote upon and submit recommendations to the DOH according to a schedule agreed upon by the DOH. Advice and recommendations are to be made in consideration of federal laws, regulations, and policies concerning psilocybin.

No later than 18 months after the effective date of this act, the board will be required to prepare and submit a report to the DOH, the Governor, and the Legislature, outlining its findings and recommendations concerning the implementation of the bill.

<u>Psilocybin Licensure Requirements</u>

An applicant for an initial or renewed license or permit related to psilocybin will be required to submit the application in a form and manner specified by the DOH. In the case of an applicant for issuance or renewal of a psilocybin product manufacturer license, psilocybin service center operator license, or psilocybin testing laboratory license, the application is to identify the proposed location of the premises that is to be operated under the license.

The DOH will promptly review and approve or deny any application for licensure or issuance of a permit. The DOH may reject an application that is not submitted in a form and manner

required by the department. An applicant whose application is rejected will not be prohibited from submitting subsequent applications for licensure or a permit, or for renewal of a license or permit. No psilocybin license or permit may be issued to any applicant who is younger than 21 years of age.

The DOH 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: has not completed the requirements for the license or permit; made false statements to the DOH; in the case of a psilocybin manufacturer, service center, or testing permit, demonstrates a lack of capacity or incompetency to carry on the management of the facility that is the subject of the application; 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; has an unsatisfactory record of compliance with the requirements of the bill; 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 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 and, 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 psilocybin; 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 for other good cause as determined by the DOH.

The application and issuance fees may not exceed the administrative costs to the DOH of processing the application and administering the provisions of the bill. A license or permit issued under the bill will be valid for one year. The DOH will be prohibited from issuing 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.

Each applicant for a license or permit issued under the bill will be required to undergo a criminal history record background check. The applicant will bear the cost of the criminal history record background check. The DOH may not approve an applicant for a license or permit under the bill if the criminal history record background information of the applicant reveals a disqualifying conviction for a crime of the first, second, or third degree involving certain offenses involving the production, distribution, or possession of controlled dangerous substances, other than certain

offenses involving cannabis or psilocybin. The DOH may offer provisional authority for an applicant to be issued a license or permit under the bill, for a period not to exceed three months, if the applicant submits to the DOH a sworn statement attesting that the applicant has not been convicted of any disqualifying conviction. The Division of State Police will be required to notify the DOH if any person required to complete a criminal history background check under the bill is subsequently convicted of a disqualifying conviction.

Under the bill, an applicant for a license or permit who has a disqualifying conviction may still be issued a license or permit if the applicant has affirmatively demonstrated to the DOH clear and convincing evidence of rehabilitation.

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

The DOH 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 DOH 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.

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 more than one psilocybin product manufacturer or more than five psilocybin service centers. The DOH 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.

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

1) the DOH finds probable cause exists that a licensee purchased or received a psilocybin product from an unlicensed source or sold, stored, or transferred a psilocybin product in an unauthorized manner;

2) the DOH determines that a person who has a financial interest in a licensee or an applicant for licensure committed or failed to commit an act that disqualifies the individual for licensure;

3) the DOH finds the licensee made any false representation or statement in the licensee's application for licensure or renewal;

4) the DOH finds the licensee made any false representation or statement to the DOH to conceal a violation of the bill 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 client of the licensee;

7) following issuance of the license, the licensee is convicted of, adjudicated guilty to, or pleads guilty to a disqualifying conviction; or

8) the DOH determines that allowing the individual to hold or retain the license would present a risk to the public health and safety.

An entity whose application for renewal of a license is denied or whose license is restricted, suspended, or revoked will be entitled to a hearing before the DOH concerning the action. The DOH will 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. Notwithstanding the lapse, suspension, or revocation of a license or permit issued under the bill, the DOH may: proceed with any investigation of, or any action or disciplinary proceeding against, the person who held the license or permit, as applicable; and revise or render void an order suspending or revoking the license or permit, as applicable. In cases involving the proposed denial of a license or permit, the applicant for licensure or a permit may not withdraw the licensure or permit application that is proposed for denial.

<u>Psilocybin Worker Permits</u>

No person who is younger than 21 years of age may be employed at any psilocybin product manufacturer, psilocybin service center, or psilocybin testing laboratory. The DOH 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 will constitute prima facie evidence that the licensee knowingly employed the person in violation of this prohibition.

No individual will be authorized to 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 DOH. Each psilocybin product manufacturer, psilocybin service center, and psilocybin testing laboratory will be required to 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.

Applications for psilocybin worker permits are to be submitted in a form and manner as required by the DOH. A psilocybin worker permit will be valid for one year and will be subject to renewal. The DOH is to establish reasonable application and issuance fees for psilocybin worker permits, which fees may not exceed the cost to the DOH of processing the application and issuing the permit.

The DOH may require applicants for a psilocybin worker permit to complete a course provided or approved by the DOH, which course may include training in: verifying client ages; detecting signs of client intoxication; safe and sanitary handling of psilocybin products; best practices for sanitation and for the safe production, processing, transportation, and storage of psilocybin products; confidentiality requirements; and any other topics the department determines to be appropriate. The department may charge, or authorize a course provider to charge, a reasonable fee, not to exceed $250 for a psilocybin worker training course. The DOH may not require an individual to attend a psilocybin worker course more than one time, except in cases where the individual's psilocybin worker permit has been suspended or revoked, in which case the DOH may require the individual to complete the course as a condition of removing the suspension or issuing a new permit to the individual.

Psilocybin Product Manufacturers and Service Centers

The DOH will designate specific activities that will be authorized for psilocybin product manufacturers, and a psilocybin product manufacturer will 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 will not be limited in the number of

endorsements the manufacturer holds at one time, and may request approval from the DOH for additional endorsements at any time. The DOH is to approve a request for an additional endorsement unless the DOH 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 will not preclude a manufacturer from submitting a subsequent request for approval of the same or any other endorsement.

The DOH will be required to establish a psilocybin product manufacturer microbusiness license, the fees for which will be no more than half the fee applicable to full psilocybin product manufacturer license. A license issued to a microbusiness will be valid for one year and may be renewed annually. A microbusiness will be required to meet the following requirements: at least 51 percent of the owners, directors, officers, and employees of the microbusiness are residents of the municipality in which the microbusiness is or will be located or a bordering municipality; the microbusiness may employ no more than 10 employees at one time, inclusive of any owners, officers, and directors; and the entire microbusiness facility occupies an area of no more than 2,500 square feet.

The DOH 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. In establishing quantity or volume restrictions, the DOH is to 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.

In no case may psilocybin manufacturing activities be conducted in an outdoor area. The bill provides that no psilocybin service center may 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, subject to certain exceptions. Psilocybin service center operators will be required to take steps to prevent noisy, lewd, disorderly, and disruptive conduct on the licensee's premises and ensure the premises are maintained in a safe and sanitary condition. Psilocybin service centers will not constitute a health care facility licensed pursuant to P.L.1971, c.163 (C.26:2H-1 et seq.).

Psilocybin product manufacturers and psilocybin service centers may not advertise any psilocybin products to the public. However, psilocybin service centers will be allowed to furnish information

concerning psilocybin products that are available from the psilocybin service center to clients present in the interior premises of the center or during the course of a preparation session, and psilocybin product manufacturers may provide information concerning the manufacturer's products to psilocybin service centers and psilocybin service facilitators.

Psilocybin service centers and psilocybin service facilitators may advertise psilocybin services, provided such advertisements do not: appeal to minors; promote excessive use of psilocybin; promote illegal activity; violate the code of professional conduct for psilocybin service facilitators; or otherwise present a significant risk to public health and safety.

Psilocybin product manufacturers may not deliver psilocybin products to any location or entity other than a psilocybin product manufacturer, psilocybin service center, or psilocybin testing laboratory. Psilocybin product manufacturers may not receive psilocybin products from any entity other than a psilocybin product manufacturer or from a psilocybin service center. Psilocybin service centers may not sell, furnish, or deliver psilocybin products to any entity other than a client, a psilocybin service center, or a psilocybin testing laboratory, and may not receive psilocybin products from any entity other than a psilocybin product manufacturer or a psilocybin service center. The DOH is to establish requirements concerning the return of psilocybin products by a psilocybin service center to a psilocybin product manufacturer, which requirements are to, at a minimum, identify the circumstances under which 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.

Psilocybin product manufacturers will be responsible for ensuring the accurate labeling of all psilocybin products produced and distributed by the manufacturer, which labels are to 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 DOH. The product labeling is to 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.

Psilocybin Service Facilitators

Each applicant for a psilocybin service facilitator license will be required to submit documentation to the DOH proving that the applicant: is 21 years of age or older; has a high school diploma or its equivalent; has completed the education and training requirements for licensure; has successfully completed any required examinations; and has met any other requirements for licensure established by the DOH. In no case may an applicant for licensure as a psilocybin service facilitator be required to hold a degree issued by an institution of higher education. 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. Psilocybin service facilitators will be authorized to provide psilocybin facilitation services at or through more than one psilocybin service center.

Psilocybin Services

Psilocybin service centers and psilocybin service facilitators will be required to verify the age of a client prior to providing any psilocybin service or selling or furnishing a psilocybin product to the client. Information collected for the purposes of verifying a client's age may not be retained by a psilocybin service center or psilocybin service facilitator and may not be used for any other purpose.

Psilocybin services comprise a preparation session, an administration session, and an optional integration session. A preparation session involves the initial screening of the client to verify the client's age and screen the client for anything that would signal psilocybin is contraindicated for the client. An administration session is when psilocybin is administered to the client by a psilocybin service facilitator, who remains with the client and guides the client throughout the session. The preparation session is required before an administration session can take place. An integration session is an optional session that follows an administration session, during which a psilocybin services facilitator works with the client to process the results of the administration session.

A preparation session and an integration 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. As a general rule, administration sessions are to be held at a psilocybin service center. However, a psilocybin service facilitator may provide psilocybin services in a private residence if, for medical reasons, the client is unable to travel to the psilocybin service center. The psilocybin service center will be required to

document the basis upon which an in-home administration session is authorized. In no case may in-home psilocybin services be provided to a client who is located outside New Jersey.

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 does not cease to provide psilocybin services during an administration session after the client has consumed a psilocybin product, except under circumstances as may be authorized by the DOH and in conformance with any guidelines and best practices as the DOH may establish for ceasing the provision of psilocybin services during an administration session.

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

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

Psilocybin service facilitators will be responsible for:

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

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

3) determining whether the client is precluded from receiving services by DOH rule;

4) prior to initiating an administration session, ensuring the client completes and signs a client information form;

5) transmitting completed client information forms to the psilocybin service center prior to initiating the administration session;

6) documenting the completion of all preparation, administration, and integration sessions, as well as the provision of all required warnings and disclosures to the client; and

7) ensuring the client is offered the opportunity to participate in an integration session following completion of an administration session.

Each psilocybin service center will be required to annually report to the DOH: the total number of clients who were provided psilocybin services during the preceding year, including the number of repeat clients served; the purposes for which clients 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; the number of clients who completed a preparation session but not an administration session; the total number of clients who elected to complete an integration session; the total number of in-house administration sessions performed; any adverse events involving a client during an

administration session; and assessments of client satisfaction with the psilocybin services provided. The DOH will be required to make this information publicly available, provided that nothing in the bill is to be construed to authorize the disclosure of any personal identifying information or health information about any individual client, and nothing in the bill is be construed to require any psilocybin service center to disclose to the DOH any personal identifying information or health information about any individual client.

No psilocybin service center, psilocybin service facilitator, or other employee of a psilocybin service center may disclose any information about any client that may be used to identify the client, any confidential health or medical information about a client, or any communications between a client and the psilocybin service center, psilocybin service facilitator, or employee of the psilocybin service center, unless:

1) the client, or a person authorized to act on the client's behalf, provides written consent authorizing the disclosure;

2) disclosure is required to prevent an imminent act that will result in serious physical harm to the client or to any other person;

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

4) as may be required by the DOH in the course of an investigation involving alleged violations of the provisions of the bill.

Psilocybin products purchased by a client from, or sold to a client by, a psilocybin service center or psilocybin service facilitator are be consumed by the client on the premises of the psilocybin service center, except in the case of a home visit, in which case the psilocybin product is to be consumed by the client at the location in which the administration session is held. Psilocybin products may not be consumed by a client except under the supervision of a psilocybin service facilitator. In order to prevent diversion, accidental ingestion, and accidental injury, the DOH will establish requirements for the disposal of partially consumed, unused, adulterated, expired, and mislabeled psilocybin products.

<u>Tracking and Testing Psilocybin Products</u>

The DOH 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. The DOH may also conduct random testing of psilocybin products for the purpose of determining whether a licensee is in compliance with the requirements of the bill. The DOH 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. The testing of psilocybin products will be restricted to laboratories licensed under the bill.

For the purpose of tracking the manufacture and administration of psilocybin products and the transfer of psilocybin products between licensed premises, the DOH will be required to either develop a new tracking system or enter into an agreement with the Cannabis Regulatory Commission authorizing the department to use the existing cannabis tracking system. The DOH will be required to 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 the bill.

The tracking system implemented by the DOH will be required, at a minimum, to be capable of tracking: the manufacture of psilocybin products; the sale of psilocybin products by a psilocybin service center operator to a client; the sale, purchase, transfer, and delivery of psilocybin products between licensees; individual product batches that may be mislabeled, adulterated, or present health or safety risks to clients; and any other information that the DOH determines is reasonably necessary to implement the requirements of the bill.

Powers of the Department of Health

The bill provides that the DOH will have certain specific duties, powers, and functions, including:

1) reviewing and making publicly available on its Internet website research, studies, and other information relating to the safety and efficacy of psilocybin in behavioral health care;

2) after the 18-month program development period, comprehensively regulating the system for producing and administering psilocybin in New Jersey; and

3) promulgating rules and regulations to implement the provisions of the bill.

The DOH will have the power to issue subpoenas, compel the attendance of witnesses, establish fees, and compel the production of various documentary materials.

The bill prohibits the DOH from requiring that a psilocybin product be manufactured by means of chemical synthesis, from prohibiting the use of naturally grown mushrooms that meet quality and safety standards, from mandating the use of patented products or procedures, and from requiring that a client be diagnosed with or have any particular medical or mental health condition as a prerequisite to being provided psilocybin services. If recommended

by the advisory board, the department may exclude individuals, or categories of individuals, from receiving psilocybin services, which exclusion may be based on preexisting diagnoses, identified risk factors, or contraindications.

Commencing six months after the effective date of the bill, the DOH will be required to post on its Internet website available research, studies, and other information relating to the safety and efficacy of psilocybin for behavioral health care, and thereafter is to periodically update the information as may be necessary to ensure the information is current and accurate.

No later than six months after the effective date of the bill, the DOH is to establish the necessary forms and commence the process of accepting applications for and approving psilocybin service facilitator training programs. No later than 18 months after the effective date of the bill, the DOH will be required to 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.

The DOH will be required to 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. An applicant for licensure will be eligible for participation in the social opportunity program if: 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; the applicant is an entity that has more than 10 full-time employees and has more than half of its employees currently residing in a distressed area; or the applicant is an entity that meets any other eligibility criteria for the social opportunity program as may be established by the DOH. The applicant will be required to have a primary residence in a distressed area for five of the past 10 years, have demonstrated economic need, and meet any other eligibility criteria for the social opportunity program as may be established by the DOH.

For the purposes of implementing the social opportunity program, the DOH will identify geographic areas that are distressed areas, establish appropriate criteria to identify social opportunity applicants, provide technical assistance to social opportunity applicants, provide reduced licensure application, renewal, and issuance fees for social opportunity applicants, and if applicable, create a process for social opportunity applicants to receive points towards a license application score.

The DOH is to additionally establish and administer an equitable access program to assist qualified economically disadvantaged individuals with the cost of receiving psilocybin services.

The DOH will be authorized to purchase, possess, seize, transfer to a licensee, or dispose of psilocybin products as is necessary for the DOH to ensure compliance with, and enforce the provisions of, the bill. The DOH may, upon providing the licensee with 72 hours' notice, examine the licensee's books and may, at any time, conduct an inspection of a licensee's premises. The DOH may allow, but will not require, a licensee's books to be maintained on the licensed premises.

The DOH may require licensees to maintain general liability insurance, in an amount the DOH 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.

Commencing one year after the end of the 18-month program development period, and annually thereafter, the DOH will be required to prepare, submit to the Governor and the Legislature, and make available on its Internet website, a report concerning the implementation and administration of the bill. The report will 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; the total number of psilocybin facilitator training programs approved; the total number of clients served during the preceding one-year period and the number of those clients who previously received psilocybin services; the purposes for which clients requested psilocybin services, including the types of behavioral health conditions and the nature of any other purposes for which psilocybin services were requested; the number of in-home administration sessions provided during the preceding one-year period; 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.

<u>Protections and Immunities</u>

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 client, who engages in conduct authorized under the bill will be immune from liability for that conduct as it pertains to the State's criminal drug laws.

Under the bill, it will be unlawful to take any adverse employment action against an employee who receives psilocybin services, 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.

Conduct permitted under the bill will not, by itself, constitute child abuse or neglect, 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, or constitute a basis to deny eligibility for any public assistance program.

Treatment for behavioral health, mental health, or substance use disorders, or other health care a client is otherwise eligible to receive, may 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.

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

A holder of a professional or occupational license, certification, or registration will 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 the bill.

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

Nothing in the bill is to be construed to: require a government medical assistance program or private health insurer to reimburse a person for costs associated with the use of psilocybin products; 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; 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; obstruct the enforcement of federal law; or deem psilocybin services to constitute a medical diagnosis or medical treatment.

Other Provisions

The bill provides that it will not be unlawful for a person over 21 years of age to possess, store, use, ingest, inhale, process, transport, deliver without consideration, or distribute without consideration, four grams or less of psilocybin. It will also not be unlawful for a person over 21 years of age to grow, cultivate, or process plants or fungi capable of producing psilocybin for personal use, or to possess the psilocybin produced if the plants and fungi are kept on the grounds of a private home or residence and are kept secure from access by persons under 21 years of age. It will further not be unlawful to assist another person who is 21 years of age or older or allow property to be used in the course of engaging in such conduct. The bill specifies that engaging in this authorized conduct will not: be considered an offense under State law or the laws of any county or municipal governing body; constitute the basis to assess against any person a civil penalty, a civil sanction, or professional or administrative discipline; constitute the basis for detention, search, or arrest of any person; or constitute the basis to deny a person any right or privilege, or to seize or forfeit the assets of any person under State law or the laws of any county or municipal governing body, provided the person is at least 21 years of age.

The bill provides that a person convicted of, or who has pending charges for, conduct authorized under the bill that would not constitute an offense or that would constitute a lesser offense were the bill in effect at the time of the offense may petition for resentencing, reversal of conviction and dismissal of case, or modification of judgment and sentence. Similarly, a person who has completed a sentence for a conviction, whether by trial or plea of guilty or nolo contendere, who would not have been guilty of the offense or who would have been guilty of a lesser offense under the bill had it been in effect at the time of the offense, will be authorized to file a petition to have the conviction dismissed, expunged, and vacated as legally invalid or redesignated as a civil infraction.

A court receiving a petition is to presume the petitioner satisfies requirements to have the conviction or charged modified or overturned, unless the State opposes the petition or alleges that granting the petition would pose an unreasonable risk of danger to an identifiable individual's safety. In the event that the State opposes a petition, the petitioner will be entitled to a hearing on the record, including the opportunity to question witnesses and present evidence supporting the petition. The State will bear the burden of proving, by clear and convincing evidence, that the petitioner does not satisfy the criteria or that granting the petition would pose an unreasonable risk of danger to an identifiable individual if alleged. Unless the State sustains its burden, the court will be required to

grant the petition. Any outstanding fines, court costs, and fees imposed in connection with the conviction at issue will be waived.

Under no circumstance will a resentencing, reversal and dismissal, modification, revocation, or acceleration result in the imposition of a supervision or imprisonment term longer than the original sentence, or the reinstatement of charges dismissed pursuant to a negotiated plea agreement, or require the payment of any additional fines or fees beyond those authorized by the bill. Any conviction that is modified, resentenced, or redesignated as a civil infraction under the bill will be considered a civil infraction for all purposes.

The bill will 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 is necessary for the implementation of the bill.