

ASSEMBLY HEALTH COMMITTEE

STATEMENT TO

ASSEMBLY COMMITTEE SUBSTITUTE FOR ASSEMBLY, No. 3852

STATE OF NEW JERSEY

DATED: JUNE 17, 2024

The Assembly Health Committee adopts an Assembly Committee Substitute for Assembly Bill No. 3852.

The substitute 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.

Psilocybin Behavioral Health Access and Services Advisory Board

The substitute bill establishes in the Department of Health (DOH) the Psilocybin Behavioral Health Access and Services Advisory Board. The board will comprise 15 members, including:

1) the Commissioner of Health, the Deputy Commissioner for Public Health Services, the Adjutant General, 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; and

3) Nine public members, which members are to be appointed by the Governor with preference given to members who have experience with psychedelic-assisted therapy and 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; 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 substitute 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 substitute 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 substitute 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 other psychedelic substances and their efficacy in ameliorating behavioral health conditions, as well as the potential for these substances to promote community, address trauma, and enhance physical and mental wellness;
- 3) the requirements, specifications, and guidelines for providing psilocybin services to a patient including: requirements, specifications, and guidelines for holding and documenting the completion of preparation sessions, administration sessions, group administration sessions, and integration therapy sessions; the contents of the psilocybin services safety screening tool and patient information form; guidelines and best practices for assessing patient risk factors or contraindications; the list of medical conditions and the symptoms of those medical conditions that would qualify a patient to receive psilocybin services; dosage guidelines for patients to be used by psilocybin service facilities; the types and severity of adverse events that constitutes a serious adverse event and that each psilocybin service center will be required to report to the department;
- 4) public health and safety standards and industry best practices for psilocybin licensees 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;

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

10) requirements and restrictions for advertising psilocybin services;

11) 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 and equitable access program established under the substitute 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 assessing whether psilocybin services should be expanded to in-home psilocybin services and whether any the State should regulate the use of any other psychedelic substances; 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 substitute bill.

Psilocybin Licensure Requirements

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 substitute 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 substitute bill. A license or permit issued under the substitute 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 substitute 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 substitute 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 regarding 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 substitute 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 substitute bill is subsequently convicted of a disqualifying conviction.

Under the substitute 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.

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 substitute 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 patient of the licensee;

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

Psilocybin Worker Permits

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. 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 a 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; 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. 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 substitute 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 except under certain circumstances provided by the substitute bill. 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 patients 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 facilitators may not advertise psilocybin services to the public. However, psilocybin service centers will be allowed to advertise psilocybin services to health care professionals in the State.

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 patient, 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.

Psilocybin product manufacturers will be responsible for ensuring the accurate labeling of all psilocybin products produced and distributed by the manufacturer. 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.

Referrals for Psilocybin Services

The substitute bill authorizes certain health care practitioners to provide referrals to patients with a qualifying medical condition for psilocybin services, provided that the health care practitioners comply with the requirements for referring patients for psilocybin services established under the substitute bill. The substitute bill defines “health care practitioner” to mean a physician, advanced practice nurse, physician assistant, psychologist, clinical social worker, or professional counselor licensed or certified pursuant to Title 45 of the Revised Statutes who is the health care practitioner responsible for the ongoing treatment of a patient's qualifying medical condition, the symptoms of that condition, or the symptoms associated with the treatment of that condition, provided, however, that the ongoing treatment will not be limited to the provision of psilocybin services to a patient solely for that purpose.

The substitute bill establishes certain restrictions for health care practitioners that prevent health care practitioners from providing referrals for psilocybin services to themselves or immediate family members. The substitute bill provides that health care practitioners may refer any patient for psilocybin services using telemedicine or telehealth, provided that the use of telemedicine or telehealth, rather than an in-person visit, is consistent with the standard of care required for assessment and treatment of the patient's condition. The substitute

bill prohibits health care practitioners from receiving certain compensation for providing referrals for psilocybin services.

Psilocybin Services

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

Psilocybin services comprise a preparation session, an administration session, and an integration therapy session. A preparation session involves the initial screening of the patient to verify the patient's age, verify that the patient has a valid referral from a health care professional, obtain any necessary information to screen the patient for anything that would signal psilocybin is contraindicated for the patient, provide the patient with any necessary health and safety disclosures, obtain informed consent, and establish the patient's goals of care. An administration session is when psilocybin is administered to the patient by a psilocybin service facilitator, who remains with the patient and guides the patient throughout the session. The preparation session is required before an administration session can take place. An integration therapy session is a mandatory therapy session that follows an administration session, during which a behavioral health care provider, in collaboration with the psilocybin service facilitator when appropriate and necessary, works with the patient to process the results of the administration session and provide any follow-up services and referrals.

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

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 patient has consumed a psilocybin product, except under circumstances as may be authorized by the DOH.

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 patient completes a preparation session prior to initiating an administration session;
- 2) ensuring the patient is furnished with verbal notice and a written copy of the warnings and other disclosures required by the DOH during the preparation session;
- 3) determining whether the patient is precluded from receiving services by DOH rule;
- 4) prior to initiating an administration session, ensuring the patient completes and signs any necessary forms;
- 5) transmitting completed forms to the psilocybin service center prior to initiating the administration session;
- 6) documenting the completion of all preparation, administration, and integration therapy sessions;
- 7) ensuring the patient completes an integration therapy session following completion of an administration session and providing any assistance to the behavioral health care provider conducting the session, as necessary and appropriate; and
- 8) providing follow-up services to the patient within 72 hours after the patient completes an administration session.

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

Each psilocybin service center will establish standard operating procedures for adverse event reporting. Each psilocybin service center will collect various outcomes data and information from patients and psilocybin service center employees.

Each psilocybin service center will be required to annually report to the DOH: the total number of patients who were provided psilocybin services during the preceding year and the number of repeat patients served, by dosage, medical condition, and the type of health care practitioner who provided the patient a referral for psilocybin

services; the total number of group administration sessions provided and the average number of patients participating in each group administration session; the average cost of psilocybin services per patient; to the extent possible, demographic information about the patients who received psilocybin services; the purposes for which patients requested psilocybin services; the number of patients who completed a preparation session but not an administration session; the total number of patients who completed an integration therapy session; any adverse events involving a patient during the provision of psilocybin services; assessments of patient satisfaction with the psilocybin services provided and employee satisfaction with any training provided; and any other information concerning the provision of psilocybin services as deemed necessary by the department. The DOH will be required to make this information publicly available in a deidentified and aggregate form, provided that nothing in the substitute bill is to be construed to authorize the disclosure of any personal identifying information or health information about any individual patient, and nothing in the substitute bill is to be construed to require any psilocybin service center to disclose to the DOH any personal identifying information or health information about any individual patient.

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

- 1) the patient, or a person authorized to act on the patient'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 patient 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 substitute bill.

Psilocybin products purchased by a patient from, or sold to a patient by, a psilocybin service center or psilocybin service facilitator are to be consumed by the patient on the premises of the psilocybin service center. Psilocybin products may not be consumed by a patient 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.

Tracking and Testing Psilocybin Products

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 substitute 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 substitute 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 develop a 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 substitute bill.

Powers of the Department of Health

The substitute 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 substitute 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 substitute 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, and from mandating the use of patented products or procedures.

The substitute bill provides that the department will require a patient to be diagnosed with, or exhibit the symptoms of, a qualifying

medical condition and to receive a referral from a health care practitioner, as prerequisite to receiving psilocybin services.

Commencing six months after the effective date of the substitute 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 24 months after the effective date of the substitute bill, the DOH is to establish the necessary forms and commence the process of accepting application for and approving psilocybin service facilitator training programs. No later than 24 months after the effective date of the substitute 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 substitute 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 substitute bill.

Protections and Immunities

A psilocybin product manufacturer, psilocybin service center, psilocybin testing laboratory, psilocybin service facilitator, employee of a psilocybin product manufacturer, psilocybin service center, or psilocybin testing laboratory, or a psilocybin service facilitator or patient, who engages in conduct authorized under the substitute bill will be immune from liability for that conduct as it pertains to the State's criminal drug laws.

Under the substitute 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 substitute 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 patient 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 substitute 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 substitute 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.