

SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No, 2283

STATE OF NEW JERSEY
221st LEGISLATURE

ADOPTED JUNE 6, 2024

Sponsored by:

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

Co-Sponsored by:

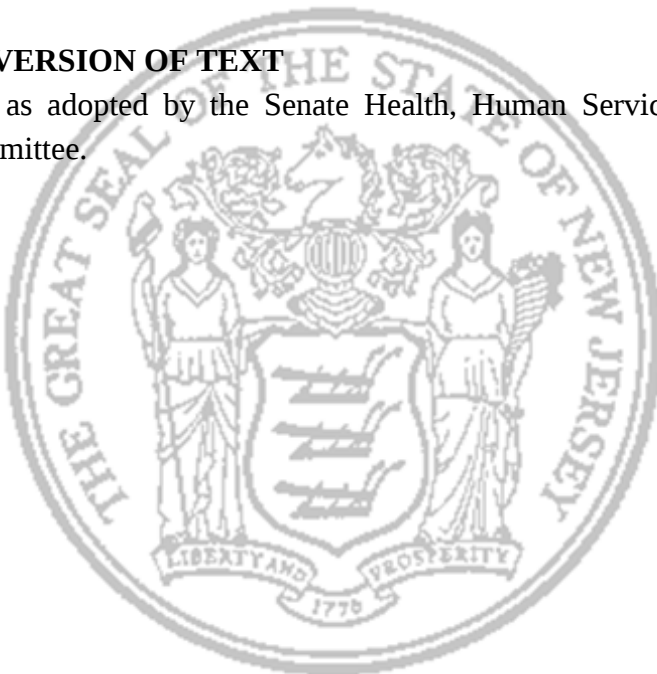
Senators Schepisi, Zwicker, Cruz-Perez and O'Scanlon

SYNOPSIS

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

CURRENT VERSION OF TEXT

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



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

4
5 **BE IT ENACTED** *by the Senate and General Assembly of the State*
6 *of New Jersey:*

7
8 1. (New section) This act shall be known and may be cited as
9 the “Psilocybin Behavioral Health Access and Services Act.”

10
11 2. (New section) The Legislature finds and declares that:

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

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

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

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

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

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

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

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

Matter underlined thus is new matter.

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

8
9 3. (New section) As used in this act:

10 “18-month program development period” means the period
11 beginning on the effective date of this act and ending 18 months
12 thereafter.

13 “Administration session” means a session at which a patient
14 consumes and experiences the effects of a psilocybin product under
15 the supervision of a psilocybin service facilitator.

16 “Adverse employment action” means refusing to hire or employ
17 an individual, barring or discharging an individual from
18 employment, requiring an individual to retire from employment, or
19 discriminating against an individual in compensation or in any
20 terms, conditions, or privileges of employment.

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

25 “Behavioral health care provider” means a psychiatrist,
26 psychiatric advanced practice nurse, psychologist, clinical social
27 worker, marriage and family therapist, any other mental health or
28 substance use disorder treatment provider licensed pursuant to Title
29 45 of the Revised Statutes, or a practitioner otherwise authorized to
30 provide behavioral health care services in the State.

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

33 “Commissioner” means the Commissioner of Health.

34 “Department” means the Department of Health.

35 “Distressed area” means an area that: is categorized as a
36 distressed area by the New Jersey Department of Labor and
37 Workforce Development; or is a State legislative district in which
38 50 percent or more of the children in the district participate in the
39 federal free lunch program or in which 20 percent or more of the
40 households in the district receive assistance under the federal
41 supplemental nutrition assistance program.

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

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

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

11 “Licensee” means a person who holds a psilocybin product
12 manufacturer license, a psilocybin service center operator license, a
13 psilocybin testing laboratory license, or a psilocybin service
14 facilitator license issued pursuant to this act.

15 “Manufacture” means the manufacture, planting, cultivation,
16 growing, harvesting, production, preparation, propagation,
17 compounding, conversion, or processing of a psilocybin product,
18 either directly or indirectly, by extraction from substances of
19 natural origin, or independently by means of chemical synthesis, or
20 by a combination of extraction and chemical synthesis, and includes
21 any packaging or repackaging of the psilocybin product or labeling
22 or relabeling of its container.

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

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

40 “Psilocybin” means psilocybin or psilocin.

41 “Psilocybin product manufacturer” means a person licensed to
42 manufacture psilocybin products pursuant to this act.

43 “Psilocybin product” means psilocybin-producing fungi and
44 mixtures or substances containing a detectable amount of
45 psilocybin.

46 “Psilocybin service center” means an establishment at which
47 administration sessions are held and other psilocybin services may
48 be provided.

1 “Psilocybin service center operator” means a person licensed to
2 operate a psilocybin service center pursuant to this act.

3 “Psilocybin service facilitator” means an individual licensed to
4 facilitate the provision of psilocybin services pursuant to this act.

5 “Psilocybin services” means services provided to a patient
6 before, during, and after the patient’s consumption of a psilocybin
7 product, including the mandatory preparation session, the
8 administration session, and the mandatory integration therapy
9 session.

10 “Psilocybin services safety screening tool” means an instrument
11 used for the systematic evaluation of the potential risks or hazards
12 for an individual receiving psilocybin services.

13 “Qualifying medical condition” means any medical condition or
14 its treatment that would qualify a patient to receive psilocybin
15 services as determined by the board.

16

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

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

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

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

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

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

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

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

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

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

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

- 1 (g) a person with professional experience conducting scientific
2 research regarding the use of psychedelic compounds in clinical
3 therapy;
- 4 (h) a pharmacist licensed pursuant to Title 45 of the Revised
5 Statutes who specializes in psychological medicine; and
- 6 (i) a person with experience with health care access.
- 7 c. The public members of the board shall serve for a term of
8 four years, provided that, of the members first appointed, two shall
9 serve for a term of two years, two shall serve for a term of three
10 years, and three shall serve for a term of four years. Public
11 members shall be eligible for reappointment to the board.
12 Vacancies in the board shall be filled in the same manner as is
13 provided for the initial appointment for the remainder of the
14 unexpired term.
- 15 d. The Governor shall appoint the public members to the board
16 no later than 60 days after the effective date of this act. The board
17 shall organize upon the appointment of the public members and
18 shall select a chairperson and a vice-chairperson from among the
19 membership. The chairperson shall appoint a secretary, who need
20 not be a member of the board.
- 21 e. A majority of the public members of the board shall
22 constitute a quorum for the purpose of conducting official board
23 business. The official adoption of advice or recommendations by
24 the board shall require the approval of a majority of the public
25 members.
- 26 f. During the 18-month program development period, the board
27 shall meet at least once every calendar month, at a time and place
28 designated by the chairperson. Following the end of the 18-month
29 program development period, the board shall meet at least quarterly
30 at a time and place designated by the chairperson. The board shall
31 meet at any time at the call of the chairperson or at the call of a
32 majority of the public members.
- 33 g. The members of the board shall serve without compensation
34 but may be reimbursed for reasonable expenses incurred in the
35 performance of their official duties, within the limits of funds made
36 available to the board for this purpose.
- 37 h. The board may establish committees and subcommittees as
38 may be necessary for the board's operation. The department shall
39 provide such stenographic, clerical, and other administrative
40 assistants and such professional staff as the board requires to carry
41 out its work. The board shall be entitled to call to its assistance and
42 avail itself of the services of the employees of any State, county, or
43 municipal department, board, bureau, commission, or agency as it
44 may require and as may be available for its purposes.
- 45
- 46 5. (New section) a. The purpose of the board established
47 pursuant to section 4 of this act shall be to provide advice and
48 recommendations to the department, upon request or upon the

- 1 board's own initiative, concerning the implementation of this act,
2 including providing recommendations to the department
3 concerning:
- 4 (1) educating the public about the use of psilocybin in
5 behavioral health care;
- 6 (2) available medical, psychological, and scientific studies,
7 social scientific research, and other information relating the safety
8 of psilocybin and any other psychedelic substances, as determined
9 by the board, and their efficacy in ameliorating behavioral health
10 conditions, including, but not limited to, clinical dependence
11 disorders, depression, anxiety disorders, and end-of-life
12 psychological distress, and the potential for psilocybin and any
13 other psychedelic substances to promote community, address
14 trauma, and enhance physical and mental wellness;
- 15 (3) the requirements, specifications, and guidelines for
16 providing psilocybin services to a patient, including:
- 17 (a) requirements, specifications, and guidelines for holding and
18 documenting the completion of preparation sessions, administration
19 sessions, and integration therapy sessions;
- 20 (b) requirements, specifications, and guidelines for holding and
21 documenting the completion of group administration sessions and
22 establishing a limit on the total number of patients who may
23 participate in a group administration session that is supervised by
24 one psilocybin service facilitator;
- 25 (c) the contents of the psilocybin services safety screening tool
26 and patient information form that a patient will be required to
27 complete and sign before the patient will be authorized to
28 participate in an administration session, including:
- 29 (i) the information that should be solicited from the patient or
30 the patient's health care practitioner or behavioral health care
31 provider to determine whether the patient should participate in the
32 administration session, including information that may identify
33 potential risk factors and contraindications;
- 34 (ii) the information that should be solicited from the patient or
35 the patient's health care practitioner or behavioral health care
36 provider to assist the psilocybin service center and the psilocybin
37 service facilitator in meeting any public health and safety standards
38 and industry best practices during the administration session; and
- 39 (iii) the health and safety warnings and other disclosures that
40 should be made to the patient before the patient participates in the
41 administration session;
- 42 (d) guidelines and best practices for assessing the type, nature,
43 and severity of a risk factor or contraindication identified in a
44 patient information form, and determining whether the risk factor or
45 contraindication:
- 46 (i) can be accommodated or mitigated in a manner that will
47 allow the patient to proceed with an administration session; or

- 1 (ii) is of a type, nature, or severity that would make it unsafe for
2 the patient to proceed with an administration session;
- 3 (e) the list of medical conditions and the symptoms of those
4 medical conditions that would qualify a patient to receive
5 psilocybin services pursuant to this act;
- 6 (f) dosage guidelines for patients, which guidelines the board
7 may periodically review and update as appropriate and psilocybin
8 service facilitators shall use to determine the appropriate dose of
9 psilocybin product a patient may consume during an administration
10 session; and
- 11 (g) the types and severity of adverse events that constitute a
12 serious adverse event and that each psilocybin service center shall
13 report to the department;
- 14 (4) public health and safety standards and industry best practices
15 for psilocybin product manufacturers, psilocybin service centers,
16 psilocybin testing facilities, and psilocybin service facilitators,
17 including, but not limited to, the implementation of security and
18 safety measures to ensure psilocybin products are stored in a safe
19 and secure manner that prevents theft, diversion, adulteration, and
20 access by unauthorized individuals;
- 21 (5) the formulation of a code of professional conduct for
22 psilocybin service facilitators, with particular consideration to
23 developing a code of ethics;
- 24 (6) the education and training requirements for psilocybin
25 service facilitators, with particular consideration of:
- 26 (a) training in facilitation skills that are affirming,
27 nonjudgmental, culturally competent, and nondirective;
- 28 (b) providing support to patients during an administration
29 session, including training in specialized skills for patient safety and
30 patients who may have a behavioral health disorder;
- 31 (c) the environment in which psilocybin services should be
32 provided; and
- 33 (d) social and cultural considerations;
- 34 (7) the examinations that psilocybin service facilitators will be
35 required to successfully complete as a condition of licensure;
- 36 (8) public health and safety standards and industry best practices
37 for holding and completing an administration session, including:
- 38 (a) the circumstances under which administration sessions
39 should be available;
- 40 (b) whether patients should be able to access common or outside
41 areas of the premises of the psilocybin service center at which the
42 administration session is held;
- 43 (c) the circumstances under which an administration session is
44 considered complete; and
- 45 (d) the transportation needs of the patient after the completion
46 of the administration session, including standards and restrictions
47 for when an administration session may be terminated after the
48 administration of a psilocybin product to a patient, along with

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

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

7 (10) requirements and restrictions for advertising psilocybin
8 services;

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

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

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

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

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

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

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

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

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

41

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

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

- 1 disorders, and end-of-life psychological distress, and the potential
2 for psilocybin to promote community, address trauma, and enhance
3 physical and mental wellness;
- 4 (2) after the 18-month program development period:
- 5 (a) to regulate the manufacturing, testing, transportation,
6 delivery, sale, and purchase of psilocybin products and the
7 provision of psilocybin services in this State in accordance with the
8 provisions of this act;
- 9 (b) to issue, renew, suspend, revoke, or refuse to issue or renew
10 psilocybin product manufacturer, psilocybin service center operator,
11 psilocybin testing laboratory, and psilocybin service facilitator
12 licenses and psilocybin worker permits;
- 13 (c) to approve and regulate psilocybin service facilitator training
14 programs; and
- 15 (d) to regulate the use of psilocybin products and psilocybin
16 services for other purposes as the department deems necessary or
17 appropriate;
- 18 (3) to adopt, amend, and repeal rules and regulations, pursuant
19 to the “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-
20 1 et seq.), as necessary to implement the provisions of this act; and
- 21 (4) to exercise all powers incidental, convenient, or necessary to
22 enable the department to implement and administer the
23 requirements of this act or any other New Jersey law that charges
24 the department with a duty, function, or power related to psilocybin
25 products and psilocybin services, which powers shall include, but
26 shall not be limited to:
- 27 (a) issuing subpoenas;
- 28 (b) compelling the attendance of witnesses;
- 29 (c) administering oaths;
- 30 (d) certifying official acts;
- 31 (e) taking depositions as provided by law;
- 32 (f) establishing reasonable fees, which fees shall not exceed the
33 amount necessary to administer the provisions of this act; and
- 34 (g) compelling the production of books, payrolls, accounts,
35 papers, records, documents, and testimony.
- 36 b. The department shall not require that a psilocybin product be
37 manufactured by means of chemical synthesis, prohibit the use of
38 naturally grown mushrooms that meet quality and safety standards,
39 or mandate the use of patented products or procedures.
- 40 c. The department shall require a patient to be diagnosed with,
41 or exhibit the symptoms of, a qualifying medical condition and to
42 receive a referral from a health care practitioner for psilocybin
43 services, as a prerequisite to being provided psilocybin services.
- 44 d. Commencing six months after the effective date of this act,
45 the department shall post on its Internet website available medical,
46 psychological, and scientific studies, research, and other
47 information relating to the safety and efficacy of psilocybin in
48 ameliorating behavioral health conditions, including, but not limited

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

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

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

16
17 7. (New section) a. A health care practitioner shall not be
18 required to be listed publicly in any psilocybin practitioner registry
19 as a condition of referring patients for psilocybin services.

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

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

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

37
38 8. (New section) a. Except as provided in subsection b. of this
39 section, no health care practitioner who has referred a patient for
40 psilocybin services pursuant to this act within the past 90 days, and
41 no member of such health care practitioner's immediate family,
42 shall be an interest holder in, or receive any form of direct or
43 indirect compensation from, any psilocybin product manufacturer,
44 psilocybin service center, psilocybin service center operator,
45 psilocybin testing laboratory, or employee thereof.

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

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

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

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

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

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

21

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

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

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

39

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

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

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

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

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

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

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

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

26 (2) has made false statements to the department;

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

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

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

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

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

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

- 1 premises will involve activities related to the production,
2 processing, or administration of psilocybin products or the
3 provision of psilocybin services, as applicable;
- 4 (7) in the case of an applicant for a psilocybin product
5 manufacturer license, a psilocybin service center operator license,
6 or a psilocybin testing laboratory license, has not demonstrated
7 financial responsibility sufficient to adequately meet the
8 requirements of the facility that is the subject of the application; or
9 (8) for other good cause as determined by the department.
- 10 g. The application and issuance fees for a new or renewed
11 psilocybin product manufacturer, psilocybin service center operator,
12 psilocybin testing laboratory, or psilocybin service facilitator
13 license or a psilocybin worker permit shall not exceed the
14 administrative costs to the department of processing the application
15 and administering the provisions of this act.
- 16 h. A license or permit issued pursuant to this act shall be valid
17 for one year.
- 18 i. The department may not issue any psilocybin product
19 manufacturer, psilocybin service center, psilocybin testing
20 laboratory, or psilocybin service facilitator license, or any
21 psilocybin worker permit, during the 18-month development period.
22
- 23 11. (New section) a. For the purposes of this section, the term
24 "applicant" shall include any owner, director, officer, or employee
25 of, and any significantly involved person in, a psilocybin product
26 manufacturer, psilocybin service center operator, or psilocybin
27 testing laboratory, as well as any applicant for issuance of a
28 psilocybin service facilitator license or a psilocybin worker permit.
- 29 b. The department shall require each applicant for licensure as
30 a psilocybin product manufacturer, psilocybin service center
31 operator, psilocybin testing laboratory, or psilocybin service
32 facilitator, and each applicant for a psilocybin worker permit, to
33 undergo a criminal history record background check. The
34 department shall be authorized to exchange fingerprint data with
35 and receive criminal history record background information from
36 the Division of State Police and the Federal Bureau of
37 Investigation, consistent with the provisions of applicable State and
38 federal laws, rules, and regulations. The Division of State Police
39 shall forward criminal history record background information to the
40 department in a timely manner when requested pursuant to the
41 provisions of this section.
- 42 c. An applicant who is required to undergo a criminal history
43 record background check pursuant to this section shall submit to
44 being fingerprinted in accordance with applicable State and federal
45 laws, rules, and regulations. No check of criminal history record
46 background information shall be performed pursuant to this section
47 unless the applicant has furnished the applicant's written consent to
48 that check. An applicant who is required to undergo a criminal

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

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

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

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

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

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

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

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

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

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

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

31 (4) the date of the crime or offense;

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

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

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

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

44

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

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

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

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

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

17
18 13. (New section) The department may require a licensed
19 psilocybin product manufacturer, psilocybin service center operator,
20 or psilocybin testing laboratory, or an applicant for a psilocybin
21 product manufacturer, psilocybin service center operator, or
22 psilocybin testing laboratory license, to submit to the department a
23 sworn statement identifying the name and address of each person
24 holding a financial interest in the licensee or the applicant for
25 licensure, and the nature and extent of the financial interest held by
26 each person holding a financial interest in the licensee or the
27 applicant for licensure.

28
29 14. (New section) a. The department shall establish and
30 administer a social opportunity program to assist individuals who
31 qualify as social opportunity applicants and who otherwise meet the
32 requirements for issuance of a psilocybin product manufacturer,
33 psilocybin service center, psilocybin service facilitator, or
34 psilocybin testing laboratory license pursuant to this act.

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

39 (1) at least 51 percent of the applicant is owned or controlled by
40 individuals who have lived in a distressed area for five of the past
41 10 years;

42 (2) the applicant is an entity:

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

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

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

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

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

9 (1) identify geographic areas that are distressed areas;

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

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

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

18 (5) if applicable, create eligibility for social opportunity
19 applicants to receive points towards a license application score.
20

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

25 (1) has a primary residence in a distressed area, as identified by
26 the department pursuant to paragraph (1) of subsection d. of section
27 14 of this act, for five of the past 10 years;

28 (2) has demonstrated economic need; and

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

31 b. The department shall adopt eligibility criteria for providing
32 financial assistance to individuals under the equitable access
33 program established pursuant to subsection a. of this section. An
34 individual who wishes to receive financial assistance from the
35 program shall submit an application in a form and manner to be
36 determined by the department.
37

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

44 (1) more than one psilocybin product manufacturer; or

45 (2) more than five psilocybin service centers.
46

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

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

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

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

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

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

- 35 (1) verifying a patient's age;
- 36 (2) verifying a patient's information and referral to receive
37 psilocybin services;
- 38 (3) conducting a psilocybin services safety screening for a
39 patient to receive psilocybin services, in collaboration with the
40 patient's health care practitioner and behavioral healthcare provider
41 to the extent possible and as necessary;
- 42 (4) providing the patient with any health and safety warnings
43 and other necessary disclosures, and obtaining informed consent
44 prior to conducting an administration session for the patient;
- 45 (5) determining the amount of psilocybin product an individual
46 is to consume during an administration session based on the dosage
47 guidelines established by the board and any of the patient's
48 potential risk factors and contraindications;

- 1 (6) detecting signs of patient intoxication;
- 2 (7) safe and sanitary handling of psilocybin products;
- 3 (8) best practices for sanitation and for the safe production,
- 4 processing, transportation, and storage of psilocybin products;
- 5 (9) confidentiality requirements;
- 6 (10) the requirements of this act, as they bear on the applicant's
- 7 duties; and
- 8 (11) any other topics the department determines to be
- 9 appropriate.
- 10 f. (1) The department may charge, or authorize a course
- 11 provider to charge, a reasonable fee, not to exceed \$250, for a
- 12 course described in subsection e. of this section.
- 13 (2) The department shall not require an individual to attend a
- 14 course described in subsection e. of this section more than one time,
- 15 except in cases where the individual's psilocybin worker permit has
- 16 been suspended or revoked by the department, in which case the
- 17 department may require the individual to complete the course as a
- 18 condition of removing the suspension or issuing a new psilocybin
- 19 worker permit to the individual.
- 20 g. The department may require a person issued both a
- 21 psilocybin product manufacturer license and a psilocybin service
- 22 center license for the same premises to require the premises be
- 23 segregated into separate areas for conducting the activities
- 24 authorized under each license, as may be necessary to protect the
- 25 public health and safety.
- 26
- 27 18. (New section) a. The department shall designate specific
- 28 psilocybin manufacturing activities that shall be authorized for
- 29 psilocybin product manufacturers, and a psilocybin product
- 30 manufacturer shall not engage in a psilocybin manufacturing
- 31 activity unless the manufacturer holds an endorsement authorizing
- 32 the manufacturer to engage in that specific activity. A psilocybin
- 33 product manufacturer shall not be limited in the number of
- 34 endorsements the manufacturer holds at one time, and a psilocybin
- 35 product manufacturer may request approval from the department for
- 36 additional endorsements at any time. The department shall approve
- 37 a request for an additional endorsement unless the department
- 38 determines that the psilocybin product manufacturer will be unable
- 39 to meet the requirements for the requested endorsement. Denial of
- 40 a request for an additional endorsement shall not preclude a
- 41 manufacturer from submitting a subsequent request for approval of
- 42 the same or any other endorsement.
- 43 b. The department may restrict the quantity or volume of
- 44 psilocybin annually produced by a psilocybin product manufacturer,
- 45 which may include establishing specific, lower quantity or volume
- 46 limits for psilocybin product manufacturers issued a microbusiness
- 47 license pursuant to subsection d. of this section. In establishing
- 48 quantity or volume restrictions pursuant to this subsection, the

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

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

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

16 (2) A microbusiness shall meet the following requirements:

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

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

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

27

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

31 b. (1) Except as provided in paragraphs (2) and (3) of this
32 subsection, a psilocybin service center shall not be approved for any
33 location that is entirely zoned for residential use or that is within
34 1,000 feet of an elementary or secondary school.

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

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

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

1 constructed within 1,000 feet of the psilocybin service center for
2 such time as the psilocybin service center continues to hold a valid
3 license issued by the department. The department may not revoke
4 the license of a psilocybin service center solely on the grounds that
5 an elementary or secondary school is newly constructed within
6 1,000 feet of the psilocybin service center.

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

11
12 20. (New section) Psilocybin product manufacturers, psilocybin
13 service centers, and psilocybin service facilitators shall not
14 advertise any psilocybin products to the public, provided that
15 nothing in this subsection shall be construed to prohibit:

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

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

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

27
28 21. (New section) a. Each applicant for a psilocybin service
29 facilitator license shall submit documentation proving that the
30 applicant:

31 (1) is 21 years of age or older;

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

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

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

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

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

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

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

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

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

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

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

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

36 f. A psilocybin service facilitator shall be responsible for:

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

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

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

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

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

- 1 guidelines established by the board and any of the patient's
2 potential risk factors and contraindications;
- 3 (6) prior to initiating an administration session, ensuring the
4 patient provides informed consent to receive psilocybin services;
- 5 (7) transmitting any completed patient information, psilocybin
6 services safety screening tool, or informed consent forms to the
7 psilocybin service center prior to initiating the administration
8 session;
- 9 (8) documenting the completion of all preparation,
10 administration, and integration therapy sessions and reporting any
11 adverse events that may have occurred in the provision of
12 psilocybin services;
- 13 (9) ensuring the patient completes an integration therapy session
14 following the completion of an administration session and
15 providing any assistance to the behavioral health care provider
16 conducting the integration therapy session, as necessary and
17 appropriate; and
- 18 (10) providing follow-up services to the patient within 72 hours
19 after the patient completes an administration session.
- 20 g. Each psilocybin service center shall either employ a
21 physician licensed in this State to serve as the center's medical
22 director or contract with an emergency medical services provider,
23 approved by the department, to ensure that emergency medical
24 services are available to patients at the psilocybin service center
25 during the center's hours of operations. A psilocybin service center
26 medical director shall be responsible for responding to any medical
27 emergencies within the center and shall be available during the
28 center's hours of operation. The medical director shall not be
29 involved in the provision of psilocybin services. Nothing in this act
30 shall be construed to permit or authorize acts by a medical director
31 prohibited by State and federal law.
- 32 h. Each psilocybin service center shall establish standard
33 operating procedures for adverse event reporting, which shall
34 include, but not be limited to:
- 35 (1) taking any necessary action to ensure the safety of the
36 patient, including, but not limited to, contacting an emergency
37 medical service provider or behavioral health crisis response service
38 provider to respond to a medical or behavioral health emergency;
- 39 (2) collecting the data and information necessary to track
40 adverse events and to investigate serious adverse events;
- 41 (3) reporting a serious adverse event to the department within 48
42 hours of becoming aware of the adverse event, in a manner to be
43 determined by the department; and
- 44 (4) investigating a serious adverse event, if necessary, to
45 determine possible causes of the adverse event.
- 46 i. To the extent possible, each psilocybin service center shall
47 collect various outcomes data and information from patients and

- 1 psilocybin service center employees, including, but not limited to,
2 information concerning:
- 3 (1) whether employees felt adequately trained to perform their
4 role;
- 5 (2) whether patients met their goals of care;
- 6 (3) whether patients will be seeking any further psilocybin
7 services;
- 8 (4) whether patients received any necessary follow-up services;
9 and
- 10 (5) any relevant demographic information as determined by the
11 department.
- 12 j. (1) Each psilocybin service center shall annually report to the
13 department:
- 14 (a) the total number of patients who were provided psilocybin
15 services during the preceding year and the number of repeat patients
16 served, by dosage, medical condition, and the type of health care
17 practitioner who provided the patient a referral for psilocybin
18 services;
- 19 (b) the total number of group administration sessions provided
20 and the average number of patients participating in each group
21 administration session;
- 22 (c) the average cost of psilocybin services per patient;
- 23 (d) to the extent possible, demographic information about the
24 patients who received psilocybin services, which information may
25 include age, race, sex, socioeconomic status, and county of
26 residence;
- 27 (e) the purposes for which patients requested psilocybin
28 services, including the number of requests received for each type of
29 behavioral health condition or other purpose for which psilocybin
30 services were requested;
- 31 (f) the number of patients who completed a preparation session
32 but not an administration session;
- 33 (g) the total number of patients who completed an integration
34 therapy session;
- 35 (h) any adverse events involving a patient during the provision
36 of psilocybin services;
- 37 (i) assessments of patient satisfaction with the psilocybin
38 services provided and employee satisfaction with any training
39 provided; and
- 40 (j) any other information concerning the provision of psilocybin
41 services as deemed necessary by the department.
- 42 (2) The department shall make the information reported
43 pursuant to paragraph (1) of this subsection publicly available in a
44 deidentified and aggregate form.
- 45 (3) Nothing in this subsection shall be construed to require any
46 psilocybin service center to disclose to the department any personal
47 identifying information or health information about any individual
48 patient.

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

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

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

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

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

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

21
22 24. (New section) a. A psilocybin product manufacturer may not
23 deliver psilocybin products to any location or entity other than a
24 psilocybin product manufacturer, psilocybin service center, or
25 psilocybin testing laboratory. A psilocybin product manufacturer
26 shall not receive psilocybin products from any entity other than a
27 psilocybin product manufacturer or, as provided in paragraph (2) of
28 subsection b. of this section, a psilocybin service center.

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

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

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

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

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

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

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

24
25 25. (New section) a. The department may require a psilocybin
26 product manufacturer to test psilocybin products before selling or
27 transferring the psilocybin products to another psilocybin product
28 manufacturer or to a psilocybin service center.

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

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

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

38
39 26. (New section) a. For the purpose of tracking the
40 manufacture and administration of psilocybin products and the
41 transfer of psilocybin products between licensed premises, the
42 department shall develop a system to track the manufacture and
43 administration of psilocybin products and the transfer of psilocybin
44 products between licensed premises.

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

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

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

8 (1) the manufacture of psilocybin products;

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

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

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

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

17

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

45

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

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

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

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

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

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

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

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

30

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

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

38

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

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

- 1 (2) establish the eligibility criteria for licensure as a psilocybin
2 product manufacturer, psilocybin service center, psilocybin testing
3 laboratory, and psilocybin service facilitator and for issuance of
4 psilocybin worker permits;
- 5 (3) establish eligibility criteria to qualify for the social
6 opportunity program established pursuant to section 14 of this act
7 and the equitable access program established pursuant to section 15
8 of this act, as well as the standards and requirements for the
9 administration of those programs;
- 10 (4) establish criteria for designating areas as distressed areas for
11 the purposes of section 14 of this act;
- 12 (5) establish best practices for psilocybin product
13 manufacturers, psilocybin service centers, psilocybin testing
14 laboratories, and psilocybin service facilitators;
- 15 (6) establish health and safety standards for psilocybin product
16 manufacturers, psilocybin service centers, psilocybin testing
17 laboratories, and psilocybin service facilitators;
- 18 (7) establish the qualification, training, education, and fitness
19 standards for licensure as a psilocybin service facilitator, with
20 particular consideration of:
- 21 (a) facilitation skills that are affirming, nonjudgmental,
22 culturally competent, and nondirective;
- 23 (b) support skills for patients during an administration session,
24 including specialized skills for patient safety and patients who may
25 have a behavioral health disorder;
- 26 (c) the environment in which psilocybin services should occur;
27 and
- 28 (d) social and cultural considerations;
- 29 (8) establish the standards for approval of one or more
30 psilocybin service facilitator training courses, which shall include:
- 31 (a) requirements for training course providers to submit to the
32 department an outline of instruction that identifies the approved
33 courses, the total number of hours of instruction, the number of
34 hours of instruction in theory, and the number of hours of
35 instruction in application of practical skills;
- 36 (b) requirements for psilocybin service facilitator training
37 courses to be modular, thereby allowing the offer of both
38 comprehensive training programs and partial training programs,
39 allowing a candidate to piece together a training curriculum from
40 among the modules offered by different training programs; and
- 41 (c) allowing the core curriculum in psilocybin service facilitator
42 training to be completed in person or through distance education,
43 provided that the practical portion of the curriculum is completed in
44 person;
- 45 (9) establish or approve, a psilocybin service facilitator
46 examination, which examination shall be offered at least twice per
47 year;

- 1 (10) establish a code of professional conduct and a code of ethics
2 for psilocybin service facilitators;
- 3 (11) establish requirements for the contents, completion, and
4 retention of the psilocybin services safety screening tool and patient
5 information forms, which forms shall:
- 6 (a) solicit the information necessary for a psilocybin service
7 center operator and a psilocybin service facilitator to determine
8 whether an administration session is appropriate for the patient,
9 including information identifying patient risk factors and
10 contraindications; and
- 11 (b) solicit the information necessary for the psilocybin service
12 center operator and the psilocybin service facilitator to meet
13 applicable public health and safety standards and industry best
14 practices during the administration session;
- 15 (12) establish requirements concerning the warnings and
16 disclosures to be furnished to patients during a preparation session;
- 17 (13) establish requirements which a health care practitioner shall
18 be required to meet in order provide a patient with a referral for
19 psilocybin services under this act;
- 20 (14) establish procedures to verify and document that a patient
21 has completed a preparation session prior to initiating an
22 administration session, as well as to document that a patient has
23 completed an administration session and an integration therapy
24 session;
- 25 (15) establish standards and protocols concerning the
26 circumstances under which a psilocybin service center or psilocybin
27 service facilitator may cease to provide psilocybin services to a
28 patient after the patient has ingested a psilocybin product, which
29 standards and protocols shall include mandatory procedures to be
30 followed as are necessary to ensure the health and safety of the
31 patient;
- 32 (16) establish requirements for licensees to maintain general
33 liability insurance, if the department deems the maintenance of
34 general liability insurance to be necessary and appropriate;
- 35 (17) establish requirements for labeling psilocybin products,
36 including, as appropriate, requirements for the psilocybin product
37 label to list all product ingredients, the source of the product, the
38 age of the product, allergen warnings, and an expiration or sell by
39 date if necessary to ensure the safety or efficacy of the product, as
40 well as anticipated activation time, potency, the number of servings
41 in the product and the size of an individual serving, and any other
42 requirements as may be appropriate for specific types of psilocybin
43 products;
- 44 (18) establish requirements for psilocybin product packaging,
45 which requirements:
- 46 (a) may include different packaging requirements for different
47 types of psilocybin products;

- 1 (b) shall seek to minimize the impact of psilocybin product
2 packaging on the environment; and
- 3 (c) may require the psilocybin product packaging to include
4 child-resistant safety features;
- 5 (19) in consultation with the Department of Agriculture:
- 6 (a) develop standards for testing psilocybin products;
- 7 (b) identify appropriate tests for psilocybin products, depending
8 on the type of psilocybin product and the manner in which the
9 psilocybin product is manufactured, including, but not limited to,
10 tests for:
- 11 (i) microbiological contaminants;
- 12 (ii) pesticides;
- 13 (iii) other contaminants;
- 14 (iv) solvents or residual solvents; and
- 15 (v) psilocybin concentration;
- 16 (c) establishing procedures for determining batch sizes and for
17 sampling psilocybin products; and
- 18 (d) establishing minimum quality and safety standards specific
19 to different types of psilocybin products;
- 20 (20) establish penalties for licensees that sell or offer for sale
21 psilocybin products that include a misleading or deceptive label,
22 that include a label that fails to accurately describe the contents of
23 the psilocybin product, or that are packaged in a manner that is not
24 consistent with psilocybin product packaging requirements;
- 25 (21) establish penalties for licensees that sell or offer for sale
26 adulterated psilocybin products, as well as protocols for identifying,
27 tracking the source of, and removing from the marketplace,
28 adulterated psilocybin products;
- 29 (22) establish standards for when the department will require
30 psilocybin product manufacturers to submit proposed psilocybin
31 product labels and proposed psilocybin product packaging to the
32 department for approval prior to the label or packaging being put
33 into use, as well as reasonable fees for conducting psilocybin
34 product label and packaging approval reviews, which fees shall not
35 exceed the cost to the department of conducting the review;
- 36 (23) establish restrictions on the maximum concentration of
37 psilocybin that is permitted in a single serving of a psilocybin
38 product and the maximum number of servings that is permitted in a
39 psilocybin product package;
- 40 (24) establish requirements for reporting to the department
41 adverse events occurring during the provisions of psilocybin
42 services, including a description of any factors that likely
43 contributed to the adverse event;
- 44 (25) establish procedures for tracking and investigating adverse
45 event reports;
- 46 (26) establish requirements and restrictions concerning the
47 advertising of psilocybin services by psilocybin service centers and
48 psilocybin service facilitators; and

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

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

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

9

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

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

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

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

23 d. obstruct the enforcement of federal law; or

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

26

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

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

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

14
15 33. (New section) A professional counselor licensed pursuant to
16 Title 45 of the Revised Statutes may refer patients for psilocybin
17 services pursuant to P.L. , c. (C.) (pending before the
18 Legislature as this bill) provided that the professional counselor
19 complies with the requirements for referring patients for psilocybin
20 services established pursuant to P.L. , c. (C.) (pending
21 before the Legislature as this bill).

22
23 34. (New section) A physician licensed pursuant to Title 45 of
24 the Revised Statutes may refer patients for psilocybin services
25 pursuant to P.L. , c. (C.) (pending before the Legislature as
26 this bill) provided that the physician complies with the requirements
27 for referring patients for psilocybin services established pursuant to
28 P.L. , c. (C.) (pending before the Legislature as this bill).

29
30 35. Section 7 of P.L.1991, c.378 (C.45:9-27.16) is amended to
31 read as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3
4 36. Section 10 of P.L.1991, c.378 (C.45:9-27.19) is amended to
5 read as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26 (2) the physician assistant complies with the requirements for
27 referring patients for psilocybin services established pursuant to
28 P.L. , c. (C.) (pending before the Legislature as this bill).
29 (cf: P.L.2019, c.153, s.46)

30
31 37. Section 10 of P.L.1991, c.377 (C.45:11-49) is amended to
32 read as follows:

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

39 (1) initiating laboratory and other diagnostic tests;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 1 (4) the prescription is dated and includes the name of the patient
2 and the name, address, and telephone number of the collaborating
3 physician;
- 4 (5) the physician is present or readily available through
5 electronic communications;
- 6 (6) the charts and records of the patients treated by the advanced
7 practice nurse are periodically reviewed by the collaborating
8 physician and the advanced practice nurse;
- 9 (7) the joint protocols developed by the collaborating physician
10 and the advanced practice nurse are reviewed, updated, and signed
11 at least annually by both parties; and
- 12 (8) the advanced practice nurse has completed six contact hours
13 of continuing professional education in pharmacology related to
14 controlled substances, including pharmacologic therapy, addiction
15 prevention and management, and issues concerning prescription
16 opioid drugs, including responsible prescribing practices,
17 alternatives to opioids for managing and treating pain, and the risks
18 and signs of opioid abuse, addiction, and diversion, in accordance
19 with regulations adopted by the New Jersey Board of Nursing. The
20 six contact hours shall be in addition to New Jersey Board of
21 Nursing pharmacology education requirements for advanced
22 practice nurses related to initial certification and recertification of
23 an advanced practice nurse as set forth in N.J.A.C.13:37-7.2.
- 24 d. The joint protocols employed pursuant to subsections b. and
25 c. of this section shall conform with standards adopted by the
26 Director of the Division of Consumer Affairs pursuant to section 12
27 of P.L.1991, c.377 (C.45:11-51) or section 10 of P.L.1999, c.85
28 (C.45:11-49.2), as applicable.
- 29 e. (Deleted by amendment, P.L.2004, c.122.)
- 30 f. An attending advanced practice nurse may determine and
31 certify the cause of death of the nurse's patient and execute the
32 death certification pursuant to R.S.26:6-8 if no collaborating
33 physician is available to do so and the nurse is the patient's primary
34 caregiver.
- 35 g. An advanced practice nurse may authorize qualifying
36 patients for the medical use of cannabis and issue written
37 instructions for medical cannabis to registered qualifying patients,
38 subject to the following conditions:
- 39 (1) the collaborating physician and advanced practice nurse
40 shall address in the joint protocols whether prior consultation with
41 the collaborating physician is required to authorize a qualifying
42 patient for the medical use of cannabis or issue written instructions
43 for medical cannabis;
- 44 (2) the authorization for the medical use of cannabis or issuance
45 of written instructions for cannabis is in accordance with standing
46 orders or joint protocols developed in agreement between a
47 collaborating physician and the advanced practice nurse, or
48 pursuant to the specific direction of a physician;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

42 (8) the advanced practice nurse complies with the requirements
43 for referring patients for psilocybin services established pursuant to
44 P.L. , c. (C.) (pending before the Legislature as this bill).
45 (cf: P.L.2019, c.153, s.47)

46
47 38. (New section) A psychologist licensed pursuant to Title 45
48 of the Revised Statutes may refer patients for psilocybin services

1 pursuant to P.L. , c. (C.) (pending before the Legislature as
2 this bill) provided that the psychologist complies with the
3 requirements for referring patients for psilocybin services
4 established pursuant to P.L. , c. (C.) (pending before the
5 Legislature as this bill).
6

7 39. (New section) A clinical social worker licensed pursuant to
8 Title 45 of the Revised Statutes may refer patients for psilocybin
9 services pursuant to P.L. , c. (C.) (pending before the
10 Legislature as this bill) provided that the clinical social worker
11 complies with the requirements for referring patients for psilocybin
12 services established pursuant to P.L. , c. (C.) (pending
13 before the Legislature as this bill).
14

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