STATE OF NEW YORK

5657

2019-2020 Regular Sessions

IN SENATE

May 10, 2019

Introduced by Sen. SAVINO -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to medical marihuana

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Subdivisions 1, 5, 7 and 12 of section 3360 of the public health law, subdivisions 1, 5, 7 and 12 as added by chapter 90 of the laws of 2014, paragraph (a) of subdivision 7 as amended by chapter 273 of the laws of 2018, are amended and three new subdivisions 5-a, 5-b and 19 are added to read as follows:

1. "Certified medical use" means the acquisition, possession, use, or, transportation of medical marihuana by a certified patient, or the acquisition, possession, delivery, transportation or administration of medical marihuana by a designated caregiver, for use as part of the treatment of the patient's [~~serious~~] condition, as authorized in a certification under this title including enabling the patient to tolerate treatment for the [~~serious~~] condition. [~~A certified medical use does not include smoking.~~]

5. "Designated caregiver" means the individual **or caregiver facility** designated by a certified patient in a registry application. A certified patient may designate up to two designated caregivers**, not counting a designated caregiver facility or designated caregiver facility employee**.

5-a. "Designated caregiver facility" means an entity that registers with the commissioner to assist one or more certified patients with the acquisition, possession, delivery, transportation or administration of medical marihuana and is: a general hospital or residential health care facility operating under article twenty-eight of this chapter; an adult care facility operating under title two of article seven of the social services law; a community mental health residence established under section 41.44 of the mental hygiene law; a hospital operating under section 7.17 of the mental hygiene law; a mental hygiene facility oper-

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

LBD11129-03-9

ating under article thirty-one of the mental hygiene law; an inpatient or residential treatment program certified under article thirty-two of the mental hygiene law; a residential facility for the care and treatment of persons with developmental disabilities operating under article sixteen of the mental hygiene law; a residential treatment facility for children and youth operating under article thirty-one of the mental hygiene law; a public school or private school operating under the education law; a research institution with an internal review board; a medical marihuana research program licensed under section thirty-three hundred sixty-four-a of this title; or any other facility as determined by the commissioner in regulation.

5-b. "Designated caregiver facility employee" means an employee of a designated caregiver facility.

7. (a) [~~"Serious condition"~~] "Condition" means:

(i) having one of the following [~~severe debilitating or life-threatening~~] conditions: cancer, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, post-traumatic stress disorder, pain that degrades health and functional capability where the use of medical marihuana is an alternative to opioid use, substance use disorder, Alzheimer's, muscular dystrophy, dystonia, rheumatoid arthritis, autism, or [~~as added by the commissioner; and~~

~~(ii) any of the following conditions where it is clinically associated with, or a complication of, a condition under this paragraph or its treatment: cachexia or wasting syndrome; severe or chronic pain; severe nausea; seizures; severe or persistent muscle spasms; or such conditions as are added by the commissioner.~~

~~(b) No later than eighteen months from the effective date of this section, the commissioner shall determine whether to add the following serious conditions: Alzheimer's, muscular dystrophy, dystonia, post-traumatic stress disorder and rheumatoid arthritis~~] any other condition certified by the practitioner.

12. "Practitioner" means a practitioner who (i) [~~is a physician licensed by New York state and practicing within the state,~~] is authorized to prescribe controlled substances within the state; (ii) [~~who~~] by training or experience is qualified to treat a [~~serious~~] condition as defined in subdivision seven of this section; and (iii) [~~has completed a two to four hour course as determined by the commissioner in regulation and registered with the department; provided however, a registration shall not be denied without cause. Such course may count toward board certification requirements. The commissioner shall consider the inclusion of nurse practitioners under this title based upon considerations including access and availability. After such consideration the commissioner is authorized to deem nurse practitioners as practitioners under this title~~] completes, at a minimum, a two hour course as determined by the commissioner. A person's status as a practitioner under this title is deemed to be a "license" for purposes of section thirty-three hundred ninety of this article.

19. "Medical marihuana research program" means a medical marihuana research program licensed under section thirty-three hundred sixty-four-a of this title.

§ 2. Subdivisions 1, 2, and 9 of section 3361 of the public health law, subdivisions 1 and 2 as added by chapter 90 of the laws of 2014 and

subdivision 9 as added by chapter 416 of the laws of 2015, are amended to read as follows:

1. A patient certification may only be issued if: (a) a practitioner has been registered with the department to issue a certification as determined by the commissioner; (b) the patient has a [~~serious~~] condition, which shall be specified in the patient's health care record; (c) the practitioner by training or experience is qualified to treat the [~~serious~~] condition; (d) the patient is under the practitioner's continuing care for the [~~serious~~] condition; and (e) in the practitioner's professional opinion and review of past treatments, the patient is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical use of marihuana for the [~~serious~~] condition.

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

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

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

§ 3. Subdivisions 1 and 2 of section 3362 of the public health law, as added by chapter 90 of the laws of 2014, are amended and a new subdivision 3 is added to read as follows:

1. The possession, acquisition, use, delivery, transfer, transportation, or administration of medical marihuana by a certified patient or designated caregiver possessing a valid registry identification card, for certified medical use, shall be lawful under this title; provided that:

(a) the marihuana that may be possessed by a certified patient shall not exceed a [~~thirty~~] **sixty** day supply of the dosage as determined by the practitioner, consistent with any guidance and regulations issued by the commissioner, provided that during the last seven days of any [~~thirty~~] **sixty** day period, the certified patient may also possess up to such amount for the next [~~thirty~~] **sixty** day period;

(b) the marihuana that may be possessed by designated caregivers does not exceed the quantities referred to in paragraph (a) of this subdivision for each certified patient for whom the caregiver possesses a valid registry identification card, up to five certified patients;

(c) the marihuana that may be possessed by designated caregiver facilities does not exceed the quantities referred to in paragraph (a) of

this subdivision for each certified patient under care or treatment of the facility;

[~~(c)~~] (d) the form or forms of medical marihuana that may be possessed by the certified patient [~~or~~], designated caregiver, or designated caregiver facility pursuant to a certification shall be in compliance with any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient in the certification; and

[~~(d)~~] (e) the medical marihuana shall be kept in the original package in which it was dispensed under subdivision twelve of section thirty-three hundred sixty-four of this title, except for the portion removed for immediate consumption for certified medical use by the certified patient.

2. Notwithstanding subdivision one of this section:

(a) possession of medical marihuana shall not be lawful under this title if it is smoked, consumed, vaporized, or grown in a public place, regardless of the form of medical marihuana stated in the patient's certification.

(b) a [~~person~~] certified patient or designated caregiver possessing medical marihuana under this title shall possess his or her registry identification card at all times when in immediate possession of medical marihuana.

(c) medical marihuana may not be smoked in any place where tobacco may not be smoked under article thirteen-E of this chapter, regardless of the form of medical marihuana stated in the patient's certification.

3. The possession, acquisition, delivery, transfer, transportation, or administration of medical marihuana by a designated caregiver facility or designated caregiver facility employee shall be lawful under this title provided that:

(a) the designated caregiver facility registers with the department on a form provided by the commissioner;

(b) such possession, acquisition, delivery, transfer, transportation, or administration is on behalf of a certified patient possessing a registry identification card;

(c) the designated caregiver facility maintains a copy of the registry identification card of each certified patient for which it possesses, acquires, delivers, transfers, transports, or administers medical marihuana; and

(d) a designated caregiver facility employee shall be identified as an employee when necessary, as provided by the commissioner.

§ 4. Subdivisions 2, 3, 5, and 11 of section 3363 of the public health law, as added by chapter 90 of the laws of 2014, are amended to read as follows:

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

(a) in the case of a certified patient:

(i) the patient's certification (a new written certification shall be provided with a renewal application);

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

(iii) the date of the certification;

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

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

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

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

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

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

(ii) if the designated caregiver is a medical marihuana research program, the name of the organization conducting the research; the address, phone number, and name of the individual leading the research or appropriate designee; and other identifying information required by the department;

(c) in the case of a designated caregiver:

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

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

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

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

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

(f) [~~**a fifty dollar application fee, provided, that the department may waive or reduce the fee in cases of financial hardship; and**~~

~~**(g)**~~] any other requirements determined by the commissioner.

3. Where a certified patient is under the age of eighteen:

(a) The application for a registry identification card shall be made by an appropriate person over twenty-one years of age. The application shall state facts demonstrating that the person is appropriate.

(b) The designated caregiver shall be (i) a parent or legal guardian of the certified patient, (ii) a person designated by a parent or legal guardian, [~~**or**~~] (iii) **in the case of such a certified patient being cared for by a designated caregiver facility, the designated caregiver facility designated by the parent or legal guardian; or (iv)** an appropriate person approved by the department upon a sufficient showing that no parent or legal guardian is appropriate or available.

5. No person may be a designated caregiver for more than five certified patients at one time**; provided however that this limitation shall not apply to a designated caregiver facility or designated caregiver facility employee**.

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

§ 5. Subdivisions 3 and 5 of section 3364 of the public health law, as added by chapter 90 of the laws of 2014, are amended and a new subdivision 14 is added to read as follows:

3. Each registered organization shall contract with an independent laboratory **permitted under section thirty-three hundred sixty-four-c of this chapter** to test the medical marihuana produced by the registered organization. The commissioner shall approve the laboratory and require that the laboratory report testing results in a manner determined by the commissioner. The commissioner is authorized to issue regulation requiring the laboratory to perform certain tests and services.

5. (a) No registered organization may sell, deliver, distribute or dispense to any certified patient or designated caregiver a quantity of medical marihuana larger than that individual would be allowed to possess under this title.

(b) When dispensing medical marihuana to a certified patient or designated caregiver, the registered organization (i) shall not dispense an amount greater than a [~~thirty~~] **sixty** day supply to a certified patient until the certified patient has exhausted all but a seven day supply provided pursuant to a previously issued certification, and (ii) shall verify the information in subparagraph (i) of this paragraph by consulting the prescription monitoring program registry under section thirty-three hundred forty-three-a of this article.

(c) Medical marihuana dispensed to a certified patient or designated caregiver by a registered organization shall conform to any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient.

14. A registered organization may contract with a person or entity to provide facilities, equipment or services that are ancillary to the registered organization's functions or activities under this section (including, but not limited to, shipping, maintenance, construction, repair, and security). All laws and regulations applicable to such facilities, equipment, or services shall apply to the contract. The registered organization and other parties to the contract shall each be responsible for compliance with such laws and regulations under the contract. The commissioner may make regulations consistent with this title relating to contracts and parties to contracts under this subdivision.

§ 6. The public health law is amended by adding a new section 3364-a to read as follows:

§ 3364-a. Medical marihuana research licenses. 1. The commissioner shall establish a medical marihuana research license that permits a licensee to produce, process, purchase, possess, transfer, and sell marihuana, subject to this section, for the following limited research purposes:

(a) to test chemical potency and composition levels;

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

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

(d) to conduct genomic or agricultural research relating to medical marihuana.

2. As part of the application process for a medical marihuana research license, an applicant must submit to the commissioner a description of the research that is intended to be conducted as well as the amount of marihuana to be grown or purchased. The commissioner shall review an applicant's research project and determine whether it meets the require-

ments of subdivision one of this section. In addition, the commissioner shall assess the application based on the following criteria:

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

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

(c) whether the amount of marihuana to be grown or purchased by the applicant is consistent with the project's scope and goals.

3. If the commissioner determines that the research project meets the requirements of subdivision one of this section, the commissioner may approve the application. If not, the application shall be denied.

4. A medical marihuana research licensee may only sell or transfer marihuana grown or produced within its operation to other medical marihuana research licensees, or otherwise for purposes of the licensee's research.

5. In establishing a medical marihuana research license, the commissioner may make regulations on the following:

(a) application requirements;

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

(c) conditions for license revocation;

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

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

(f) licensee reporting requirements;

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

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

6. A marihuana research license issued under this section shall be issued in the name of the applicant or applicants, specify the location at which the marihuana researcher intends to operate, which shall be within the state, and shall not allow any other person to use the license except as under subdivision four of this section.

7. Participation by certified patients in any medical marihuana research program shall be voluntary.

8. The application fee for a medical marihuana research license shall be determined by the commissioner on an annual basis.

9. Each medical marihuana research licensee shall issue an annual report to the commissioner. The commissioner shall review such report and make a determination as to whether the research project continues to meet the research qualifications under this section.

§ 7. The public health law is amended by adding a new section 3364-b to read as follows:

§ 3364-b. Registration of designated caregiver facilities. 1. To obtain, amend or renew a registration as a designated caregiver facility, the facility shall file an application with the commissioner. The application shall include:

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

(b) operating certificate or license number where appropriate;

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

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

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

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

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

3. The application shall be approved, denied or determined incomplete or inaccurate by the commissioner within thirty days of receipt of the application. If the application is approved, the commissioner shall issue a registration as soon as is reasonably practicable.

4. Registrations under this section shall remain valid for two years from the date of issuance.

§ 8. The public health law is amended by adding a new section 3364-c to read as follows:

§ 3364-c. Laboratory permits. 1. The commissioner shall approve and permit one or more independent laboratories to test medical marihuana. To be permitted as an independent laboratory under this section, a laboratory must apply to the department in a form and manner prescribed by the commissioner and must demonstrate the following to the satisfaction of the commissioner:

(a) the owners and directors of the laboratory are of good moral character;

(b) the laboratory and its staff have the skills, resources, and expertise needed to accurately and consistently perform all testing required;

(c) the laboratory has in place and will maintain adequate policies, procedures, and facility security to ensure proper collection, labeling, accessioning, preparation, analysis, result reporting, disposal, and storage of medical marihuana;

(d) the laboratory is physically located in New York state;

(e) the laboratory has a certificate of approval as an environmental laboratory issued by the commissioner under title one of article five of this chapter; and

(f) the laboratory meets all requirements prescribed by this chapter and the commissioner in regulation.

2. The owner of an independent laboratory permitted under this section shall not hold a registration as a registered organization and shall not have any direct or indirect ownership interest in such registered organization. No board member, manager, owner, partner, principal stakeholder, or member of a registered organization, or such person's immediate family, shall have an interest or voting rights in any independent laboratory permittee. No registered organization shall have any direct or indirect ownership interest in such laboratory.

3. An independent laboratory shall not be required to be licensed by the federal drug enforcement administration.

§ 9. Subdivision 9 of section 3365 of the public health law, as added by chapter 90 of the laws of 2014, is amended to read as follows:

9. [~~The commissioner shall register no more than five~~] A registered [~~organizations~~] organization that [~~manufacture~~] manufactures medical marihuana [~~with~~] may have no more than [~~four~~] eight dispensing sites wholly owned and operated by [~~such~~] the registered organization. The commissioner shall ensure that such [~~registered organizations and~~] dispensing sites are geographically distributed across the state. The

commission [~~may~~] **shall** register additional registered organizations **reflecting the demographics of the state**.

§ 10. Subdivision 1 of section 3365-a of the public health law, as added by chapter 416 of the laws of 2015, is amended to read as follows:

1. There is hereby established in the department an emergency medical marihuana access program (referred to in this section as the "program") under this section. The purpose of the program is to expedite the availability of medical marihuana to avoid suffering and loss of life, during the period before full implementation of and production under this title, especially in the case of patients whose [~~serious~~] condition is progressive and degenerative or is such that delay in the patient's medical use of marihuana poses a serious risk to the patient's life or health. The commissioner shall implement the program as expeditiously as practicable, including by emergency regulation.

§ 11. Subdivision 1 of section 3369 of the public health law, as added by chapter 90 of the laws of 2014, is amended to read as follows:

1. Certified patients, designated caregivers, **designated caregiver facilities, designated caregiver facility employees, medical marihuana research program employees,** practitioners, registered organizations and the employees of registered organizations shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for the certified medical use or manufacture of marihuana, or for any other action or conduct in accordance with this title.

§ 12. Section 3369-d of the public health law, as added by chapter 90 of the laws of 2014, is amended to read as follows:

§ 3369-d. Pricing. [~~1. Every sale of medical marihuana shall be at the price determined by the commissioner. Every charge made or demanded for medical marihuana not in accordance with the price determined by the commissioner, is prohibited.~~

~~2. The commissioner is hereby authorized to set the per dose price of each form of medical marihuana sold by any registered organization. In setting the per dose price of each form of medical marihuana, the commissioner shall consider the fixed and variable costs of producing the form of marihuana and any other factor the commissioner, in his or her discretion, deems relevant to determining the per dose price of each form of medical marihuana.~~] **Registered organizations shall submit documentation of any price and change in price per dose for any medical marihuana product to the commissioner within fifteen days of setting or changing the price. Prior approval by the commissioner shall not be required for any price or change of price. However, the commissioner is authorized to modify the price per dose for any medical marihuana product if necessary to maintain public access to appropriate medication.**

§ 13. This act shall take effect immediately; provided, however, that the amendments to title 5-A of article 33 of the public health law made by sections one, two, three, four, five, six, seven, eight, nine, ten, eleven and twelve of this act shall not affect the repeal of such title and shall be deemed repealed therewith. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such effective date.