S T A T E O F N E W Y O R K

7476

2015-2016 Regular Sessions

I N A S S E M B L Y

May 13, 2015

Introduced by M. of A. GOTTFRIED -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to medical use of marihuana; and repealing certain provisions of such law relating thereto

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Legislative findings and intent. The legislature finds that thousands of New Yorkers have serious medical conditions that can be improved by medically-approved use of marihuana. The law should not stand between them and treatment necessary for life and health. This legislation follows the well-established public policy that a controlled substance can have a legitimate medical use. Many controlled substances that are legal for medical use (such as morphine and steroids) are illegal for any other use. The purposes of article 33 of the public health law include allowing legitimate medical use of controlled substances in health care, including palliative care.

Title 5-A of article 33 of the public health law, and the amendments to it in this act, establish a medical model of care which regulates medical marihuana as a recommended medicine in keeping with recognized medical public health and safety standards. This policy and this legislation do not in any way diminish New York state's strong public policy and laws against illegal drug use, nor should it be deemed in any manner to advocate, authorize, promote, or legally or socially accept the use of marihuana for children or adults, for any non-medical use. This legislation is an appropriate exercise of the state's legislative power to protect the health of its people under article 17 of the state constitution and the tenth amendment of the United States constitution.

Furthermore, the legislature finds that New York state has a significant and ongoing economic and non-regulatory interest in the financial viability of organizations that sell marihuana for medical use. The

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

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legislature finds that the financial viability of such organizations would be greatly diminished and threatened by labor-management conflict, such as a strike at a facility that cultivates marihuana, especially because of the need for enhanced security concerning the products. Replacements during a strike would be difficult to arrange and cause delay far more significant than a strike elsewhere. Accordingly, the legislature finds that the state has a substantial and compelling proprietary interest in this matter, and finds that labor peace is essential for any organization to conduct business relating to the sale of medical marihuana.

It is the legislative intent that this act be implemented consistently with these findings and principles, through a reasonable and workable system with appropriate oversight; strong "seed to sale" regulation to prevent diversion, abuse, and other illegal conduct; reasonable access to and appropriate use of medical marihuana by certified patients; evaluation; and continuing research.

S 2. Subdivisions 1, 7, 8, 12 and 15 of section 3360 of the public health law, as added by chapter 90 of the laws of 2014, are amended 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.]

7. [(a)] "Serious 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, ALZHEIMER'S DISEASE, TRAUMATIC BRAIN INJURY, DYSTONIA, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, WASTING SYNDROME, CROHN'S DISEASE, POST TRAUMATIC STRESS DISORDER, RHEUMATOID ARTHRITIS, LUPUS, inflammatory bowel disease, neuropathies, Huntington's disease, 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.]

8. "Medical marihuana" means marihuana as defined in subdivision twenty-one of section thirty-three hundred two of this article, intended for a certified medical use[, as determined by the commissioner in his or her sole discretion. Any form of medical marihuana not approved by the commissioner is expressly prohibited].

12. "Practitioner" means a practitioner who (i) is a physician, PHYSICIAN ASSISTANT OR NURSE PRACTITIONER, licensed OR CERTIFIED by New York state and practicing within the state, ACTING WITHIN HIS OR HER LAWFUL SCOPE OF PRACTICE; (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.]

15. "Individual dose" means a single measure of raw medical marihuana or non-infused concentrates to be determined and clearly identified by a patient's practitioner for the patient's specific certified condition. [For ingestible or sub-lingual medical marihuana products, no individual dose may contain more than ten milligrams of tetrahydrocannabinol.]

S 3. Subdivision 10 of section 3363 of the public health law, as added by chapter 90 of the laws of 2014, is amended to read as follows:

10. A registry identification card shall:

(a) contain the name of the certified patient or the designated caregiver as the case may be;

(b) contain the date of issuance and expiration date of the registry identification card;

(c) contain a registry identification number for the certified patient or designated caregiver, as the case may be and a registry identification number;

(d) contain a photograph of the individual to whom the registry identification card is being issued, which shall be obtained by the department in a manner specified by the commissioner in regulations; provided, however, that if the department requires certified patients to submit photographs for this purpose, there shall be a reasonable accommodation of certified patients who are confined to their homes due to their medical conditions and may therefore have difficulty procuring photographs;

(e) be a secure document as determined by the department;

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

(g) any other requirements determined by the commissioner IN REGULATIONS.

S 4. Subdivisions 4, 6 and 13 of section 3364 of the public health law, as added by chapter 90 of the laws of 2014, are amended and two new subdivisions 14 and 15 are added to read as follows:

4. (a) A registered organization may lawfully, in good faith, sell, deliver, distribute or dispense medical marihuana to a certified patient or designated caregiver upon presentation to the registered organization of a valid registry identification card for that certified patient or designated caregiver. When presented with the registry identification card, the registered organization shall provide to the certified patient or designated caregiver a receipt, which shall state: the name, address, and registry identification number of the registered organization; the name and registry identification number of the certified patient and the designated caregiver (if any); the date the marihuana was sold; any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient; and the form and the quantity of medical marihuana sold. The registered organization shall retain a copy of the registry identification card and the receipt for six years.

(b) The [proprietor of a] registered organization shall file or cause to be filed any receipt and certification information with the department by electronic means on a real time basis as the commissioner shall require by regulation. When filing receipt and certification information electronically pursuant to this paragraph, the proprietor of the registered organization shall dispose of any electronically recorded prescription information in such manner as the commissioner shall by regulation require.

6. When a registered organization sells, delivers, distributes or dispenses medical marihuana to a certified patient or designated caregiver, it shall provide to that individual a safety insert, which will be developed and approved by the commissioner and include, but not be limited to, information on:

(a) methods for administering medical marihuana in individual doses,

(b) any potential dangers stemming from the use of medical marihuana,

(c) how to recognize what may be problematic usage of medical marihuana and obtain appropriate services or treatment for problematic usage, and

(d) other information as determined by the commissioner IN REGULATIONS.

13. The commissioner is authorized to make [rules and] regulations restricting the advertising and marketing of medical marihuana, which shall be consistent with the federal regulations governing prescription drug advertising and marketing.

14. A REGISTERED ORGANIZATION MAY CONTRACT WITH A PERSON OR ENTITY TO PROVIDE FACILITIES, EQUIPMENT OR SERVICES THAT ARE PART OF OR INCIDENTAL TO THE REGISTERED ORGANIZATION'S FUNCTIONS OR ACTIVITIES UNDER THIS SECTION. ALL LAWS AND REGULATIONS APPLICABLE TO THE REGISTERED ORGANIZATION SHALL APPLY TO THE CONTRACT. THE REGISTERED ORGANIZATION AND OTHER PARTIES TO THE CONTRACT SHALL EACH BE RESPONSIBLE AND ACCOUNTABLE 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.

15. A REGISTERED ORGANIZATION MAY LAWFULLY, IN GOOD FAITH, SELL, DELIVER, OR DISTRIBUTE MEDICAL MARIHUANA TO A REGISTERED ORGANIZATION, IN ACCORDANCE WITH THE REGISTRATION OF BOTH REGISTERED ORGANIZATIONS.

S 5. Subdivisions 1, 3, 8 and 9 of section 3365 of the public health law, as added by chapter 90 of the laws of 2014, are amended to read as follows:

1. Application for initial registration. (a) An applicant for registration as a registered organization under section thirty-three hundred sixty-four of this title shall include such information prepared in such manner and detail as the commissioner may require, including but not limited to:

(i) a description of the activities in which it intends to engage as a registered organization;

(ii) that the applicant:

(A) is of good moral character;

(B) possesses or has the right to use sufficient land, buildings, and other premises (which shall be specified in the application) and equipment to properly carry on the activity OR ACTIVITIES described in the application, or in the alternative posts a bond of not less than two million dollars;

(C) is able to maintain effective security and control to prevent diversion, abuse, and other illegal conduct relating to the marihuana;

(D) is able to comply with all applicable state laws and regulations relating to the activities in which it intends to engage under the registration;

(iii) that the applicant has entered into a labor peace agreement with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees. The maintenance of such a labor peace agreement shall be an ongoing material condition of certification.

(iv) the applicant's status under subdivision one of section thirty-three hundred sixty-four of this title; and

(v) the application shall include the name, residence address and title of each of the officers and directors and the name and residence address of any person or entity that is a member of the applicant. Each such person, if an individual, or lawful representative if a legal entity, shall submit an affidavit with the application setting forth:

(A) any position of management or ownership during the preceding ten years of a ten per centum or greater interest in any other business, located in or outside this state, manufacturing or distributing drugs;

(B) whether such person or any such business has been convicted of a felony or had a registration or license suspended or revoked in any administrative or judicial proceeding; and

(C) such other information as the commissioner may reasonably require.

3. Granting of registration. (a) The commissioner shall grant a registration or amendment to a registration under this section if he or she is satisfied that:

(i) the applicant will be able to maintain effective control against diversion of marihuana;

(ii) the applicant will be able to comply with all applicable state laws;

(iii) the applicant and its officers are ready, willing and able to properly carry on the manufacturing or distributing activity for which a registration is sought;

(iv) the applicant possesses or has the right to use sufficient land, buildings and equipment to properly carry on the activity OR ACTIVITIES described in the application;

(v) it is in the public interest that such registration be granted; the commissioner may consider whether the number of registered organizations in an area will be adequate or excessive to reasonably serve the area;

(vi) the applicant and its managing officers are of good moral character;

(vii) the applicant has entered into a labor peace agreement with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees; and

(viii) the applicant satisfies any other conditions as determined by the commissioner.

(b) If the commissioner is not satisfied that the applicant should be issued a registration, he or she shall notify the applicant in writing of those factors upon which further evidence is required. Within thirty days of the receipt of such notification, the applicant may submit additional material to the commissioner or demand a hearing, or both.

(c) The fee for a registration under this section shall be a reasonable amount determined by the department in regulations; provided, however, if the registration is issued for a period greater than two years the fee shall be increased, pro rata, for each additional month of validity.

(d) Registrations issued under this section shall be effective only for the registered organization and shall specify:
(i) the name and address of the registered organization;
(ii) which activities of a registered organization are permitted by the registration;
(iii) the land, buildings and facilities that may be used for the permitted activities of the registered organization; and
(iv) such other information as the commissioner shall reasonably provide to assure compliance with this title.
(e) Upon application of a registered organization, a registration may be amended to allow the registered organization to relocate within the state or to add or delete permitted registered organization activities or facilities. The fee for such amendment shall be two hundred fifty dollars.
8. The department shall begin issuing registrations for registered organizations as soon as practicable after the [certifications] CERTIFICATION required by section thirty-three hundred sixty-nine-b of this title [are] IS given.
9. The commissioner shall register [no more than five] registered organizations [that manufacture medical marihuana with no more than four dispensing sites wholly owned and operated by such registered organization] AND FACILITIES TO PROMOTE REASONABLE ACCESS TO MEDICAL MARIHUANA IN THE INTEREST OF CERTIFIED PATIENTS AND THE PUBLIC. DURING THE FIRST TWO YEARS AFTER THIS TITLE TAKES EFFECT, THE COMMISSIONER SHALL REGISTER NO MORE THAN TWENTY REGISTERED ORGANIZATIONS THAT MANUFACTURE MEDICAL MARIHUANA. The commissioner shall ensure that [such] registered organizations and dispensing sites are geographically distributed across the state AND SHALL NOT REQUIRE THAT DISPENSING SITES BE OWNED OR OPERATED BY THE REGISTERED ORGANIZATION LICENSED TO MANUFACTURE MEDICAL MARIHUANA. [The commission may register additional registered organizations.]
S 6. Section 3369 of the public health law is amended by adding a new subdivision 5 to read as follows:
5. A REGISTRY IDENTIFICATION CARD, OR ITS EQUIVALENT, THAT IS ISSUED UNDER THE LAWS OF ANOTHER STATE, DISTRICT, TERRITORY, COMMONWEALTH, OR POSSESSION OF THE UNITED STATES THAT ALLOWS THE MEDICAL USE OF MARIHUANA HAS THE SAME FORCE AND EFFECT AS A REGISTRY IDENTIFICATION CARD ISSUED BY THE DEPARTMENT, SO LONG AS THE VISITING PATIENT'S CONDITION IS A SERIOUS CONDITION, AS ATTESTED TO IN WRITING BY A PRACTITIONER. WHERE A REGISTERED ORGANIZATION DISPENSES MEDICAL MARIHUANA TO A PATIENT UNDER THIS SUBDIVISION, A COPY OF THE ATTESTATION SHALL BE PROVIDED TO THE REGISTERED ORGANIZATION.
S 7. Section 3369-a of the public health law, as added by chapter 90 of the laws of 2014, is amended to read as follows:
S 3369-a. Regulations. 1. The commissioner shall make regulations to implement this title. REGULATIONS UNDER THIS TITLE SHALL BE REASONABLE AND CONSISTENT WITH THIS TITLE, THE LEGISLATIVE INTENT, AND VERIFIABLE CLINICAL, LEGAL OR PUBLIC SAFETY CONSIDERATIONS.
2. THERE IS HEREBY ESTABLISHED IN THE DEPARTMENT AN ADVISORY COMMITTEE ON MEDICAL USE OF MARIHUANA (THE "ADVISORY COMMITTEE") TO ADVISE THE COMMISSIONER ON MAKING REGULATIONS UNDER THIS TITLE AND ON ANY MATTERS RELATING TO THE IMPLEMENTATION OF THIS TITLE AS THE COMMISSIONER SHALL DETERMINE. THE ADVISORY COMMITTEE SHALL CONSIST OF FIFTEEN MEMBERS. THE MEMBERS OF THE ADVISORY COMMITTEE SHALL BE APPOINTED AS FOLLOWS: EIGHT TO BE APPOINTED BY THE GOVERNOR, TWO TO BE APPOINTED BY THE GOVERNOR ON THE RECOMMENDATION OF THE TEMPORARY PRESIDENT OF THE SENATE, ONE TO BE

APPOINTED BY THE GOVERNOR ON THE RECOMMENDATION OF THE MINORITY LEADER OF THE SENATE, TWO TO BE APPOINTED BY THE GOVERNOR ON THE RECOMMENDATION OF THE SPEAKER OF THE ASSEMBLY, ONE TO BE APPOINTED BY THE GOVERNOR ON THE RECOMMENDATION OF THE MINORITY LEADER OF THE ASSEMBLY, AND ONE TO BE APPOINTED BY THE GOVERNOR ON THE RECOMMENDATION OF THE ATTORNEY GENERAL OF THE STATE OF NEW YORK. THE ADVISORY COMMITTEE SHALL INCLUDE BUT NOT BE LIMITED TO: HEALTH CARE PRACTITIONERS, PATIENTS OR REPRESENTATIVES OF PATIENTS WITH SERIOUS CONDITIONS, EXPERTS IN THE REGULATION OF CONTROLLED SUBSTANCES FOR MEDICAL USE, MEDICAL MARIHUANA INDUSTRY PROFESSIONALS AND LAW ENFORCEMENT. THE ADVISORY COMMITTEE SHALL BE RESPONSIBLE FOR REVIEWING THE APPEAL OF ANY PATIENT OR CAREGIVER WHOSE REGISTRY APPLICATION HAS BEEN DENIED BY THE DEPARTMENT. THE ADVISORY COMMITTEE SHALL MAKE RECOMMENDATIONS REGARDING ANY SUCH APPEAL TO THE COMMISSIONER, WHO SHALL MAKE THE FINAL DETERMINATION. THE COMMISSIONER MAY ALSO FORM SUBCOMMITTEES OF THE ADVISORY COMMITTEE. THE COMMISSIONER SHALL FORM A SUBCOMMITTEE TO ASSIST AND ADVISE THE COMMISSIONER AND THE ADVISORY COMMITTEE ON CLINICAL MATTERS RELATING TO MEDICAL MARIHUANA, INCLUDING BUT NOT LIMITED TO EXPANDING OR RETRACTING THE CATEGORIES OF DISEASES TO BE CONSIDERED SERIOUS CONDITIONS FOR PURPOSES OF THIS TITLE, THE MEMBERS OF WHICH SHALL PREDOMINANTLY BE CLINICAL PROFESSIONALS IN APPROPRIATE AREAS OF EXPERTISE AND SHALL ALSO INCLUDE REPRESENTATIVES OF PATIENTS AND THE GENERAL PUBLIC. MEMBERS OF A SUBCOMMITTEE NEED NOT BE MEMBERS OF THE ADVISORY COMMITTEE. MEMBERS OF THE ADVISORY COMMITTEE SHALL SERVE FOR A TERM OF FOUR YEARS. MEMBERS OF A SUBCOMMITTEE SHALL SERVE AT THE PLEASURE OF THE COMMISSIONER. MEMBERS OF THE ADVISORY COMMITTEE OR A SUBCOMMITTEE MAY RECEIVE REIMBURSEMENT BY THE DEPARTMENT FOR THEIR REASONABLE AND NECESSARY EXPENSES INCURRED AS MEMBERS OF THE ADVISORY COMMITTEE OR A SUBCOMMITTEE. A PUBLIC EMPLOYEE MAY BE A MEMBER OF THE ADVISORY COMMITTEE OR A SUBCOMMITTEE.

S 8. Section 3369-b of the public health law, as added by chapter 90 of the laws of 2014, is amended to read as follows:

S 3369-b. Effective date. Registry identification cards or registered organization registrations shall be issued or become effective no later than eighteen months from signing or until such time as the commissioner [and the superintendent of state police certify] CERTIFIES that this title can be implemented in accordance with public health and safety interests, whichever event comes later.

S 9. Sections 3369-c and 3369-d of the public health law are REPEALED and section 3369-e is renumbered section 3369-c.

S 10. This act shall take effect immediately; provided that the amendments to title 5-a of article 33 of the public health law made by sections two through nine of this act shall not affect the expiration and repeal of such title and shall expire and be deemed repealed therewith.