Medical Marijuana in New York State: Overview

New York State Association of Counties

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Compassionate Care Act

On July 7, 2014 Governor Cuomo signed the Compassionate Care Act. The function of this statute is to create the State’s first medical marijuana program. The Act regulates the manufacturing, sale and use of medical marijuana. This law is designed to relieve pain and suffering from those who are suffering serious disease, while providing restrictions that protect the public. The law was written to maintain discretion for physicians to prescribe medical marijuana in accordance with regulatory requirements set forth by the State Department of Health (DOH) Commissioner.

The DOH allowed for a public comment period which began in October of 2014, and issued proposed regulations on December 31, 2014. The regulations were finalized on March 31, 2015 and were formally adopted on April 15, 2015.

On April 27, 2015, the DOH made an announcement that the Department will begin accepting applications from businesses that are interested in becoming registered organizations to manufacture and dispense medical marijuana under the Compassionate Care Act.

- Application Window Open 4/27/2015
- Deadline for Submission of Application Questions 5/05/2015
- Deadline for Department Response to Application Questions 5/21/2015
- Deadline for Department Receipt of Applications 6/5/2015
- Registrations Issued July 2015

Overview

Patient Eligibility
Medical marijuana will be made available for those who receive a Registry Identification Card issued by the Department of Health. The patient will then have to go to a physician that has been certified by the DOH to prescribe medical marijuana as a form of treatment.

The serious conditions for which medical marijuana can be prescribed include: cancer, HIV/AIDS, Amyotrophic Lateral Sclerosis (ALS), Parkinson’s Disease, Multiple Sclerosis, damage to nerve tissue of the spinal cord with neurological indication on intractable spasticity, inflammatory bowel disease, neuropathies, and Huntington’s Disease, as well as any additional condition authorized by the DOH Commissioner.

Administration of Medical Marijuana
The law puts into place a process for patients to obtain, and manufactures to dispense, medical marijuana. Organizations seeking to manufacture or distribute medical marijuana must be registered with the DOH and conform to a list of requirements. The law allows for five registered organizations to operate up to four dispensaries statewide. In order to ensure patient access, dispensing facilities will be geographically dispersed throughout the state. Licenses will be valid for two years.
All manufacturing and dispensing of medical marijuana will take place in New York State. Registered organizations will be able to dispense medical marijuana to individuals who present a registry identification card. The organization will not be able to dispense more than a 30-day supply.

**Distribution of Tax**
The law puts in place a 7 percent excise tax on every sale of medical marijuana by a registered organization to a certified patient or designed caregiver. Proceeds from the excise tax will be collected in a special account managed by the State Comptroller. The Comptroller will then allocate the revenue in the following manner: 22.5% to the county where the medical marijuana was manufactured; 22.5% to the county in the State where the medical marijuana was dispensed; 5% to the State Office of Alcoholism and Substance Abuse Services to be used for additional drug abuse prevention, counseling, and treatment services; and 5% to the Division of Criminal Justice Services to support law enforcement measures related to this law.

**Criminal Penalties for Abuse of Medical Marijuana**
The law makes it a Class E felony for a practitioner to certify an individual is eligible to facilitate the possession of medical marijuana if he or she knows or reasonably should know the person who has no need for it. The law also makes it a misdemeanor for recipients of medical marijuana to sell or trade the medical marijuana, or retain beyond what is needed for treatment for their own use.

**Medical Marijuana Regulations**

**Practitioners**
A physician must have a current license to practice in New York State and be qualified to treat any of the ten serious conditions. In order to prescribe medical marijuana, the doctor must complete a four-hour course that address methods of prescribing medical marijuana, usage and other related factors. Once the practitioner has provided the appropriate information and completed the course work they will be registered by the DOH to issue patient certifications.

Physicians are required to consult the Prescription Drug Monitoring Program registry (PDMP) to review the patient’s controlled substance history prior to making or issuing a patient certification.

**Certified Patient**
Individuals applying for certified patient registrations with the DOH must be:
- a resident of New York State,
- undergoing treatment in New York for the condition for which they are seeking medical marijuana,
- cared for by a New York physician who has registered with DOH to prescribe medical marijuana,
- under that doctor’s care for the condition for which they are seeking medical marijuana,
- certified by the doctor to receive therapeutic or palliative benefit from medical marijuana; and
- diagnosed with a “serious condition,” as defined by the law.
The patient must have a certification issued by a registered practitioner, the certification will include patient information and diagnosis. Certification expires after one year from the date the doctor signs it, or the doctor can specify an earlier termination date. No patient or caregiver can legally possess more than a 30 day supply as determined by the practitioner and consistent with any DOH regulations. Patients will be able to refill their medical marijuana prescription during the last 7 days of their 30-day supply.

Registered Organizations

A registered organization shall be a for-profit business entity or not-for-profit corporation organized for the purpose of acquiring, possessing, manufacturing, selling, delivering, transporting, distributing or dispensing medical marijuana for certified use. The application must contain the chief executive officer’s information; identification of manufacturing facilities; identification of manufacturing equipment; standard operating procedures; quality assurance plans; company’s organization system; labor peace agreement information; financial statements; dispensing information; construction timeline; corporate subsidiaries; staffing information (all staff members must be over 21); and staff members with knowledge of good agricultural practices (GAP).

Applications must include a non-refundable fee of $10,000. The registration fee for the registration period shall be $200,000 via certified check. The registration fee will be returned if the applicant is not given a registration.

Once the DOH has registered an organization the registration will be valid for two years from the date of issuance. Registrations are non-transferable and may be revoked by the DOH if there is a failure to operate to the satisfaction of the commissioner.

Registered organizations must:
• have sufficient facilities and land or a bond of $2 million,
• comply with all state laws,
• enter into a labor peace agreement,
• provide accounting information for both manufacturing and dispensing facilities,
• manufacture and dispense approved medical marijuana products,
• maintain compliance information,
• maintain information regarding soil, hydroponic materials, fertilizers and pesticides,
• create laboratory testing availability; and
• dispose of unusable items properly.

Registered organizations shall not:
• dispense marijuana from the same location as it is manufactured,
• grow or manufacture marijuana at any site other than the approved manufacturing facility,
• distribute products or samples at no cost,
• change composition of the registered organization,
• modify operating plans; or
• operate a dispensary within 1000 feet of a school and/or a place of worship.
Manufacturing Medical Marijuana

Manufacturing shall include but not be limited to the cultivation, harvesting, extraction, packaging, and labeling of medical marijuana. In the manufacturing process, the organization must use good agricultural practices, use water from a public water supply, and use pesticides authorized by the Department of Agriculture and Markets.

The Department of Health regulations specify that “approved medical marijuana products” are the final manufactured products delivered to the patient that represents a specific brand with a defined cannabinoid content and active and inactive ingredients, and be prepared in a specific dosage form to be administered by a practitioner.

The DOH regulations allow that each registered organization may produce up to five brands of medical marijuana products that have a specific concentration of Tetrahydrocannabinol (THC) and Cannabidiol (CBD), which will be demonstrated by the registered organization through laboratory testing. Smoking is not an approved route of administration. The registered organization’s dispensing locations should ONLY offer the following forms for administration.

- Liquid and oil preparations for administration with the use of a tube
- Metered liquid or oil preparations for vaporization
- Capsules
- Edible food products must be approved by the DOH commissioner

All medical marijuana items will be packaged at the manufacturing site and contain information regarding: manufacture, type of item, THC and CBD content, quantity of items in package, date or packaging, expiration as well as, storage and safety requirements.

Dispensaries for Medical Marijuana

A dispensary must have a New York State licensed pharmacist on the premises whenever it is open for business. Pharmacists employed in dispensing facilities are required to complete the four-hour educational course.

Dispensing facilities must:
- Only sell items approved by the DOH,
- Only sell items to certified patients and caregivers,
- Not distribute more than a 30-day supply of the approved item,
- Maintain a visitor log,
- Not allow use at the facility;
- Have a security cameras, maintain 24-hour footage, alarm capability, and panic procedures.

Pricing

The price of the medical marijuana shall be the cost to manufacture, market, and distribute approved medical marijuana products plus reasonable profit. The DOH shall set the per unit
price of each form of approved medical marijuana product sold based on their analysis of information provided to them by registered organizations.

Once the DOH has determined an approved price, the price shall remain in effect for the entire period of the registered organizations registration. Health insurers will not be required to provide coverage for medical marijuana.

**Requirements for Labelling, Packaging & Advertising**

All registered organization and dispensaries must:

- Secure and properly label all medical marijuana,
- Include warning labels on packaging,
- Determine and provide information on the clinical strength of marijuana.