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HEALTH LAW

Expert Analysis

A Primer on New York's Medical Marijuana Law

fter many years of efforts by patients, families, physicians, elected officials, and other advocates, New York's Legislature passed a bill¹ permitting the use of marijuana for medical purposes. Governor Andrew Cuomo signed the bill into law on July 5, 2014, adding New York to the more than 20 states that have enacted some form of law permitting medical marijuana.

Known as the Compassionate Care Act, the new law is very carefully crafted and appears to address many of the medical, social, economic and law enforcement aspects of the medical marijuana issue. This article will highlight the most significant parts of this complex new law. The substantive provisions are contained in a new Title V-A to Article 33 of the New York Public Health Law (PHL), but it also adds new provisions to the Tax, Finance and Penal Laws.

No Smoking

Patients who are prescribed medical marijuana will receive it only in pill form or by way of inhaling a vapor. The law does not permit possession or use of smokeable marijuana for a medical or any other purpose. The possession, use or sale of smokeable marijuana is still a criminal offense under New York Penal Law Article 221.

Medical Conditions

The new law will allow prescriptions for medical marijuana only for defined "severe debilitating or life-threatening" medical conditions ("Serious Condition"):

- Cancer
- HIV/AIDS
- Amyotrophic lateral sclerosis (Lou Gehrig's Disease)
- Parkinson's Disease
- Multiple sclerosis

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- Spinal cord damage or injury
- Epilepsy
- Inflammatory bowel disease
- Neuropathics
- Huntington's Disease
- Such other conditions as may be added by the Commissioner of the Department of Health.

Medical marijuana may also be prescribed for medical conditions that are clinically associated with or a complication of a Serious Condition, or treatment of a Serious Condition, including:

- Cachexia (severe wasting syndrome)
- Severe or chronic pain
- Severe nausea
- Seizures
- Severe or persistent muscle spasms
- Such other conditions as may be added by the Health Commissioner.

Thus, medical marijuana cannot be prescribed merely for chronic pain or nausea, but only if the pain or nausea is caused by a Serious Condition or arises as an effect of its treatment.

The law authorizes the Health Commissioner—within 18 months of the effective date of the law—to determine whether to add the following to the definition of a Serious Condition:

- Alzheimer's Disease
- Muscular dystrophy
- Dystonia
- Post-traumatic stress disorder
- Rheumatoid arthritis

Who Can Prescribe

The law limits the ability to prescribe medical marijuana to physicians licensed by and practic-

ing within New York State, who are by training or experience qualified to treat the specified Serious Conditions, have completed a two-to-four hour course (as set forth in regulations to be promulgated by the Health Commissioner), and have been registered with the Health Department. The law requires the Health Commissioner to consider including nurse practitioners along with physicians as registered prescribers of medical marijuana.

Patients will be certified to use medical marijuana only if the prescription is issued by a Health Department-registered practitioner, the patient has a Serious Condition which is documented in the patient's medical record, the patient is under the practitioner's continuing care for the Serious Condition, and 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 adjunct treatment of the Serious Condition with medical marijuana. Certification of the patient must include:

- The patient's name, address and date of birth;
- A statement that the patient has a Serious Condition and is under the practitioner's care for same:
- A statement attesting that the patient has met all of the above criteria for certification;
- The date; and
- The name, address, federal registration number, telephone number, and handwritten signature of the certifying practitioner.

The practitioner is authorized to state a professional opinion that the patient would benefit from medical marijuana only until a specified date; or if the patient is terminally ill, until the patient dies. The practitioner must include in the certification any recommendation or limitation in his or her professional opinion on the appropriate form and dosage of medical marijuana.

The practitioner (or an appropriate designee) must consult the New York Prescription Monitoring Drug Program Registry to review a patient's controlled substance history prior to making or issuing a certification for medi-

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cal marijuana. The practitioner must give the certification to the patient and keep a copy of the certification in the patient's medical record.

The Health Department will issue the patient (or designated caregiver) a registry identification card that will expire no later than one year after the date the certification is signed by the practitioner. However, if the practitioner specifies an earlier date, the card will reflect the earlier date. If the practitioner specifies that the patient is terminally ill and the certification will not expire until the patient dies, then the card will reflect this and will not expire until the patient dies.

The registry identification card issued by the Health Department will contain the name of the patient (or designated caregiver), photo, date of issuance and expiration, registry identification number, and any recommendation on limitation by the practitioner. The Health Department database of those issued such cards will be confidential and exempt from Freedom of Information Law requirements.

Possession of Dosage

A certified patient may possess up to a 30-day supply of the prescribed dosage of medical marijuana, but during the last seven days of a 30-day period, may also possess the next 30-day supply of the dosage. Medical marijuana in the possession of a designated caregiver may not exceed what the certified patient is authorized to possess, and a designated caregiver may only possess medical marijuana for up to a maximum of five certified patients. Anyone with authorized possession of medical marijuana must carry his/her registry identification card when in such possession.

Medical marijuana must be kept in the original package in which it was dispensed. The law prohibits medical marijuana from being "smoked, consumed, vaporized or grown" in a public place.

Manufacturers, Dispensers

The law creates a category of Registered Organizations (RO), which can be for-profit or not-for-profit corporations, for entities organized for the purpose of acquiring, possessing, manufacturing, selling, delivering, transporting, distributing or dispensing marijuana for medical use. An applicant wishing to be designated as an RO must:

- Provide a description of its proposed activities as an RO;
- Demonstrate good moral character;
- Possess or have the right to use land, buildings or other premises, and equipment to properly carry out its activities, or post a bond of \$2 million;
- Demonstrate that it has the ability to maintain effective security and control to prevent diversion, abuse, and other illegal conduct relating to the marijuana;
- Demonstrate its ability to comply with

applicable state laws and regulations;

- Enter into and maintain in effect a labor peace agreement with a bona fide labor organization to represent the RO's employees; and
- Identify the name, residence address and title of each officer and director, and any person or entity that is a member of the RO.

The law limits the number of ROs with dispensing sites in New York to five, with no more than four dispensing sites wholly owned and operated by each RO. These must be geographically distributed throughout the state. The Health Commissioner is authorized to register additional ROs that do not have dispensing sites.

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An RO producing medical marijuana must contract with an independent laboratory, approved by the Health Commissioner, to test its product. The test results are to be reported to the Health Commissioner, who is authorized to issue regulations setting forth the tests and services to be performed by the laboratory.

Medical marijuana may be dispensed to a patient or caregiver only upon presentation of that person's registry identification card. Along with the medical marijuana, the RO must issue a receipt containing the RO's name, address and identification number; the name, address and identification number of the certified patient or caregiver; the date of sale; any practitioner recommendation or limitation as to the form or dosage of the marijuana; and the form and quantity of marijuana sold. The RO must keep copies of these receipts in its records for six years.

The RO also has to include a safety insert in each dose of marijuana dispensed. The form of the insert will be developed by the Health Commissioner and must include information on:

- Methods for administering marijuana in individual doses;
- Any potential dangers stemming from the use of medical marijuana;
- How to recognize problematic usage of marijuana and how to obtain appropriate services as treatment for problematic usage; and
- Such other information as determined by the Health Commissioner.

The law prohibits the RO from employing a person who has been convicted of any felony for sale or possession of drugs, narcotics or controlled substances. This prohibition applies to managers or employees who come into con-

tact with or handle medical marijuana if their conviction occurred less than 10 years (not counting time spent in incarceration) prior to becoming employed.

The RO can only manufacture and dispense medical marijuana in an indoor, enclosed, secure facility (which can be a greenhouse) that is located in New York State. Regulations will be promulgated by the Health Commissioner setting forth specific requirements for the facility. The RO must also determine the quality, safety and clinical strength of the medical marijuana that it manufactures and dispenses, and must provide documentation of same to the Health Department and to any person or entity to which the RO provides medical marijuana.

No Self-Referral

It is an indication of just how carefully this law was crafted that it even includes a prohibition on self-referral by the prescribing practitioner under PHL §238 et seq. In other words, a practitioner authorized to prescribe medical marijuana may not refer a patient to an RO if the practitioner (or immediate family member) has an ownership or investment interest in, or compensation arrangement with the RO that dispenses the medical marijuana.

Non-Discrimination

The law declares that certified patients are deemed to have a "disability" as defined in the state human rights and other laws, and prohibits employers and professional licensing boards from discriminating against certified patients, designated caregivers, practitioners, ROs and employees of ROs "solely for the certified medical use or manufacture of marihuana, or for any other action or conduct in accordance with this title." However, the law specifically allows employers to enforce policies prohibiting employees from performing duties while impaired by a controlled substance.

Excise Tax and Trust Fund

The law imposes a 7 percent excise tax on the gross receipts from the sale of medical marijuana by an RO, to be paid by the RO and not separately charged to the retail customer. The RO must submit a monthly statement to the Health Department showing its receipts from the sale of medical marijuana during the preceding month, the amount of excise tax due, and payment of the tax. The law requires that these statements be kept confidential by the Health Department.

The net proceeds of the excise tax are to be deposited in a newly created Medical Marihuana Trust Fund; 22½ percent of the Fund's money will be distributed to the counties in New York State where the medical marijuana was manufactured, and allocated in proportion to the gross sales originating from medical marijuana manufac-

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tured in each county. Another 22½ percent will be distributed to the counties in New York State where the medical marijuana was dispensed, and allocated in proportion to the gross sales occurring in each county.

Five percent of the Fund's moneys will be distributed to the state's Office of Alcoholism and Substance Abuse Services for additional drug abuse prevention, counseling, and treatment services. Another 5 percent will be distributed to the State Division of Criminal Justice Services for the purpose of initiating a program of discretionary grants to state and local law enforcement agencies—on a demonstrated need basis—and may be used for such agencies' personnel costs. All of these distributions are subject to allocation each year by the Legislature.

Price and Payment

The law authorizes the Health Commissioner to set the per-dose price of each form of medical marijuana. For the most part, patients will have to pay for medical marijuana on their own. The law specifically states that health insurers and the state Medicaid program will not be required to provide coverage for medical marijuana.

Effective Date and Sunset

Registry identification cards or RO registrations shall be issued or become effective within 18 months after the governor's signing of the bill or at such time as both the Health Commissioner and the Superintendent of the State Police certify that the law "can be implemented in accordance with public health and safety interests," whichever is later. However, if either the Health Commissioner or the State Police Superintendent finds that the medical marijuana program poses a risk to public health or safety, the law authorizes the governor to terminate all licenses issued to ROs.

In an unusual move, the Legislature included a provision allowing the law to expire seven years after it takes effect. Presumably, the lawmakers wanted to have the seven-year period to gauge the actual utilization and effectiveness of medical marijuana, as well as to have the option to end the program if major abuses become evident.

Penalties for Abuse

In recognition of the likelihood of abuses in the prescription and use of medical marijuana, its re-sale or diversion, and other problems, the law adds new criminal penalties. It is a Class E felony for a practitioner to certify a patient for medical marijuana when the practitioner knows or has reasonable grounds to know that the patient has no medical need for such certification, or that the certification was requested for a purpose other than to treat a Serious Condition. It is a Class B misdemeanor if a person sells, trades, delivers, or otherwise provides medical marijuana to another with knowledge or reasonable grounds to know that the recipient is not registered to use medical marijuana. It is a Class A misdemeanor for a certified patient or caregiver to knowingly obtain, possess, store or maintain an amount of medical marijuana in excess of the amount he or she is authorized to possess.

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Federal Law

It is important to emphasize that the sale, purchase, possession, or use of marijuana outside of the tightly restricted medical marijuana exception is still a prosecutable crime under New York law. Moreover, even though this law creates an exception under New York law for medical marijuana, any sale, purchase, possession or use of marijuana remains illegal under the federal Controlled Substances Act.³ Bills have been introduced in Congress to carve out an exception to the federal drug laws for state laws permitting use of marijuana, but none have yet passed.

The Department of Justice has issued carefully worded—and sometimes conflicting—guidance on state laws allowing medical marijuana. For example, in 2013, the Justice Department notified all U.S. attorneys that, in states that have enacted laws legalizing marijuana in some form "and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale and possession of marijuana, conduct in compliance with those laws and regulations is less likely to threaten the federal priorities..." of enforcement of the Controlled Substances Act. As such, according to the Justice Department, in states that have effective measures to prevent marijuana diversion, that prohibit access to marijuana by minors, and that have a tightly regulated market in which revenues are tracked and accounted for, then:

...consistent with the traditional allocation of federal-state efforts in this area, enforcement of state law by state and local law enforcement and regulatory bodies should remain the primary means of addressing marijuanarelated activity.4

However, this is non-binding guidance, and the

Justice Department could change its position in the future.

There are still other practical and legal obstacles arising from the federal ban on sales of marijuana. First, patients prescribed marijuana will likely have to pay cash for it, since the use of checks, credit or debit cards, or other banking transactions could be considered as part of transactions that are illegal under federal law. Major credit card issuers refuse to allow their cards to be used for marijuana purchases of any kind. Next, the ROs could encounter difficulties in opening bank accounts to deposit their revenues from the manufacture and sale of medical marijuana, because banking transactions involving money obtained from the sale of what federal law declares are illegal drugs can be construed as money-laundering. In addition, while the ROs will have to pay federal income taxes on their medical marijuana revenues, they may not be able to deduct their expenses for growing, processing and dispensing medical marijuana because doing so is still illegal under federal law. These and other matters will have to be addressed.

Conclusion

A week after the Legislature acted on the medical marijuana bill, a front-page story in The New York Times⁵ reported that there is little to no scientific evidence supporting the use of marijuana for some of the medical conditions referred to in this and other state laws, including Lou Gehrig's Disease, Parkinson's Disease, epilepsy, and rheumatoid arthritis. The article also noted that there is a dearth of clinical trials for medical marijuana that is primarily attributable to the Controlled Substances Act's classification of marijuana as a Schedule 1 drug with "no currently accepted medical use," and a high potential for abuse.

Since New York's medical marijuana law automatically sunsets after seven years, perhaps that will provide enough time to conduct research and clinical trials into the efficacy, if any, of marijuana for treating these various medical conditions, and to resolve the various obstacles presented by the federal ban. In the meantime, practitioners, patients, caregivers, and entities who will be involved in the prescription, use, possession, manufacturing or dispensing of medical marijuana are on notice as to New York's comprehensive regulations and restrictions with respect to this drug.

- 1. A6357E, S7923
- 2. The new law uses the spelling "marihuana." 3. 21 U.S.C. Ch. 13, Subchapter I.
- 4. U.S. Dept. of Justice, "Guidance Regarding Marihuana En-

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5. Catherine Saint Louis, "Politicians' Prescriptions for Marihuana Defy Doctors and Data," The New York Times, Friday, June 27, 2014, p.1.

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