

Health Care Law

New York's Medical Marijuana Program

In June 2014, Governor Cuomo signed into law legislation that will allow New York to join 22 other states and the District of Columbia in allowing residents to purchase and use marijuana for medicinal purposes.¹ As with the many other states that allow for the use of medical marijuana, the law lays the framework for a complex regulatory system that tasks the Department of Health ("DOH") with tightly controlling the growth, sale, and distribution of medical marijuana.

The regulations set forth stringent requirements on those entities that would grow, manufacture, and distribute medical marijuana, as well as limitations on the individuals that can obtain it. The regulations, which became official on April 15, 2015,² were crafted through a "very critical lens to ensure that the entire program would not be subject to enforcement action or legal challenges."³ While the legislation legalizes medical marijuana under New York law, federal law continues to prohibit its possession and use, creating a complex legal landscape for those involved with medical marijuana.

Certified Users

Medical marijuana will be made available to those suffering symptoms caused by "severe diseases," defined by statute to include cancer, HIV/AIDS, multiple sclerosis, and similar illnesses.⁴ The Commissioner of DOH has authority to expand the list of diagnoses, but has declined to exercise it.

Patients eligible for medical marijuana will be certified by a practitioner who is approved to certify a patient's use of marijuana (patients are not "prescribed" marijuana, but are "certified" to use it). A practitioner will only be able to certify a patient to use medical marijuana if he or she has treated the patient for the condition requiring the use of marijuana.

Upon a patient's certification by a physician, the patient (and his or her caregiver, if appropriate) will then apply for an identification card from DOH that will allow him or her to purchase marijuana at a dispensary. The patient or caregiver must have the ID card with them at all times they possess marijuana products; failure to do so can have repercussions under the penal code. The patient will need to be re-certified every year, unless he or she is deemed to be suffering from a "terminal illness," in which case the certification would last for the patient's lifespan.

A certified patient can also designate a caregiver who will be allowed to purchase and possess medical marijuana on the patient's behalf if the patient is unable to obtain the marijuana on his or her own.

Authorized Marijuana Dispensaries

Patients will obtain their medical marijuana from dispensaries operated by one of five "Registered Organizations" ("ROs"). ROs will be required to manage the manufacturing process "from seed to sale," meaning growth, manufacturing, and dispensing. Patients may have to

travel to obtain marijuana products, however, as the law only allows for four dispensaries per RO, meaning there will only be 20 dispensaries in the state.

When a patient does visit a dispensary to purchase marijuana, the dispensary will more closely resemble a pharmacy than a dispensary one might see in other states. This is due in part to the fact that marijuana cannot be sold under the New York law in flower form, nor can it be smoked.

Patients will receive pills or vials of oil that contain the appropriate "brand" of product for their consumption. ROs will manufacture five different "brands," and a patient's certification will restrict the brands which he or she may purchase. Each "brand" will have a varying ratio of tetrahydrocannabinol ("THC") to cannabidiol ("CBD"); two of the active ingredients in marijuana (THC causes the anti-depressant-like effects associated with marijuana, while CBDs do not, but may be linked to some of the medical benefits that have been associated with marijuana).⁵

Patients will also have to bring cash with them to the dispensary. As discussed in more detail below, marijuana businesses are generally prohibited from using credit cards, and no insurance will cover the marijuana product as of yet. The DOH will set the price for all marijuana sold by a RO. Though there has yet to be an indication of how much marijuana products will cost, the regulations state that the DOH will review the RO's proposed price and consider it in light of the RO's practices, historical price, and past sales (if applicable) in either approving, modifying, or rejecting the proposed price. Patients may

then consume the medical marijuana as directed by their doctor, but they may not vaporize the product anywhere that smoking is prohibited, such as schools, hospitals, or restaurants.

Reconciling State and Federal Laws

Despite New York's intricate regulatory scheme, the complex interplay between the federal prohibition and the proliferation of statewide legalization remains in flux. ROs and certified patients will face a difficult legal landscape that will present everything from potential criminal liability to financing issues.

Marijuana remains illegal under federal law. The Controlled Substances Act⁶ ("CSA") and its regulations classify marijuana as a Schedule 1 narcotic, meaning it has "a high potential for abuse," "no currently accepted medical use in treatment," and "a lack of accepted safety" in its use.⁷ Its manufacture, distribution, or possession in the quantities a RO will likely possess is a felony punishable by at least 10 years in prison, and possession by patients can also qualify as a federal felony.⁸

The growing state legalization trend has not gone unnoticed by the Department of Justice ("DOJ"), however, and the agency has issued three separate memoranda on the enforcement of the CSA, each progressively taking a more permissive stance. The most recent memorandum, issued by Deputy Attorney General James Cole on August 29, 2013, states that DOJ does not intend to use its resources to prosecute crimes relating to marijuana if the offenders are otherwise

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in compliance with their state's regulatory scheme and are not threatening enumerated federal priorities including the prevention of marijuana business's involvement with organized crime, violence, or other illegal activity, preventing public health risks associated with marijuana use (such as driving under the influence), and possession of marijuana on federal property.⁹

While this memo provides guidance to U.S. Attorneys as to how to effectively deploy resources and exercise prosecutorial discretion, it provides no shield from prosecution under the CSA, nor does it change the fact that marijuana possession and use remains illegal. No U.S. Attorney in New York has made a public statement as to their intent to follow the memo's guidance or otherwise enforce the CSA against state-compliant New York entities or persons.

The CSA is not the only federal legislation ROs will have to contend with. The intended medical use of marijuana in New York may cause it to fall into the definition of a "drug" under the Food, Drug, and Cosmetic Act and its regulations (the "FDCA").¹⁰ If medical marijuana were to be classified as a "drug," it would have to go through rigorous research and clinical trials before it could be put to market, just as any new pharmaceutical would.

The FDA has not issued guidance either on how it classifies marijuana or if it intends to enforce regulatory oversight of it, though it has posted a statement on its website noting marijuana has not undergone testing as other new drugs do, and calling for additional research into marijuana and its uses. Despite the lack of testing, the FDA has taken notably few enforcement actions in other states with similar regulatory schemes to New York's.

ROs will also face challenges in conducting business with banks due to multiple laws that prevent banking transactions with the proceeds of illegal businesses. These laws include anti-money laundering statutes¹¹ which make it a felony to enter into a transaction with illegal proceeds (which applies to banks and ROs) and the unlicensed money transmitter statute¹² which makes it a felony to operate a money transmitting business that involves money derived from criminal offenses.

Banks are also liable under the Banking Secrecy Act ("BSA"), which requires banks to, amongst other things, report suspicious activity to the Financial Crime Enforcement Network ("FinCEN").¹³

FinCEN has released its own guidance on the BSA, stating that while reporting financial transactions with marijuana businesses is mandatory, otherwise normal transactions with a marijuana business otherwise in compliance with its state's regulatory scheme should be marked "Marijuana Limited" and contain a minimal amount of information. More suspect transactions are to be reported as "Marijuana Priority," and be treated as any other suspicious activity report would.¹⁴ DOJ has also applied its CSA memorandum reasoning to financial crimes.¹⁵

Banks remain reluctant to do business with marijuana producers, however, due to these laws and the belief they may be aiding and abetting a violation of the CSA. In addition to issues securing financing from banks, ROs will have to operate as cash-only businesses, as major credit card companies have similarly refused to become involved in marijuana.

Interstate Conflicts

Further muddying the legal waters, Oklahoma and Nebraska filed a lawsuit against Colorado in the United States Supreme Court to attempt to invalidate Colorado's legalization of recreational marijuana, claiming they have been harmed by an increase in marijuana possession occurring in their states.¹⁶

While the suit is predicated on the fact that marijuana remains illegal on the federal level, it makes an interesting argument in attacking Colorado's regulatory scheme for the production, sale, and taxation of marijuana instead of the underlying legality of possessing and using marijuana. The Supreme Court's ruling may set precedent that may either facilitate the further legalization of marijuana, or curtail distribution in states in which it is already legal.

While that action awaits resolution in the Supreme Court, U.S. Senators Booker, Gillibrand, and Paul have co-sponsored the CARERS Act,¹⁷ which would remove many of the federal hurdles discussed above. If passed, the federal bill would reschedule marijuana as a Schedule 2 drug instead of a Schedule 1 drug. Schedule 2 drugs are tightly regulated, but can be prescribed by a physician; other Schedule 2 drugs include Ritalin and Oxycodone.

Rescheduling marijuana would allow states that allow medical marijuana (recreational marijuana would remain illegal), such as New York, to operate in compliance with the CSA. The bill would also provide safe harbors to banks transacting with marijuana businesses and remove CBD from the definition of "marijuana," allowing CBD extractions to enter interstate commerce. The bill would also remove the prohibition on VA doctors referring medical marijuana to patients and expand research opportunities into marijuana.

New York is on the cusp of joining nearly half the states that allow their residents to obtain marijuana for medical purposes. There remains a long way to go, however, in registering patients, selecting ROs, and getting the program operational and providing for patients by the legislation's effective date in January 2016. Once the ROs are up and running and patients are able to obtain marijuana products, there may still be a myriad of issues imposed by the complicated legal landscape relating to marijuana.

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1 Codified at N.Y. Pub. Health Law § 3360 *et seq.*
2 Codified at 10 NYCRR § 1004 *et seq.*
3 N.Y. Dept. of Health, *Summary of Assessment of Public Comment* (March 31, 2015), available at www.nytimes.com.

4 N.Y. Pub. Health Law § 3360.
5 See Abir T. El-Afy, et al., *Antidepressant-like effect of Δ9-tetrahydrocannabinol and other cannabinoids isolated from Cannabis sativa L.*, 95 *Pharmacology, Biochemistry, and Behavior* 454-42 (2010).

6 21 U.S.C. § 841 *et seq.*
7 21 U.S.C. § 812(b)(1).
8 21 U.S.C. § 841(b)(1)(A)(vii).
9 James M. Cole, Deputy Attorney General, U.S. Department of Justice, *Memorandum for All United States Attorneys: Guidance Regarding Marijuana Enforcement* (August 29, 2013), available at www.nytimes.com.

10 21 U.S.C. § 301 *et seq.*
11 18 U.S.C. §§ 1956-1957
12 18 U.S.C. § 1960
13 18 U.S.C. § 5311 *et seq.*
14 *BSA Expectations Regarding Marijuana-Related Businesses* (Feb. 14, 2014), available at www.nytimes.com.

15 James M. Cole, Deputy Attorney General, U.S. Department of Justice, *Guidance Regarding Marijuana Related Financial Crimes* (February 14, 2014), available at www.nytimes.com.
16 Matt Fennar, *SCOTUS Seeks Fed's Views On Marijuana Lawsuit Against Colorado*, www.huffingtonpost.com (May 4, 2015).

17 Compassionate Access, Research Expansion, and Respect States Act of 2015, 114th Congress S.683 (2015).