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#### Publication Information

Williams, Karl G. (2015). "Medical Marijuana and Pharmacy Practice." *New York State Pharmacist* 89.5, 10-12.

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## Medical Marijuana and Pharmacy Practice

### Abstract

By way of the Compassionate Care Act of 2014, New York has become the 23<sup>rd</sup> state to create a process that will permit patients suffering from a “serious condition” to receive medical marijuana (or “cannabis”). Among those, it is the second state to prohibit the crude delivery system of smoking (Minnesota), and the third to involve pharmacists in the dispensing process (Connecticut and Minnesota). Because virtually every practicing pharmacist in New York will be caring for patients receiving some form of cannabinoid therapy, it is important to discuss the basic outlines established by the law and regulations.

### Keywords

fsc2016

### Disciplines

Pharmacy and Pharmaceutical Sciences

### Comments

Published by the Pharmacists Society of the State of New York. Inc.: <https://pssny.site-ym.com/>

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# Medical Marijuana and Pharmacy Practice

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By way of the Compassionate Care Act of 2014, New York has become the 23<sup>rd</sup> state to create a process that will permit patients suffering from a “serious condition” to receive medical marijuana (or “cannabis”). Among those, it is the second state to prohibit the crude delivery system of smoking (Minnesota), and the third to involve pharmacists in the dispensing process (Connecticut and Minnesota). Because virtually every practicing pharmacist in New York will be caring for patients receiving some form of cannabinoid therapy, it is important to discuss the basic outlines established by the law and regulations.

The Act provided for the basic policies and framework for the patient care process, product development, and product distribution. Also, the Act gave the Department of Health (“DoH”) authority to write regulations to further clarify specific details that are necessary for safe, secure, and responsible implementation of this therapy. The DoH regulations were finalized and published on April 15, 2015 and published in Title 10 of New York’s Code of Rules and Regulations.

Patients may receive medical cannabis if a properly qualified physician concludes that the patient

will realize a “therapeutic or palliative benefit” for one of ten listed serious conditions. The list includes the following:

- Cancer
- HIV/AIDS
- ALS
- Parkinson’s disease
- Multiple sclerosis
- Spinal cord damage exhibiting intractable spasticity
- Epilepsy
- Inflammatory bowel disease
- Neuropathies
- Huntington’s disease

Also, cachexia, severe or chronic pain, severe nausea, seizures, and muscle spasms, associated with any of the listed diseases. In addition, the Commissioner, in his discretion, may add Alzheimer’s disease, muscular dystrophy, dystonia, post-traumatic stress disorder, and rheumatoid arthritis within eighteen months of the effective date of the law; that is January 2016.

As mentioned, smoking is not an approved medication delivery system under the Compassionate Care Act. The regulations specify that the following are permissible: liquid or oils for oromucosal use, metered oil/liquid for vaporization, and capsules for oral administration. Edible food products are not currently permitted in the regulations. The

Commissioner may approve additional formulations at a later time.

A physician who treats one or more of these conditions, and has registered with DoH to provide this therapy, may issue a “certification” for primary or adjunctive treatment if, in his or her “professional opinion”, the patient will benefit. Notice that the certification is *not* a prescription in the traditional sense. Prescription has a discrete definition under the Code of Federal regulations, and inconsistent with its use in ordering a Schedule I controlled substance. It is perhaps better to view the certification as an *alternative* to the prescription. Like a prescription, the practitioner is directed to consider the form of cannabis, route of administration, particular strain, variety, quantity, dosage, and any limitations on therapy. Also, the certifying physician (or a designee) is required to review the prescription monitoring program (or “PMP”, as established in the iSTOP law) registry prior to certification for the “purpose of reviewing a patient’s controlled substance history”.

Once certified by the physician, patients must then submit an application to the DoH for a registry ID card enabling the acquisition,

lawful possession, and use of a specified product for a maximum 30-day supply. Also, the law provides for registration of “designated caregivers” who may assist patients in this process. This may include picking up the medication from the dispensary, assistance with dosing, and temporary possession as long as the caregiver has registered and has an official ID card. The registry ID card expires one year from the date the certification is signed by the physician unless the patient is terminally ill, in which case the physician may specify that certification will terminate on the death of the patient.

Medical cannabis will be supplied by “registered organizations” that have been approved by the DoH. Each of five registered organizations will be integrated (“seed-to-sale”) to cultivate, formulate products, and dispense to registered patients or caregivers. Each “registered organization” is permitted to operate four dispensaries, located separately from the production facilities, in various locations around the state. The dispensaries will be located in the following counties: Nassau, New York (2), Onondaga (3), Erie (2), Suffolk, Clinton, Monroe, Broome, Albany (3), Westchester (2), Queens, Ulster, and Bronx.

On receipt of a proper registry ID card, dispensary personnel

(unlike pharmacies) are *required* to check the PMP registry to ensure that the patient will not have more than a 30-day supply with a 7-day grace period. That is, the patient may receive a refill within seven days of the time the previous supply would be exhausted. This is the same standard followed by community pharmacists for controlled substances. In addition, dispensary personnel will attach a patient-specific label to the unopened package that includes

- Name and registry ID number of the patient (and designated caregiver, if any);
- Certifying physician;
- Dispensing facility name, address, and phone number;
- Dosing and administration instructions;
- Quantity and date dispensed; and
- Any recommendation or limitation as to use of the medication.

Also, at the time of dispensing, a safety insert shall be provided which will include information on administration methods, potential dangers associated with use, how to recognize problem usage and obtain appropriate treatment, and other relevant information. Finally, the dispensary is required to, within 24 hours, report dispensed products to the DoH. This is similar to any controlled substance delivered to/for a patient in the pharmacy context. This step will

provide the information that, among other things will populate the PMP.

#### Impact on Pharmacy Practice

Given the noted similarities to community pharmacies (and perhaps contrary to intuition), it is important to state explicitly that dispensaries are *not* pharmacies. Unlike pharmacies that are regulated by the Department of Education, dispensaries are licensed and regulated by the Department of Health. An interesting provision in the law reads: “Medical marijuana shall not be deemed to be a “drug” for the purposes of article one hundred thirty-seven of the education law”. This would seem to limit regulation by the Board of Pharmacy/Department of Education and cements DoH as the sole regulatory authority concerning the organization and products. Also, dispensaries are permitted to distribute *only* medical cannabis products and associated administration devices, unless other products are specifically approved by the department.

Dispensaries will be similar to pharmacies in many ways that are extremely important to the profession. Perhaps chief among those is that “dispensing facilities shall not be open or in operation unless an individual with an active New York state pharmacist license...is on premises and directly supervising the activity within the facility”. That

*(Continued on page 12)*

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is, each dispensary will require a supervising pharmacist to ensure the integrity of the dispensing process and, presumably, management of the inventory. This language is general enough to imply the need for authority to control processes, because there will surely be accountability if something goes wrong.

In addition to the supervisory role, there is an implicit clinical role for the pharmacist provided in the regulations. Section 1004.21(d) provides that no employee shall “counsel...on the use, administration of, and the risks...unless...a pharmacist...or under the direct supervision of...the pharmacist on-site in the dispensing facility.” The pharmacists must complete a four-hour training program approved by the commissioner. Since the unprofessional conduct rules of the Board of Regents prohibit delegation of counseling to any unlicensed person, counseling (properly) must be conducted by a pharmacist or an intern. Among other things this implies the maintenance of an accurate medication profile and counseling as provided for in the pharmacy regulations.

### Liability

The threat of legal risk at the hands of the federal government has been the subject of recent speculation. Pharmacists may well recall the 2005 case of *Gonzales v. Raich* where the US Supreme Court affirmed the authority of the federal government to intervene into a state’s medical cannabis

process, despite even the slimmest effect on interstate commerce. Indeed, as clearly discussed in “*Marijuana – Medical or??*”, in the Fourth Quarter 2014 Edition of the *New York State Pharmacist*, the federal government is currently exercising “enforcement discretion”. That is, the US Department of Justice has publicly stated that it will continue in this policy as long as states making cannabis available to its citizens exercise a high level of integrity in the process through “strict regulatory schemes”. Given New York’s highly regulated process, and given the emerging understanding of the importance of cannabis in patient care, federal liability has become extremely remote for New York’s pharmacists.

### Conclusions

Pharmacists in clinical practice in New York, regardless of the nature of the practice, will be in a position to ensure that patients receiving medical cannabis therapy will receive optimal care. Indeed, there is a legal and moral obligation to become adequately prepared to provide this care. Most directly for those practicing in a dispensary, it will be necessary to obtain a complete patient medication profile for the purpose of prospective review for contraindications, drug-drug interactions, and other potential drug therapy prob-

lems that may be addressed during counseling. Although it will not be dispensed in the hospital environment, community practice, or long-term care setting, pharmacists will need to be aware of the fact of cannabinoid therapy for essentially the same reasons. Consistent with this, we will need to educate ourselves about cannabinoids to affect patient care.

*New York Laws of 2014, Chapter 90. The details are contained in Article 33 of the Public Health Law at §§3360-3369-e.*

*10 NYCRR, Chapter XIII, §§1004.1 through 1004.23.*

*10 NYCRR 1004.10(g).*

[https://www.health.ny.gov/regulations/medical\\_marijuana/application/selected\\_applicants.htm](https://www.health.ny.gov/regulations/medical_marijuana/application/selected_applicants.htm) (accessed 8/24/2015).

*PHL §3364(5)(B)(i)*

*10 NYCRR 1004.17, compare to 10 NYCRR 80.73(f) PHL §3368(1)(b). 10 NYCRR §1004.12 (a). 8 NYCRR 29.7(a)(21)(ii)(b)(6). 8 NYCRR 63.6(b)7,8. 545 US 1 (2005).*

*McGuire, Don R, Volume 88, Issue 4, page 10, Fourth Quarter 2014.*

<http://www.justice.gov/opa/pr/justice-department-announces-update-marijuana-enforcement-policy> (accessed on 9/18/2015), announcing memo of Deputy Attorney General James M. Cole of August 29, 2013.

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