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New York's Medical Cannabis Law

The Compassionate Care Act[i], signed into law on July 5, 2014, will enable patients with a "serious condition" to receive medical cannabis if the qualified certifying physician believes the patient will receive "therapeutic or palliative benefit". Unlike other states, New York will only permit refined dosage forms, specifically eliminating the crude delivery method of smoking. The Department of Health ("DoH") published regulations further clarifying specific details necessary for safe, secure, and responsible implementation of this new therapy. It is important to realize that virtually all of New York's practicing pharmacists will be involved in the care of patients receiving medical cannabis.

On July 31, 2015, the DoH awarded registrations to five companies to develop horizontally-integrated ("seed-to-sale") processes to grow, develop dosage forms, and distribute products to patients. Each "registered organization" is permitted to operate 4 dispensaries. These 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[ii].

Patients suffering from the following diseases may receive medical cannabis:

- Cancer
- HIV/AIDS
- ALS
- Parkinson's disease
- Multiple sclerosis
- Spinal cord damage exhibiting intractable spasticity
- Epilepsy
- Inflammatory bowel disease
- Neuropathies
- Huntington's disease, and
- The following: cachexia, severe or chronic pain, severe nausea, seizures, muscle spasms, associated with any of the listed diseases.

Also, the Commissioner, in his discretion, may add Alzheimer's, muscular dystrophy, dystonia, post-traumatic stress disorder, and rheumatoid arthritis on or before January 5, 2016. Patients must be certified by a physician (nurse practitioners may be added in the Commissioner's discretion) who is qualified to treat the above and has completed a 4-hour education program developed for the DoH. Notice that the certification is *not* a prescription in the traditional sense, but an alternative to the prescription. Also, the certifying physician is required to review the

prescription monitoring program (PMP) registry prior to certification. Once certified by the physician, patients must then submit an application to the DoH for a registry ID card enabling the acquisition and lawful possession of a specified product. Also, the law provides for "designated caregivers" to assist patients in this process; a patient may have up to two.

Despite the obvious similarities, dispensaries are ***not*** pharmacies. Unlike pharmacies, regulated by the Department of Education, dispensaries are licensed and regulated by the Department of Health. Dispensaries are permitted to distribute only medical cannabis products. The regulations specify that "dispensing facilities shall not be open or in operation unless… [a NYS licensed/registered] pharmacist…is on premises and directly supervising" […][iii].

The dispensing process begins when the patient, or a designated caregiver, presents a registry ID card for up to a 30-day supply for a particular product and dosage. Unlike pharmacies, dispensaries are *required* to consult the PMP to ensure that the patient will not receive a renewal supply more than seven days early.[iv] Presumably, this will be the responsibility of the pharmacist. Also, the dispensary is required to, within 24 hours, report dispensed products to the DoH, similar to any controlled substance in the pharmacy context.[v] Like prescription-requiring products, the dispensary is required to attach a patient-specific label to the unopened package which includes:

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

In addition to the familiar dispensing role specified above, 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." Since the unprofessional conduct rules of the Board of Regents prohibit delegation of counseling[vi] to any unlicensed person, counseling (properly) must be conducted by a pharmacist or an intern.

An interesting provision in the law reads: "Medical marihuana shall not be deemed to be a "drug" for the purposes of article one hundred thirty-seven of the education law".[vii] This would seem to limit regulation of the Board of Pharmacy and cements DoH as the sole regulatory authority concerning the organization and products. However, the Act is silent about the professional regulation of pharmacists and presumably the professional regulatory role of the Office of Professions and Board of Pharmacy remains intact in this context. Among other things this implies the maintenance of an accurate medication profile and counseling as provided for in the pharmacy regulations[viii] Also, pharmacists providing direct patient care will need to be aware

of patients receiving cannabis for the purpose of prospective drug use review and to provide adequate counseling.

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[i] New York Laws of 2014, Chapter 90.
[ii] https://www.health.ny.gov/regulations/medical_marijuana/application/selected_applicants.htm (accessed 8/24/2015).
[iii] 10 NYCRR 1004.12(a).
[iv] PHL 3364(5).
[v] 10 NYCRR 1004.17, compare to 10 NYCRR 80.73(f).
[vi] 8 NYCRR 29.7(a)(21)(ii)(b)(6).
[vii] PHL §3368(1)(b).
[viii] 8 NYCRR 63.6(b)7,8.