May 6, 2022

New York State Office of Cannabis Management
PO Box 2071
Albany, NY 12220

Re: Comment on New York Proposed Regulations, Part 113 – Medical Cannabis

The International Cannabis Bar Association ("INCBA") is pleased to submit comments to the New York Office of Cannabis Management on its Proposed Regulations for Medical Cannabis under Part 113.

INCBA is an association of over 800 attorneys and legal support staff that operate in the US and abroad to serve the legal needs of the cannabis industry. While INCBA is an international association, it is headquartered in the United States, and we understand the deep impact of New York's medical regulation on the industry in the state, the country, and ultimately, the world.

INCBA supports the hard work of the New York State Office of Cannabis Management has dedicated to this effort, and make the following comments in an effort to further improve the New York program. We note that certain other jurisdictions in the United State provide documentation comparing the existing versions with the new proposed version, showing proposed deletions, additions, and changes. This "redline" allows for easier commenting, more directed citations, and clarity on proposed changes versus existing regulations.

INCBA comments are as follows on the current set of proposals:

Compliance with Federal Law. Section 113.6(b)(5) [the draft regulations mislabel this section as a "Part"] regarding a standard operating procedure manual for all proposed activities involving medical cannabis, states: "All procedures must conform to all applicable federal and state rules, regulations, and laws as amended." Cultivation cannabis and manufacturing cannabis products remain illegal under the federal Controlled Substances Act.

Suggestion: delete requirement that procedures comply with "all applicable federal rules, regulations, and laws," or alternatively, define "applicable" as excluding the federal Controlled Substances Act.

Labor Peace Agreement. Under section 113.6 titled "Application for Initial Registration as a Registered Organization," it appears that an application must include documentation evidencing that the applicant "has entered into" a labor peace agreement (LPA). Proposed subsection 113.6(b)(12) states in part, "The application shall set forth or be accompanied by the following: [. . .] documentation that the applicant has entered into a labor peace agreement, as required by section thirty five of Article 3 of the Cannabis Law, with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees. The maintenance of such a labor peace agreement shall be an ongoing material condition of registration[.]" Similarly, under proposed Section 113.7 titled "Consideration of Registered Organization Applications," proposed Subsection 113.7(b)(9) states, "In deciding whether to grant an application, or amendment to a registration, the board shall consider whether: [. . .] (9) the applicant has entered into a labor peace agreement with a bona-fide labor organization, as defined in Article 1 of the Cannabis Law, that is actively engaged in representing or attempting to represent the applicant's employees[.]" While the MRTA does require an LPA with "a bona fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees," the Act grants CCB discretion on application requirements and level of proof. (See MRTA §35.1.(a)(iii): "in such manner and detail as the board may require"; MRTA §35.3.(a)(vii): " if [the board] are satisfied that".) At the time of an applicant's initial registration (and perhaps thereafter as well) no such bona fide labor organization may exist; indeed, if an applicant is not yet operational or even registered, it seems unlikely that a bona fide labor organization would be "actively engaged in representing or attempting to represent the applicant's employees." Therefore it is not fair to require documentation on the existence of an LPA at these times.

Suggestions: add "if any" after "a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees." Alternatively, the board could require applicants to certify that if a bona-fide labor organization actively engages in representing or attempting to represent the applicant's employees, then the applicant or RO will enter into a labor peace agreement. (See, e.g., New York City Administrative Code §6-145(b) and §6-145(b).)

Extraction Methods. Section 113.12(a) states: "A registered organization shall use either carbon dioxide (CO2), and/or alcohol for phytocannabinoid extraction." Solventless extraction, another widely-used extraction method, is safe, effective, and growing in popularity (solventless products include widely used "rosin").

Suggestion: add solventless extraction to the list of permissible extraction methods.

Vaporized Medical Products. Section 113.12(c)(2)(i) states "unless prior written approval of the office is received, medical cannabis vaporization devices shall be a closed system with a pre-filled disposable cartridge that attaches to a rechargeable battery, or a single-use product that cannot be recharged." Single-use products that cannot be recharged promote the proliferation of hazardous e-waste; rechargeable devices and re-fillable cartridges would reduce that waste stream. Additionally, use of the term "disposable" implies that patients should throw the devices into the garbage instead of recycling them, contrary to the State's Beyond Waste strategy1. Finally, the regulations should include carveouts for vaporization devices that can be used with medical cannabis flower, as well as for cannabis inhaler devices (which are similar to asthma inhalers).

Suggestions: remove "disposable" or replace it with "recyclable"; disallow single-use devices; expressly allow re-fillable cartridges; allow medical flower vaporizers and medical cannabis inhalers.

Excipients and Ingredients. Section 113.12(c)(2)(iii) contains a list of prohibited excipients and ingredients used in vaporized and inhaled medical cannabis products, which include "synthetic terpenes" and "medicinal compounds." Neither of these terms is defined in the proposed regulations, potentially leading to confusion among ROs and patients. "Synthetic cannabis additives" also are prohibited under Section 113.12(n), but that term is not defined either. Section 113.1 excludes from the definition of phytocannabinoids "synthetic cannabinoids as that term is defined in subdivision (g) of schedule I of section thirty-three hundred six of the public health law."

Suggestion: define "synthetic terpenes," "synthetic cannabis additives," and "medicinal compounds."

Recycling Programs. Section 113.12(i)(2) states: "Registered organizations may implement a recycling program for medical cannabis product packaging with prior written approval of the office." We are grateful to the Board for adding recycling programs to the licensed industry, but why require applicants to seek and obtain "prior written approval"?

Suggestion: remove the requirement for "prior written approval" and add to the regulations minimum standards for how a recycling program for medical cannabis product packaging shall be structured and operated.

[1] https://www.dec.ny.gov/docs/materials_minerals_pdf/frptbeyondwaste.pdf

Hemp and Hemp Extracts. Section 113.12(n) states in part: "a registered organization may, in accordance with guidance provided by the office, use hemp, or extracts derived from hemp, grown or processed under the authority of the New York State Department of Agriculture and Markets hemp grower program or the office's cannabinoid hemp program . . . in the manufacturing of medical cannabis products." Hemp and hemp extracts containing less than 0.3% THC by dry weight are federally legal and may be sold interstate. By restricting to those additives to New York grown or processed hemp only, the Board is opening itself up to challenges under federal dormant commerce clause. (See Article 1, Section 8, Clause 3 of the U.S. Constitution; Dean Milk Co. v. City of Madison, Wisconsin, 340 U.S. 349 (1951)).

Suggestion: remove the requirement that hemp and hemp extracts be New York-grown-or-processed only.

Requirements for Dispensing Facilities. Section 113.13(b) states: "Dispensing facilities shall only sell approved medical cannabis products, related products necessary for the administration of medical cannabis, and items that promote health and well-being subject to disapproval of the office." Reference to "approved medical cannabis products" implies that the office's approval of each product is required. Additionally, it is unclear which products are "subject to disapproval of the office."

Suggestions: clarify that ROs may sell medical cannabis products that comply with the regulations, and do not require office approval on a product-by-product basis. Also please clarify that only "items that promote health and well-being" are subject to office disapproval.

Security - Safes. Section 113.14 titled "Security Requirements for Manufacturing and Dispensing Facilities" lists certain minimum security standards, including that "[a]ll approved safes, vaults or any other approved equipment or areas used for the manufacturing or storage of cannabis and medical cannabis products must be securely locked or protected from entry, except for the actual time required to remove or replace cannabis or medical cannabis products." (Section 113.14(i).) A cannabis security expert notes that sometimes insurance policies will only cover thefts involving specific types of safes. For example, operators often use gun safes, only to learn later that these safes are easily broken into and typically do not meet the requirements of standard cannabis insurance policies.
Suggestion: recommend requiring ROs to use only TL-rated safes or safes that are approved in writing by the RO's insurance policy.

Security - Transport Requirements. Section 113.14(l)(4) and (5) directs that "employee(s) shall not make any unnecessary stops in between" departure and destination, and that they must "ensure that all medical cannabis product delivery times are randomized." These standards are not clearly defined and likely to lead to confusion and disputes.

Suggestion: clarify what is an "unnecessary stop," and what it means for delivery times to be "randomized."

FOIL. License applications often include personally identifying information, trade secrets, and other confidential business information that, if disclosed, could cause substantial injury to the applicant. All license applicants, including RO applicants, should be allowed to pre-designate certain portions that they believe are exempt from disclosure under New York's Freedom of Information Law (FOIL). For example, under the proposed Part 116 for conditional adult-use retail dispensary licenses, applications must include "designation of each portion of the application that applicant considers to be exempt from disclosure under the New York State Freedom of Information Law." (Proposed Section 116.2(a)(34).)

Suggestion: add a provision to Section 113.6 allowing RO applicants the right to designate portions of their applications as "exempt from disclosure under the New York State Freedom of Information Law."

Disposal. §113.25(a) states: "disposal of medical cannabis shall mean that the medical cannabis has been rendered unrecoverable and beyond reclamation." Rendering items "beyond reclamation" is inconsistent with the goal of promoting recycling within the industry.

Suggestion: rather than requiring waste to be "unrecoverable and beyond reclamation" consider requiring waste be rendered "unusable." That would prevent medical cannabis waste from being misused as cannabis products while still allowing for the recycling of medical cannabis waste.

Technical Suggestion
Section 113.13. Appears to have two "(i)" [letter "I"] subsections (before the (g) subsection).

Conclusion

INCBA Applauds the hard work and dedication of the New York Office of Cannabis Management and hopes that our additions help the Office create functional, efficient, and transparent regulations for the medical cannabis industry in New York. INCBA Stands in support of your mission and is available for any specific input or advice that the office may seek from lawyers that have dedicated their career to implementing these regulatory schemes.

Sincerely,

Christopher Davis
Executive Director, INCBA, on behalf of INCBA and the INCBA Legislative Advisement Committee.