

Repeal of Part 1004 of Title 10 NYCRR and Addition of Part 113 to Title 9 NYCRR. Pursuant to the authority vested in the Cannabis Control Board by Sections 13 and 43 of the Cannabis Law, Chapter II of Subtitle B of Title 9 of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, and a new Part 113 is added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 113

MEDICAL CANNABIS

Part 113 – Medical Cannabis

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§ 113.1 Definitions.

For the purposes of this Part, the following terms shall have the following meanings:

(a) *Adverse event* means any untoward medical occurrence associated with the use of a medical cannabis product in humans.

(b) *Advertising* means disseminating communications in any manner or by any means, for the purpose of causing, directly or indirectly, the purchase or use of a medical cannabis product brand or medical cannabis product, including but not limited to websites, social media, brochures, prints ads, TV, radio, streaming, out of home, and digital advertisements.

(c) *Artificially derived phytocannabinoid* means a phytocannabinoid that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from cannabis sativa. Artificially derived phytocannabinoid does not include: a naturally-occurring chemical substance that is separated from cannabis sativa by a chemical or mechanical extraction process; phytocannabinoids that are produced by decarboxylation of the phytocannabinoid's respective naturally-occurring carboxylic acid form without the use of a chemical catalyst; any other chemical substance identified by the Board.

(d) *Board* means Cannabis Control Board.

(e) *Brand or Branding* means the name, entity name, or doing business as name, registered trademark, logo, symbol, motto, selling message, recognizable pattern of colors, or any other identifiable marker that identifies one (1) medical cannabis registrant or medical cannabis registrant's medical cannabis products as distinct from those cannabis products of other medical cannabis registrants or adult-use cannabis licensees and is used in, among other things, any packaging, labeling, advertising or marketing.

(f) *Caring for* means treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition.

(g) *Certificate of analysis* means a certified report from a cannabis laboratory meeting the testing requirements of section 113.15 of this Part.

(h) *Certified medical use* means the acquisition, cultivation, manufacture, delivery, harvest, possession, preparation, transfer, transportation, or use of medical cannabis for a certified patient, or the acquisition, administration, cultivation, manufacture, delivery, harvest, possession, preparation, transfer, or transportation of medical cannabis by a designated caregiver or designated caregiver facility, or paraphernalia relating to the administration of cannabis, including whole cannabis flower, to treat or alleviate a certified patient's medical condition or symptoms associated with the patient's medical condition.

(i) *Certified patient* means a patient who is a resident of New York or receiving care and treatment in New York State and is certified in accordance with section 113.3 of this Part.

(j) *Child-Resistant* means a resealable package for dispensing any cannabis product intended for more than a single use or containing multiple doses, that is designed or constructed to be significantly difficult for children under five (5) years of age to open and not difficult for adults to use properly as defined by 16 C.F.R. §1700.15 and 16 C.F.R. §1700.20.

(k) *Condition* means having one of the following conditions: cancer, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, post-traumatic stress disorder, pain that degrades health and functional capability (where the use of medical cannabis is an alternative to opioid use), substance use disorder, Alzheimer's, muscular dystrophy, dystonia, rheumatoid arthritis, autism or any other condition certified by the practitioner.

(l) *Control* means the power, from a business organization and ownership perspective, to order or direct the management, managers, or policies of a person.

(m) *Date of expiration or expiration date* means the date prior to which an unopened medical cannabis product meets applicable standards of identity, potency, and quality at the time of use, as determined by appropriate stability testing, subject to any storage conditions stated on the labeling.

(n) *Designated caregiver applicant* means a natural person who is applying to obtain, amend or renew a registry identification number.

(o) *Designated caregiver facility* means a facility that registers with the Office to assist one (1) or more certified patients with the acquisition, possession, delivery, transportation or administration of medical cannabis and is a: general hospital or residential health care facility operating pursuant to Article 28 of the Public Health Law; an adult care facility operating pursuant

to Title 2 of Article 7 of the Social Services Law; a community mental health residence established pursuant to section 41.44 of the Mental Hygiene Law; a hospital operating pursuant to section 7.17 of the Mental Hygiene Law; a mental hygiene facility operating pursuant to Article 31 of the Mental Hygiene Law; an inpatient or residential treatment program certified pursuant to Article 32 of the Mental Hygiene Law; a residential facility for the care and treatment of persons with developmental disabilities operating pursuant to Article 16 of the Mental Hygiene Law; a residential treatment facility for children and youth operating pursuant to Article 31 of the Mental Hygiene Law; a private or public school; research institution with an internal review board; or any other facility as determined by the Office.

(p) *Exit package* means a receptacle into which medical cannabis products are placed at the point of sale. The exit package is optional.

(q) *Financial Interest* means any actual or future right to ownership, investment or compensation arrangement with another person, either directly or indirectly, through business, investment, spouse, parent or child. Person with a financial interest does not include a passive investor.

(r) *Form of medical cannabis* or *Form* means “form of medical cannabis” as defined by Article 1 of the Cannabis Law.

(s) *Lot* means a quantity of a medical cannabis product that has a homogenous and uniform phytocannabinoid concentration and product quality, produced according to a stable processing protocol specific to that product, during the same cycle of manufacture.

(t) *Lot unique identifier (Lot number or bar code)* means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of manufacturing, testing, holding, distribution or recall of a lot of medical cannabis product can be determined.

(u) *Manufacturing* shall include, but not be limited to cultivation, harvesting, extraction (or other processing), packaging and labeling.

(v) *Medical cannabis license* means a registration provided to a registered organization. Medical cannabis license and registration as it pertains to a registered organization shall be used interchangeably.

(w) *Medical cannabis product* is the final manufactured product of medical cannabis, as defined in section 3 of Article 1 of the Cannabis Law, delivered to the patient that represents a specific phytocannabinoid concentration and form and active and inactive ingredients, prepared in a specific dosage and form, to be administered as recommended by the practitioner.

(x) *Office* means the Office of Cannabis Management.

(y) *Person responsible for making health care decisions* means, in association with certified patients under the age of eighteen (18) or otherwise incapable of consent, a person legally authorized to make health care decisions for the patient, including decisions on the use of medical cannabis and the designation of caregivers.

(z) *Phytocannabinoids* refers to any of the chemical compounds, excluding terpenes or any other compounds determined by the Office, that are the active principles of the cannabis sativa, including but not limited to tetrahydrocannabinol (THC) and CBD, and does not include synthetic cannabinoids as that term is defined in subdivision (g) of schedule I of section 3306 of the Public Health Law.

(aa) *Post-consumer recycled material* means new material produced using material resulting from the recovery, separation, collection and reprocessing of material that would otherwise be disposed of or processed as waste and that was originally sold for consumption. It does not include post-industrial material, or material generated by means of combustion, incineration, pyrolysis, gasification, solvolysis, chemical recycling and any high-heat or conversion process.

(ab) *Practitioner* means an individual who is licensed, registered or certified by New York State to prescribe controlled substances within the state. Nothing in this Part shall be interpreted so as to give any such person authority to act outside their scope of practice as defined by Title 8 of the Education Law. Additionally, nothing in this Part shall be interpreted to allow any unlicensed, unregistered, or uncertified person to act in a manner that would require a license, registration, or certification pursuant to Title 8 of the Education Law.

(ac) *Principal packaging display panel* means the panel of the package or the marketing layer that the registered organization intends to be displayed at the dispensing site.

(ad) *Registered organization* means an organization registered as defined under section 3 of the Cannabis Law.

(ae) *Registered organization applicant* means an organization that has a significant presence in New York State and is applying to be registered or to renew a registration as a registered organization.

(af) *Registry application* means an application properly completed and filed with the Office by a certified patient in accordance with Article 3 of the Cannabis Law and this Part.

(ag) *Registry identification card* means a document that identifies a certified patient or designated caregiver, as provided under Article 3 of the Cannabis Law.

(ah) *Resealable* means a package that maintains its child-resistant effectiveness, as well as preserving the integrity of cannabis products for multiple doses.

(ai) *Serious adverse event* means one (1) or more of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

(aj) *Significant presence* means significant presence as defined in Cannabis Law section 3(1).

(ak) *Synthetic cannabis additives* refer to any chemical substances that do not naturally occur in cannabis sativa.

(al) *Synthetic terpenes* refer to any terpenes that do not naturally occur in cannabis sativa or that are produced and created by chemical synthesis or biosynthesis that changes the molecular structure of a chemical substance to create a terpene that is naturally occurring in cannabis sativa.

(am) *Tamper-evident* means, with respect to a device or process, bearing a seal, a label or a marking that makes unauthorized access to or tampering with a package, product or container easily detectable.

(an) *Use by date* means the date prior to which an opened medical cannabis product meets applicable standards of identity, potency, and quality at the time of use, as determined by appropriate stability testing, subject to any storage conditions stated on the labeling.

§ 113.2 Practitioner Eligibility.

(a) No practitioner shall be authorized to issue a patient certification as set forth in section 113.3 of this Part unless the practitioner:

(1) is qualified, by training or experience as determined by the Board, to treat patients with one (1) or more of the conditions set forth in section 113.3(a)(7) of this Part;

(2) is licensed, registered or certified by New York State to prescribe controlled substances within the state;

(3) is acting within their scope of practice as defined by Title 8 of the Education Law and is in good standing as determined by the Office; and

(4) has completed at a minimum a two (2) hour course approved by the Office as set forth in subdivision (b) of this section.

(b) The Office shall approve at least one (1), if not more, courses for practitioners seeking to certify patients for medical cannabis, which shall be a minimum of two (2) hours in duration. The educational content of such course shall include: the pharmacology of cannabis; contraindications; side effects; adverse reactions; overdose prevention; drug interactions; dosing; routes of administration; risks and benefits; warnings and precautions; abuse and dependence; and such other components as determined by the Office.

§ 113.3 Practitioner Issuance of Certification.

(a) Requirements for Patient Certification. A practitioner who is eligible pursuant to 113.2 of this Part may issue a certification for the use of medical cannabis by a qualifying patient subject to completion of subdivision (k) of this section. Such certification shall contain:

- (1) the practitioner's name, business address, telephone number and email address;
- (2) the practitioner's license number as issued by the New York State Department of Education;
- (3) the practitioner's Drug Enforcement Administration registration number for prescribing controlled substances in New York State;
- (4) a statement that the practitioner is licensed and in good standing in New York State and possesses an active registration with the Drug Enforcement Administration for prescribing controlled substances in New York State;
- (5) a statement that the practitioner is caring for the patient in relation to the patient's condition;
- (6) the patient's name, date of birth, residential address, telephone number and email address, if available;
- (7) the patient's condition, which may include any of the condition(s) listed below:
 - (i) cancer;

- (ii) positive status for human immunodeficiency virus or acquired immune deficiency syndrome, provided that the practitioner has obtained the patient's consent for disclosure of this information that meets the requirements set forth in section 2782 of the Public Health Law;
- (iii) amyotrophic lateral sclerosis;
- (iv) Parkinson's disease;
- (v) multiple sclerosis;
- (vi) damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;
- (vii) epilepsy;
- (viii) inflammatory bowel disease;
- (ix) neuropathies;
- (x) Huntington's disease;
- (xi) post-traumatic stress disorder;

(xii) pain that degrades health and functional capability where the use of medical cannabis is an alternative to opioid use;

(xiii) substance use disorder;

(xiv) Alzheimer's disease;

(xv) muscular dystrophy;

(xvi) dystonia;

(xvii) rheumatoid arthritis;

(xviii) autism; or

(xix) any other condition certified by the practitioner.

(8) a statement that by training or experience, the practitioner is qualified to treat the condition, listed pursuant to paragraph (7) of this subdivision;

(9) a statement that, 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 adjunctive treatment with medical cannabis for the condition;

(10) any recommendations or limitations the practitioner makes to the certified patient or the patient's designated caregiver;

(11) to the extent that a practitioner seeks to authorize the use of medical cannabis by a patient who temporarily resides in New York State for the purpose of receiving care and treatment from the practitioner, the practitioner shall so state on the patient's certification; and

(12) the practitioner's signature and date upon the certification and a signed certification provided to the patient.

(b) Additional Requirements for Patient Certification where the patient is under the age of eighteen (18) or is otherwise incapable of consent. A practitioner who is eligible pursuant to section 113.2 of this Part may issue a certification for the use of medical cannabis by a qualifying patient, where such a patient is under the age of eighteen (18) or is otherwise incapable of consent, subject to completion of subdivision (a) and (k) of this section and such additional information on the certification as follows:

(1) an attestation that the practitioner obtained a statement from the person responsible for making health care decisions that they are:

(i) legally authorized to make health care decisions on behalf of the patient under the age of eighteen (18) or otherwise incapable of consent;

(ii) consenting on the patient's behalf, the use of medical cannabis product(s) and any device used for its administration; and

(iii) identifying the designated caregiver for the patient under the age of eighteen (18) or otherwise incapable of consent, including such designated caregiver's full name, address, date of birth, telephone number and email address, if available; and

(2) the designated caregiver identified in subparagraph (iii) of paragraph (1) of this section shall be exempt from the requirements set forth in section 113.5 of this Part.

(c) The practitioner shall provide the signed certification to the certified patient, or for those individuals under the age of eighteen (18) or incapable of consent, the person responsible for making healthcare decisions pursuant to paragraph (1) of subdivision (b) of this section.

(d) The designated caregiver who is identified in accordance with section 113.3(b) of this Part, shall be deemed registered with the Office.

(e) Should the person responsible for making health care decisions identified in accordance with section 113.3(b) of this Part or the parent or legal guardian in accordance with Cannabis Law Section 32(3)(b)(ii) decide to change or elect to add additional designated caregiver(s), such designated caregiver must comply with the registration requirements of section 113.5 of this Part.

(f) Should the person responsible for making health care decisions identified in accordance with section 113.3(b) of this Part or the parent or legal guardian in accordance with Cannabis Law Section 32(3)(b)(ii) decide to change the designated caregiver identified in section 113.3(b)(1)(iii) of this Part, they shall notify the practitioner to update the requirements set forth in section 113.3 of this Part.

(g) Requirements of Patient Special Certification. The practitioner may issue a special certification if the patient's condition is progressive and degenerative or that delay in the patient's certified medical use of cannabis poses a risk to the patient's life or health. Such certification shall be on a form provided by the Office and shall contain the requirements set forth in subdivision (a) of this section.

(h) Expiration of Certification.

(1) The certification shall state the date upon which the certification shall expire, which shall be no longer than one (1) year after the date it was issued, unless the patient is terminally ill.

(2) If the practitioner issues a certification to a patient who is terminally ill, the certification shall not expire until the patient's death or the practitioner re-issues the certification to terminate the certification on an earlier date.

(3) If the practitioner issues a certification to a patient who is not a resident of New York State but is receiving care and treatment in this state, the certification shall be valid for a period of time

which is no longer than the patient is reasonably anticipated to be residing in New York State for the purposes of care and treatment, but in no event shall it be valid for more than one (1) year after the date it was issued.

(i) **Submission of Certification to the Office.** Practitioners shall utilize a form, which may be in an electronic format, developed by the Office for the certification required in subdivision (a) of this section. The practitioner shall submit to the Office, the information required by subdivision (a) of this section, in a manner determined by the Office, including by electronic transmission through a secure website.

(j) **Record Retention.** The practitioner shall also maintain a copy of the signed certification, which shall include all information required in subdivision (a) of this section, and for those under the age of eighteen (18) or incapable of consent, all the additional information required in subdivision (b) of this section, for a period of five (5) years, in the patient's medical record.

(k) **Consultation of Prescription Monitoring Program Registry.** Prior to issuing, modifying or renewing a certification, the practitioner shall consult the prescription monitoring program registry pursuant to section 3343-a of the Public Health Law for the purpose of reviewing a patient's controlled substance history. Practitioners may authorize a designee to consult the prescription monitoring program registry on their behalf, provided that such designation is in accordance with section 3343-a of the Public Health Law.

§ 113.4 Registration Filing Exemptions for Certified Patients and Designated Caregivers.

(a) A patient issued a valid certification by a practitioner, in accordance with section 113.3 of this Part, who is eighteen (18) years of age or older and capable of consent, shall be deemed registered and exempt from filing a registry application with the Office, for purpose of registering as a patient and to obtain a patient registry identification card, pursuant to the applicable patient registration provisions and pursuant to section 32 of the Cannabis Law.

(b) A patient, who is under eighteen (18) years of age, or who is otherwise incapable of consenting to medical treatment, and who is issued a valid certification by a practitioner in accordance with section 113.3 of this Part, shall be deemed registered and exempt from filing a registry application with the Office, for purpose of registering as a patient and to obtain a patient registry identification card, pursuant to the applicable patient registration provisions under section 32 of the Cannabis Law.

§ 113.5 Designated Caregiver Registration.

(a) Designation of Caregivers. A certified patient may designate up to five (5) designated caregivers, not including designated caregiver facilities or the employees of a designated caregiver facility, in a manner determined by the Office. A designated caregiver shall be a natural person. The application for issuance or renewal of a registry identification card shall include the following information:

- (1) name of the proposed designated caregiver(s);
- (2) address of the proposed designated caregiver(s);

- (3) date of birth of the proposed designated caregiver(s); and
- (4) any other individual identifying information concerning the proposed designated caregiver(s) required by the Office.

(b) Notwithstanding a designation in accordance section 113.3(b) of this Part, a certified patient's designation of caregivers subsequent to the initial certification process shall not be valid unless and until the proposed designated caregiver successfully applies for and receives a designated caregiver registry identification number.

(c) A natural person selected by a certified patient as a designated caregiver shall apply to the Office for initial registration or renewal of such registration on a form or in a manner determined by the Office. The proposed designated caregiver shall submit an application to the Office which shall contain the following information and documentation:

- (1) the full name, address, date of birth, telephone number, email address if available, and signature of the designated caregiver applying for registration;
- (2) a statement that the designated caregiver applying for registration agrees to secure and ensure proper handling of all medical cannabis products;
- (3) acknowledgement that a false statement in the application is punishable under section 210.45 of the Penal Law.

(d) For a proposed designated caregiver facility as defined in section 113.1 of this Part, the designated caregiver facility shall submit:

(1) the facility's full name, address, operating certificate or license number where appropriate, email address, and printed name, title, and signature of an authorized facility representative;

(2) if the facility has a prior designated caregiver facility registration, the registry identification number;

(3) a statement that the facility agrees to secure and ensure proper handling of all medical cannabis products; and

(4) an acknowledgement that a false statement in the application is punishable under section 210.45 of the Penal Law;

(e) For a proposed designated caregiver that is a cannabis research license holder under Article 3 of the Cannabis Law, the designated caregiver shall submit;

(1) the full name of the research license holder, address, research license number, email address, and the name, title and signature of an authorized representative of the research license holder;

- (2) if the research license holder already is a designated caregiver in accordance with this section, such license holder shall provide the registry identification number;
- (3) a statement that the research license holder agrees to secure and ensure proper handling of all medical cannabis products;
- (4) an acknowledgement that a false statement in the application is punishable under section 210.45 of the Penal Law; and
- (5) any other identifying information as determined by the Office;
- (f) Prior to issuing or renewing a designated caregiver registration, the Office may verify the information submitted by the proposed designated caregiver. The proposed designated caregiver shall provide, at the Office's request, such information and documentation, including any consents or authorizations that may be necessary for the Office to verify the information.
- (g) The Office shall approve, deny, or determine incomplete or inaccurate an application to issue or renew a designated caregiver registration as soon as is reasonably practicable.
- (h) The Office shall notify the designated caregiver applicant in writing, by email, by telephone, or in another manner as determined appropriate by the Office if an application is incomplete or factually inaccurate and shall explain what documents or information is necessary for the Office to consider the application complete and accurate.

(i) A designated caregiver applicant shall have thirty (30) days from the date of a notification of an incomplete or factually inaccurate application to submit the materials required to complete, revise or substantiate information in the application. If the designated caregiver applicant fails to submit the required materials within such thirty (30) day time period, the application shall be denied by the Office.

(j) Designated caregiver applicants whose applications are denied pursuant to subdivision (f) of this section may submit a new initial or renewal application for a designated caregiver registration.

(k) The Office shall deny a designated caregiver registration for a designated caregiver applicant who:

(1) is already a designated caregiver for four (4) currently certified patients or has an application pending that, if approved, would cause the proposed designated caregiver to be a designated caregiver for more than four (4) currently certified patients. This provision does not apply to designated caregiver facilities or research license holders as defined in section 113.1 of this Part; or

(2) in accordance with subdivision (e) of this section, fails to provide complete or factually accurate information in support of their initial or renewal application.

§ 113.6 Application for Initial Registration as a Registered Organization.

(a) No person shall produce, grow, or sell medical cannabis or hold itself out as a New York State registered organization unless it has complied with Article 3 of the Cannabis Law, this Part, and is registered by the Board.

(1) An application for initial registration as a registered organization shall include no more than four dispensing sites that will be wholly owned and operated by such registered organization in accordance with Subdivision 8 of Section 35 of the Cannabis Law.

(2) Additional dispensing sites beyond the initial four shall be subject to the requirements set forth in subdivision (h) of section 113.7 of this Part.

(b) In order to operate as a registered organization, an entity shall file an application on forms or in a manner prescribed by the Board. The application shall be signed by the chief executive officer duly authorized by the board of a corporate registered organization applicant, or a general partner or owner of a proprietary registered organization applicant. The application shall set forth or be accompanied by the following:

(1) the name, address, phone and email address of the registered organization applicant;

(2) identification of all real property, buildings and facilities that will be used in manufacturing, as defined in section 113.1 of this Part, or dispensing of the medical cannabis products, including confirmation that the real property, buildings and facilities used for dispensing

are not within five hundred feet of school grounds as such term is defined in the Education Law or two hundred feet from a house of worship;

(3) identification of equipment, as determined by the Board in the application, that will be used to carry out any manufacturing, processing, transportation, distributing, sale and dispensing activities;

(4) a business plan that includes a description of the activities, authorized by Article 3 of the Cannabis Law, to be conducted by the registered organization applicant. In addition, the plan shall include a description detailing how the registered organization applicant proposes to provide services to areas of the state, unserved or underserved as, in accordance with section 35 of the Cannabis Law; a description containing details of how the registered organization applicant proposes: to be reflective of the demographics of the state, to be representative of communities disproportionately impacted by cannabis prohibition, as set forth in guidance by the Office. Unless waived by the Office, the plan shall include, to the satisfaction of the Office, the following information;

(i) executive summary;

(ii) entity description;

(iii) description of the medical cannabis products and devices to be offered or sold;

(iv) services to be offered by the registered organization applicant;

(v) market analysis;

(vi) implementation strategy; and

(vii) any other information requested by the Office:

(5) a standard operating procedure manual for all proposed manufacturing activities. Manufacturing procedures shall include use of good agricultural practices (GAPs) for cultivation, as well as good manufacturing practices (GMPs) in accordance with Parts 111 or 117 of Title 21 of the Code of Federal Regulations, as appropriate for the type of medical cannabis product being manufactured and as otherwise determined appropriate by the Office. All procedures must conform to all applicable state rules, regulations, and laws as amended. In addition to all proposed manufacturing activities, standard operating procedures must address:

(i) medical cannabis product returns;

(ii) complaints;

(iii) adverse events, with notification to the Office within 24 hours of any serious adverse events;

- (iv) recalls;
 - (v) storage and disposal of cannabis and any medical cannabis product not meeting testing requirements set forth in section 113.15 of this Part;
 - (vi) any other procedures as determined by the Office.
- (6) quality assurance program with quality assurance officer oversight, including but not limited to plans to detect, identify and prevent manufacturing and dispensing incidents, to track contamination incidents and document the source of such incidents, and to conduct corrective action for these incidents;
- (7) description of systems to be used for tracking, record keeping, record retention and reporting surveillance relating to all activities involving medical cannabis;
- (8) an attestation that the registered organization applicant will submit seed to sale data from their system of record to the Office in a format as determined by the Office;
- (9) copies of the organizational and operational documents of the registered organization applicant, including but not limited to, as applicable: organizational charts, capitalization tables, certificate of incorporation, partnership agreement, and any other documents and/or agreements requested by the Office;

(10) the name, residence address and title of each of the board members, officers, managers, owners, partners, principal stakeholders, directors and any person or entity that is a member of the registered organization applicant. Each such person (if an individual, or lawful representative, if a legal entity) shall submit an affidavit with the application setting forth:

(i) any position of management, interest or ownership during the preceding ten (10) years of a ten (10) percent or greater interest in any other cannabis business, or registered organization applicant, located in or outside New York State, manufacturing or distributing drugs including indirect management, interest, or ownership of parent companies, subsidiaries, or affiliates; and

(ii) whether such person or any such business has been convicted of a felony or had a registration or license suspended or revoked in any administrative or judicial proceeding, and if applicable, the history of violations or administrative penalties with respect to any license to cultivate, manufacture, distribute or sell adult-use cannabis or medical cannabis. In addition, any managers who are a member of the registered organization applicant or entity that is a member of the registered organization applicant who may come in contact with or handle medical cannabis, including medical cannabis products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee;

(11) documentation that the registered organization applicant has entered into a labor peace agreement, as required by section 35 of Article 3 of the Cannabis Law, with a bona-fide labor organization that is actively engaged in representing or attempting to represent the registered

organization applicant's employees prior to the issuance of the registration. The maintenance of such a labor peace agreement shall be an ongoing material condition of registration;

(12) a statement that the registered organization applicant shall comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the registration;

(13) copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts related to the organization's real property interests, that shows that the registered organization applicant possesses or has the right to use sufficient land, buildings, and other premises as specified in the application and equipment to properly carry on the activities for which registration is sought. In the alternative, the registered organization applicant shall post a bond of not less than two (2) million dollars; provided, however, that if the registered organization applicant posts a bond in lieu of providing the documentation requested herein, the registered organization applicant's submission of the applicable executed deeds, leases and rental agreements shall be required prior to the issuance of a registration to the registered organization applicant, if selected; In accordance with the social-equity plan established pursuant to section 87 of the Cannabis Law, the Board may waive such requirements when the registered organization applicant is a social and economic equity applicant, provided, however, that prior to issuance of the registration, the registered organization applicant must submit to the Office, copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts related to the organization's real property interests, and, provided further that whenever any registered organization applicant proposes to lease a premises for the activities described in

its operating plan, the lease agreement shall clearly set forth as a purpose the manufacturing and/or dispensing of medical cannabis, as applicable, and include the following language:

"The landlord acknowledges that its rights of reentry into the premises set forth in this lease do not confer on it the authority to manufacture or dispense on the premises medical cannabis in accordance with Article 3 of the Cannabis Law and agrees to provide the New York State Office of Cannabis Management, 1220 Washington Ave. Harriman Campus, Building 9, 4th Fl. Albany, NY 12226, with notification by certified mail of its intent to reenter the premises or to initiate dispossess proceedings or that the lease is due to expire, at least thirty (30) days prior to the date on which the landlord intends to exercise a right of reentry or to initiate such proceedings or at least sixty (60) days before expiration of the lease.";

(14) a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation or arranging for the assistance in preparing the application;

(15) a proposed construction timetable;

(16) a statement as to whether the registered organization applicant, any controlling person of the registered organization applicant, any manager, any sole proprietor registered organization applicant, any general partner of a partnership applicant, any officer and member of the board of directors of a corporate applicant, and corporate general partner had a prior discharge in bankruptcy or was found insolvent in any court action;

(17) if any controlling person of the registered organization applicant maintains a ten (10) percent interest or greater in any firm, association, foundation, trust, partnership, corporation, or other entity or if such entity maintains a ten (10) percent interest or greater in the registered organization applicant, and such entity will or may provide goods, leases, or services to the registered organization, the value of which is or would be five hundred dollars or more within any one (1) year, the name and address of the entity shall be disclosed together with a description of the goods, leases or services and the probable or anticipated cost to the registered organization;

(18) if the registered organization applicant is a corporate subsidiary or affiliate of another corporation, disclosure of the parent or affiliate corporation including the name and address of the parent or affiliate, the primary activities of the parent or affiliate, the interest in the registered organization applicant held by the parent or affiliate and the extent to which the parent will be responsible for the financial and contractual obligations of the subsidiary;

(19) the most recent certified financial statement of the registered organization applicant, audited by an independent certified public accountant and prepared in accordance with generally accepted accounting principles (GAAP) applied on a consistent basis, including a balance sheet as of the end of the registered organization applicant's last fiscal year and income statements for the past two (2) fiscal years, or such shorter period of time as the registered organization applicant has been in operation;

(20) if construction, lease, rental or purchase of the manufacturing or dispensing site has not been completed, a statement indicating the anticipated source and application of the funds to be used in such purchase, lease, rental or construction;

(21) a staffing plan for staff involved in activities related to the cultivation of cannabis, the manufacturing or dispensing of medical cannabis products or staff with oversight responsibilities for such activities, which shall include:

(i) a senior staff member with a minimum of one (1) year experience in good agricultural practices (GAP);

(ii) a quality assurance officer who shall exercise oversight of the organization's practices and procedures and who has documented training and experience in quality assurance and quality control procedures;

(iii) a requirement that all staff be eighteen (18) years of age or older. Any employee eighteen (18) years of age or older and under twenty-one (21) years of age may not have direct interaction with customers inside a registered organization's dispensing site;

(iv) a requirement that all staff involved in the manufacturing of medical cannabis be trained in and conform to general sanitary practices; and

(v) policies and procedures to ensure that the registered organization shall not be managed by or employ anyone who has been convicted within three (3) years of the date of hire, of any felony related to the functions or duties of operating a business, unless the Office determines that the manager or employee is otherwise suitable to be hired as set forth in section 34 subdivision 7 of Article 3, or section 137 of the Cannabis Law;

(22) an environmental sustainability program plan for medical cannabis product packaging, which may include, but is not limited to, strategies to collect reusable medical cannabis packaging components, sustainable packaging strategies that use non-plastic, compostable or recyclable materials, or packaging materials exceeding 25% post-consumer recycled content; and

(23) any other information as may be required by the Office.

(c) An application under this section may be amended while the application is pending before the Board, if approved by the Board upon good cause shown.

(d) The registered organization applicant shall verify the truth and accuracy of the information contained in the application. The Board, in its discretion, may reject an application if it determines that information contained therein is not true and accurate.

(e) A registered organization applicant and registered organization shall have an obligation to ensure that the information, documentation, attestations, and assurances submitted to the Office are not fraudulent, false, or misleading.

(f) The information furnished in an application and in any supplemental statement related thereto shall be presumed correct and shall be binding upon a registered organization as if correct. All information furnished in an application or supplemental statement shall be deemed material in:

(1) any prosecution for perjury;

(2) any proceeding to suspend, cancel or revoke a registration or impose a fee or other penalty; and

(3) the approval or denial of a registration.

(g) A registered organization applicant shall identify any conflict of interest, including, without limitation, any relationship or affiliation of the registered organization applicant that currently exists with any member, employee, consultant or agent of the Office or the Board. The conflict of interest may be actual or perceived. If any conflict of interest should arise during the term of the application process, the registered organization applicant shall notify the Office in writing of such conflict.

(h) Only complete applications may be processed. The processing of an application shall not constitute an acknowledgment that the requirements of the Cannabis Law and this subchapter have been satisfied.

§ 113.7 Consideration of Registered Organization Applications.

(a) Registered organization applicants for approval to operate as registered organizations shall submit an application to the Office, containing the information required in section 113.6 of this Part, in a manner and format determined by the Office.

(b) Applications, as well as renewal applications, shall be accompanied by a non-refundable application fee in the amount of \$10,000 unless the Board determines otherwise due to the nature and scope, or size of the activities for which the registered organization is applying.

(c) The registration fee for the registration period, as well as any renewal registration period, shall be \$200,000, unless the Board determines otherwise due to the nature and scope, or size of the activities for which the registered organization is applying.

(d) Registered organization applicants granted a registration shall immediately submit the registration fee by certified check, or another method approved by the Board.

(e) In deciding whether to grant an application for registration or amendment to a registration, the Board shall consider whether:

(1) the registered organization applicant will be able to manufacture medical cannabis products, each with a consistent phytocannabinoid profile (the concentration of total

tetrahydrocannabinol (THC) and total cannabidiol (CBD) will define the product) and each able to pass the required quality control testing;

(2) the registered organization applicant will produce sufficient quantities of medical cannabis products as necessary to meet the needs of certified patients;

(3) the registered organization applicant will be able to maintain effective control against diversion of cannabis, medical cannabis, and medical cannabis products;

(4) the registered organization applicant is able to comply with all applicable state and local laws and regulations;

(5) the registered organization applicant is ready, willing and able to properly carry on the activities set forth in this Part;

(6) the registered organization applicant possesses or has the right to use sufficient real property, buildings and equipment to properly carry on the activity described in its operating plan;

(7) it is in the public interest that such registration be granted including:

(i) whether the number of registered organizations in an area will be adequate to reasonably serve the area, including whether there is sufficient geographic distribution across the state;

- (ii) whether the registered organization applicant is a minority owned business, woman owned business enterprise (or both), a service-disabled veteran-owned business, or from communities disproportionately impacted as those terms are defined in section 87 of the Cannabis Law and as determined by the Board;
- (iii) whether the registered organization provides education and outreach to practitioners;
- (iv) whether the registered organization promotes the research and development of medical cannabis and patient outreach;
- (v) the affordability of medical cannabis products offered by the registered organization;
- (vi) whether the registered organization is culturally, linguistically, and medically competent to provide services to unserved and underserved areas;
- (vii) whether the registered organization is reflective of the demographics of the state, and representative of communities disproportionately impacted by cannabis prohibition;
- (viii) whether the registered organization promotes racial, ethnic and gender diversity in their workforce; and
- (ix) whether the registered organization minimizes or eliminates adverse environmental impacts, including but not limited to water energy and water usage, carbon emissions, waste,

pollutants, and single-use plastics, and complies with the energy and environmental regulations set forth in section 113.26 of this Part;

(8) the board members, officers, managers, owners, partners, principal stakeholders, directors, and members of the applicant's organization are of good moral character and competent to perform the duties of a registrant, including but not limited to consideration of any enforcement action or investigation against any of these individuals or related entities in another jurisdiction;

(9) the registered organization 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 registered organization applicant's employees;

(10) upon evaluation, the registered organization applicant's proposed business plan and proposed manufacturing and dispensing sites, including but not limited to the location and construction timeline for the proposed facilities are found to be suitable to meet the needs of the program; and

(11) the registered organization applicant and its board members, officers, managers, owners, partners, principal stakeholders, directors, and members of the applicant's organization have any history of administrative violations or disciplinary actions taken against them by any regulatory or licensing authority in any jurisdiction during the past five (5) years.

(f) The registered organization applicant shall allow reasonable access to the Office or its authorized representatives for the purpose of conducting an on-site survey or inspection of the applicant's proposed manufacturing or dispensing sites.

(g) If the Office is not satisfied that the registered organization applicant should be issued a registration, the Office shall notify the registered organization applicant in writing of those factors upon which further evidence is required. Within thirty (30) days of the receipt of such notification, the applicant may submit additional material to the Office or demand a hearing, or both.

(h) Upon application to the Board, a registered organization's registration may be amended to allow the registered organization to relocate within the state or to add or delete permitted registered organization activities or facilities. The Board shall consider whether to grant or deny the application for amendment of the registration utilizing the criteria set forth in subdivision (e) of this section. The fee for such amendment review shall be \$2,000. A registered organization may apply to add an additional four dispensing sites; provided that:

(1) the registered organization's first four dispensing sites are operational;

(2) the first two additional dispensing sites shall be located in underserved or unserved geographic locations, as determined by the Board, and shall be operational before consideration will be given for the remaining two dispensing sites; and

(3) a fee is received for each new dispensing facility application of \$2,000.

(i) Registrations issued shall be valid for two (2) years from the date of issuance.

§ 113.8 Applications for Renewal of Registration as Registered Organization.

(a) An application to renew any registration issued under this Part shall be filed with the Office not more than six (6) months nor less than four (4) months prior to the expiration thereof. If a renewal application is not filed at least four (4) months prior to the expiration thereof, the Board may determine that the registration shall have expired and become void on such expiration date.

(b) Applications shall be accompanied by a non-refundable application fee and a registration fee as set forth in section 113.7 of this Part, made by certified check. Only applications completed in accordance with this Part as determined by the Board and for which the application and registration fees have been submitted shall be considered if submitted in a timely manner. The registration fee shall be returned to the registered organization applicant if the registered organization applicant is not granted a renewal registration under this section.

(c) The application for renewal shall include such information prepared in the manner and detail as the Board may require, including but not limited to:

(1) any material change(s) as determined by the Office in the information, circumstances or factors listed in section 113.6 of this Part;

- (2) every known complaint, charge or investigation, pending or concluded during the period of the registration, by any governmental or administrative agency with respect to:
- (i) each incident or alleged incidence involving the theft, loss, or possible diversion of medical cannabis manufactured, distributed, or dispensed by the registered organization; and
 - (ii) compliance by the registered organization applicant with local or state laws, or regulations of the Board, including but not limited to, with respect to any controlled substance listed in section 3306 of the Public Health Law; and
- (3) information concerning the registered organization applicant's ability to carry on the activity for which it is registered, including but not limited to, medical cannabis product shortages or wait lists occurring during the registration period;
- (4) a summary of quality assurance testing for all medical cannabis products produced in the prior year, including but not limited to, the percentage of lots of each product passing all required testing, the percentage of lots failing contaminant testing, the percentage of lots failing product requirements, all recalls of product lots and all adverse events reported; and
- (5) an updated environmental sustainability packaging program plan and a report of key metrics including, but not limited to, the total amount of packaging material, by weight, sold, offered for sale, or distributed into the state by the registered organization during the renewal period and the total costs of packaging material.

(d) The Board shall consider applications for renewal in accordance with the criteria set forth in section 113.7 of this Part.

(e) If the Board determines that the registered organization applicant's registration should not be renewed, the Board shall serve upon the registered organization applicant or their attorney of record, in person or by registered or certified mail, an order directing the registered organization applicant to show cause why their application for renewal should not be denied. The order shall specify in detail the ways in which the registered organization applicant has not satisfied the requirements for renewal.

(1) Within ten (10) business days of receipt of such an order, the registered organization applicant may submit additional material to the Board or demand a hearing, or both. If a hearing is demanded, the Board shall fix a date as soon as reasonably practicable.

(2) If the registered organization applicant fails to submit additional material to the Board within ten (10) business days as requested, and the registered organization applicant does not demand a hearing within such time period, the application for renewal of registration shall be denied.

(f) If a registered organization's application for renewal of registration is denied, the registered organization shall submit a proposed plan for closure in accordance with subdivision (c) paragraph (2) of section 113.11 of this Part.

§ 113.9 Registrations Non-transferable.

(a) Registrations issued under this Part shall be effective only for the registered organization and shall specify:

(1) the name and address of the registered organization;

(2) name of the contact person for the registered organization;

(3) the activities the registered organization is permitted to perform under the registration for each approved location; and

(4) the real property, buildings and facilities that may be used for the permitted activities of the registered organization.

(b) Registrations are not transferable or assignable, including, without limitation, to another registered organization.

(c) A registered organization shall not change its composition, including but not limited to, a change in ownership, structure or control, without notification to the Board and without prior written approval of the Board. Failure to notify the Board and receive prior written approval of

such changes may result in civil penalties or revocation of the registered organization's registration. For purposes of this subdivision, a change shall include, but not be limited to:

(1) the sale or acquisition of 5% or more equity in the registered organization or in an entity holding a controlling interest in the registered organization, except for the following situations:

(i) passive investments whereby the individual investor buys and holds a diversified mix of assets and who does not participate in the day-to-day decisions of running the company and has no control over the registered organization; or

(ii) where an individual owns employee stock options which gives the employee a right to buy or exercise a set number of shares of the registered organization's stock but does not convey actual ownership or control over the registered organization; or

(2) any change in control, where an individual, corporation or entity will be in a position to control the decision-making of a registered organization, including but not limited to:

(i) control of more than 50% of the voting rights or has the power to appoint more than 50% of the directors;

(ii) any individual or entity who has an agreement that specifies the way in which they may vote, to work collectively, and in the aggregate, have 50% or more of voting rights or has the power to appoint more than 50% of the directors;

(iii) contract away the rights to control the organization or the right to exercise control over the business, or other rights as determined by the Board, to a person or entity that is not a member of the governing body of the organization; or

(iv) right to veto significant events which may include, but are not limited to, any sale of all, or substantially all, of the registered organization's assets, a merger or consolidation, a change in ownership or control, liquidation, dissolution of a registered organization, or other events as determined by the Board, or

(3) the appointment or removal of any member of the governing body of such organization, including but not limited to, those who have control in the appointment of members to the governing body; or

(4) any officer, owner, partners, directors, or any person or entity who has the power to direct or cause the direction of the management and policies of the organization.

(d) Registered organizations seeking to materially change their composition pursuant to subdivision (c) of this section, shall submit an application to the Board at least sixty (60) days prior to the proposed date of execution, acquisition or change. In determining whether to approve such application, the Board may set terms or conditions under which it may allow the continued operation of the registered organization. The Board shall consider whether to grant or deny the

application utilizing the criteria set forth in section 113.7 of this Part. The fee for such amendment shall be \$5,000.

§ 113.10 Failure to Operate.

(a) A registration shall be surrendered to the Board upon written notice and demand if the registered organization fails to begin operations, to the satisfaction of the Board, of a manufacturing or dispensing site within the six (6) months of the date of issuance of the registration.

(b) A registered organization who is required to surrender its registration in accordance with this section shall not be entitled to any refund of fees paid to the Office.

§ 113.11 Registered Organizations; General Requirements.

(a) In addition to the requirements in Cannabis Law and as otherwise set forth in this Part, a registered organization shall:

(1) make its books, records, manufacturing and dispensing site architectural and engineering design drawings, including a description of energy sources, type and location of engineering systems in use for heating, cooling, ventilation and electrical distribution, water supply and sewage, policies and procedures, and manufacturing and dispensing sites, available to the Office or its authorized representatives within 48 hours of notice for monitoring, on-site inspection, and audit purposes, including but not limited to periodic inspections or evaluations of facilities, methods, procedures, materials, staff and equipment to assess compliance with requirements set

forth in Article 3 of the Cannabis Law and this Part. The operating plan must be onsite and readily accessible at each facility at all times;

(2) only manufacture and dispense medical cannabis products in New York State in accordance with Article 3 of the Cannabis Law and this Part;

(3) only dispense medical cannabis products in an indoor, enclosed, secure facility located in New York State;

(4) submit medical cannabis product(s), samples and manufacturing materials to the Office upon request;

(5) retain a subset of each lot of medical cannabis product to allow for testing in the future if requested by the Office. The retained samples shall:

(i) be stored unopened as indicated on the label and in the original packaging;

(ii) be readily identifiable as belonging to its specific lot; and

(iii) be a statistically representative quantity to allow for complete testing of the product at least two (2) times and shall be retained by the registered organization for at least thirty (30) days following the date of expiration.

(6) implement policies and procedures to notify the Office within twenty-four (24) hours of the following:

(i) any serious adverse events;

(ii) any incident involving theft, loss or possible diversion of medical cannabis products;

(iii) any suspected or known security breach or other facility event that may compromise public health and/or safety, or which requires response by public safety personnel or law enforcement;
and

(iv) any vehicle accidents or incidents occurring during transport of medical cannabis products;
and

(7) within ten (10) days of the occurrence of one of the above events, the registered organization shall submit a complete written incident report to the Office detailing the circumstances of the event, any corrective actions taken, and where applicable, confirmation that appropriate law enforcement authorities were notified.

(8) quarantine any lot of medical cannabis product as directed by the Office, and not transport, distribute, dispense or destroy such lot unless prior approval is obtained from the Office;

(9) dispose of unusable medical cannabis products that have failed laboratory testing or any cannabis used in the manufacturing process pursuant to section 113.25 of this Part;

(10) maintain records required by Article 3 of the Cannabis Law and this Part for a period of five (5) years, unless otherwise stated, and make such records available to the Office upon request.

Such records shall include:

(i) documentation, including lot numbers where applicable, of all materials used in the manufacturing of the medical cannabis product to allow tracking of the materials, including but not limited to, soil, soil amendment, nutrients, hydroponic materials, fertilizers, growth promoters, pesticides, fungicides, and herbicides;

(ii) cultivation, manufacturing, packaging and labeling production records; and

(iii) laboratory testing results.

(11) post the certificate of registration issued by the Office in a conspicuous location on the premises of each manufacturing facility and dispensing site;

(12) amend its operating plan as directed by the Office;

(13) provide all employees with adequate training and proper safety equipment where necessary; and

(14) implement procedures to notify the Office if the dispensing site closes during its normal hours of operation, the reason for the closure, and when the dispensing site is expected to resume normal hours of operation.

(b) Registered organizations shall not:

(1) dispense medical cannabis products from the same location where the cannabis is grown or manufactured, except for the operation of home delivery services;

(2) grow cannabis or produce medical cannabis at any site other than a facility or site approved by the Office as set forth in the registered organization's registration;

(3) distribute products or samples at no cost except as may be allowed by the Office;

(4) make substantial alterations to the structure or architectural design of a manufacturing or dispensing site without prior written approval of the Office;

(5) make the following modifications to a registered facility:

(i) change the location without prior approval of the Board; or

(ii) expand or reduce the size of a registered facility without prior written approval of the Office;

(6) materially modify or revise its operating plan, including its policies and procedures, without filing the revised operating plan in a manner as prescribed by the Office;

(7) locate a dispensing site on the same street or avenue and within five hundred (500) feet of school grounds as such term is defined in the Education Law or two hundred (200) feet from a house of worship. The measurements in this paragraph of this subdivision are to be taken in straight lines from the center of the nearest entrance of the premises sought to be used as a dispensing site used by certified patients or designated caregivers to enter to the nearest point of the school grounds or house of worship; or

(8) change the name of the registered organization, including the name by which the organization does business, without receipt of prior written approval of the Office.

(c) In the event that a registered organization elects to cease operation of all permitted activities and surrender its registration, the registered organization shall:

(1) notify the Office in writing at least 120 days prior to the anticipated date of closure of the manufacturing and each dispensing site.

(2) include a proposed plan for closure in the written notice. The plan shall be subject to Office approval in accordance with Office protocols, and shall include timetables and describe the procedures and actions the registered organization shall take to:

- (i) notify affected certified patients and designated caregivers of the closure;
 - (ii) properly destroy, transfer or otherwise dispose of all the registered organization's supply of cannabis and medical cannabis products in accordance with the requirements set forth in section 113.25 of this Part;
 - (iii) maintain and make available to the Office all records required to be maintained under this Part for a period of five (5) years; and
 - (iv) maintain compliance with these regulations and any other conditions required by the Office until the approved closure date;
- (3) The registered organization shall take no action to close a manufacturing or dispensing site prior to Office approval of the plan for closure; and
- (4) The registered organization's failure to notify the Office of intent to cease any operations, failure to submit an approvable plan, and/or to execute the approved plan may result in the imposition of civil penalties, not to exceed \$2,000, and shall be a basis for the Board to revoke the registration of the registered organization under such terms as the Board determines is appropriate based on public health and safety considerations. In addition, the Office reserves the right to exercise any other remedies available to it.

§ 113.12 Manufacturing Requirements for Medical Cannabis Products.

(a) Requirements for extraction. Unless otherwise approved in writing by the Office, a registered organization may only use the methods, equipment, solvents, gases and mediums set forth in this section when creating cannabis extracts and only in a manner exhibiting minimal potential for human health related toxicity.

(1) All extraction processes and activities must:

(i) be conducted by employees adequately trained in the operation of the extraction equipment to be utilized, as well as the emergency plan for incidents;

(ii) demonstrate control of all sources of ignition, and occur in a spark-free environment where appropriate for the type of extraction method used;

(iii) ensure proper ventilation;

(iv) have ongoing equipment monitoring and maintain a record of regular maintenance of equipment based on equipment specifications;

(v) follow all applicable fire, safety and building codes, regulations, laws and guidance in the use and storage of solvents, including but not limited to, maximum quantities to be held onsite;

(vi) evidence the purity of any chemical solvents used and make any certificate of analysis or other documentation evidencing such purity and shall make such evidence readily available to employees and to the Office upon request.

(2) Unless a registered organization obtains prior written approval from the Office, extraction shall only be conducted using the following methods:

(i) use of mechanical extraction methods, such as screens or presses, or heat, steam distillation, ice water and other methods without employing solvents or gases;

(ii) use of a professional grade, closed-loop CO₂ gas extraction system that is of a supply equivalent to food or beverage grade of at least 99.5 percent purity;

(iii) Ethanol, provided that all ethanol used shall be of a grade that meets or exceeds specifications of official compendiums as defined in section 321 of Title 21 of the United States Code (USC);

(iv) use of a volatile solvent or hydrocarbon extraction method, provided that the method:

(a) utilizes a commercial, professional grade closed-loop system designed to recover the solvent;

(b) utilizes the following permissible volatile solvent-based or hydrocarbon extraction substances, which must be accompanied by a certificate of analysis which establishes that said substances have a minimum purity level of 99 percent:

- (1) Butane;
- (2) Propane;
- (3) A different volatile solvent or hydrocarbon with prior written approval by the Office prior to use;

(c) In addition, for all proposed volatile solvent based or hydrocarbon extraction, a registered organization shall submit to the Office, prior to receiving approval to commence extraction operations, documentation which demonstrates, to the satisfaction of the Office, the following additional requirements for all designated extraction equipment, rooms, or other areas where volatile solvents used for extraction are handled or stored:

- (1) final certification letter from a licensed professional engineer or registered architect which certifies the completed installation of a professionally designed, commercially manufactured extraction system, that is compliant with all applicable state or local fire, safety or building codes;
- (2) a letter or equivalent document as determined by the Office from the municipal jurisdiction's fire marshal, local building code authority, or its equivalent, stating that the facility is approved to conduct the proposed activities and that the registered organization has demonstrated compliance with all applicable fire codes and/or regulations; and
- (3) a certificate of occupancy, or equivalent document, from the local building official that all permits for extraction related rooms or areas have been closed as applicable.

(b) A registered organization shall only produce medical cannabis products according to the following requirements:

(1) each medical cannabis product, in its final form, shall be defined as having a specific concentration of total Tetrahydrocannabinol (THC) and total Cannabidiol (CBD) and shall have a consistent phytocannabinoid profile. The concentration of the following phytocannabinoids, at a minimum, must be reported:

(i) tetrahydrocannabinol (THC);

(ii) tetrahydrocannabinol acid (THCA);

(iii) cannabidiol (CBD);

(iv) cannabinadiolic acid (CBDA);

(v) any other marketed phytocannabinoid;

(vi) any other phytocannabinoid component at > 0.2 percent of the phytocannabinoid profile;

and

(vii) terpenoid content, if the registered organization will be marketing or advertising terpenoid content, or including terpenoid content as a part of the medical cannabis product labeling.

(2) the final medical cannabis product shall not contain less than ninety (90) percent, nor more than 110 percent, of the concentration of total THC or total CBD, as indicated on the label.

However:

(i) where the total THC concentration is less than five (5) milligrams per dose, the concentration of total THC shall be within 0.5 milligrams per dose;

(ii) where the total CBD concentration is less than five (5) milligrams per dose, the concentration of total CBD shall be within 0.5 milligrams per dose; and

(iii) unless otherwise approved by the Office, the concentration of total THC and CBD in milligrams per single dose for any sample of a product submitted for testing must be within twenty-five (25) percent of the mean concentration of total THC and CBD in milligrams per single dose for that submitted lot with the exception that, for products with a specified total THC and CBD concentration less than two (2) milligrams per single dose, the concentration of each sample for that low concentration phytocannabinoid shall be within 0.5 milligrams per dose of the mean concentration.

(3) the registered organization shall offer and make available to patients at least one (1) medical cannabis product that has a low THC and a high CBD content (e.g., a 1:20 ratio of THC to CBD);

(4) the registered organization shall offer and make available at least one (1) medical cannabis product that has approximately equal amounts of THC and CBD;

(5) for each medical cannabis product offered, the registered organization shall utilize a name that complies with the requirements of section 113.12(k) of this Part; and

(6) each registered organization shall have a manufacturing schedule that ensures the ability to produce adequate supply of any offered medical cannabis product, unless otherwise allowed by the Office, to ensure continuity of care for certified patients;

(c) Excipients for all forms of administration must be demonstrated safe for use in the proposed form. All vaporized and inhaled medical cannabis products shall meet the following additional requirements:

(1) unless prior written approval of the Office is received, medical cannabis vaporization devices for concentrates shall be a closed system with a pre-filled single-use cartridge that attaches to a rechargeable battery, or a single-use product;

(2) electronic vaporization devices shall have internal or external temperature controls to prevent combustion and have a heating element made of inert material such as glass, ceramic or stainless steel and not plastic or rubber;

(3) except for cannabis or hemp-derived terpenes, excipients and ingredients must be pharmaceutical grade unless otherwise approved by the Office, and shall not include:

(i) synthetic terpenes;

(ii) polyethylene glycol (PEG);

(iii) vitamin E acetate;

(iv) medium chain triglycerides (MCT oil);

(v) medicinal compounds;

(vi) illegal or controlled substances;

(vii) artificial food coloring;

(viii) benzoic acid;

- (ix) diketones; and
 - (x) any other compound or ingredient as determined by the Office;
- (4) not contain any flavors or flavoring agents, except for cannabis-derived or hemp-derived terpenes; and
- (d) A registered organization shall:
- (1) use good agricultural practices (GAPs);
 - (2) use good manufacturing practices (GMPs) and demonstrate compliance with GMP by submitting to the Office proof of a qualified third-party GMP audit of the registered organization's extraction and/or manufacturing facility operations and any related certification or audit report within one year of commencing operations and be maintained for the duration of the registration;
 - (3) conform to all applicable laws and rules of New York State;
 - (4) use water from a public water supply or present a plan, approved by the Office, which demonstrates the ability to obtain sufficient quantities of water of equal or greater quality as that from a public water supply and to monitor the quality of such water on an ongoing basis;

- (5) only use pesticides that are registered by the New York State Department of Environmental Conservation or that specifically meet the United States Environmental Protection Agency registration exemption criteria for Minimum Risk Pesticides, and only in accordance with 6 NYCRR section 325.2(b);
 - (6) process the leaves and flowers of the female cannabis plant only, in a safe and sanitary manner;
 - (7) perform visual inspection of the harvested plant material to ensure there is no mold, mildew, pests, rot or gray or black plant material;
 - (8) have a separate secure area for temporary storage of any medical cannabis or medical cannabis product that needs to be destroyed; and
 - (9) provide continual environmental monitoring for temperature, ventilation and humidity at all locations in the manufacturing facility where unprocessed leaf and flower material is stored, until further extraction or other processing is completed.
- (e) Production of any medical cannabis product shall be in accordance with general sanitary conditions. Poisonous or toxic materials, including but not limited to, insecticides, rodenticides, detergents, sanitizers, caustics, acids and related cleaning compounds must be stored in a separate area from the cannabis and medical cannabis products in prominently and distinctly labeled

containers, except that nothing herein precludes the convenient availability of detergents or sanitizers to areas where equipment, containers and utensils are washed and sanitized.

(f) Medical cannabis products shall be limited to the following forms of administration:

(1) metered liquid or oil preparations;

(2) solid and semisolid preparations (e.g. capsules, chewable and effervescent tablets, lozenges);

(3) metered ground plant preparations;

(4) whole flower;

(5) topical forms and transdermal patches; or

(6) any other form approved by the Board.

(g) Medical cannabis may not be incorporated into food or beverage products by the registered organization, unless approved by the Board

(h) The registered organization shall identify each lot of medical cannabis product with a lot unique identifier.

(i) The registered organization shall package the final form of the medical cannabis product at the manufacturing site. The original seal shall not be broken except for quality testing at an approved laboratory, for adverse event investigations, by the Office, by the certified patient or designated caregiver, designated caregiver facility, an authorized cannabis research license holder, or by the registered organization for internal quality control testing or disposal.

(j) Medical Cannabis Product Packaging Minimum Standards.

(1) A medical cannabis product package shall:

(i) be packaged and labeled in its final form at the manufacturing facility;

(ii) be easily readable and firmly affixed to the package;

(iii) be child-resistant unless otherwise approved by the Office;

(iv) be tamper-evident;

(v) fully enclose the product, minimize oxygen exposure and prevent the contamination and/or degradation of the medical cannabis product; and

(vii) not impart any toxic or deleterious substance onto the medical cannabis product.

(2) Unless otherwise approved by the Office, a registered organization shall maintain a copy of the certificate showing that each medical cannabis package into which the registered organization places medical cannabis products is child-resistant and complies with the requirements of 16 CFR §1700.15 for Poison Prevention Packaging Standards and 16 CFR §1700.20 for Testing Procedure for Special Packaging.

(3) An exit package is optional and is not required to be labeled but may include the registered organization's name or logo, provided that the name or logo complies with the provisions of subdivision 113.12 (k) of this section.

(4) Registered organizations shall implement a recycling program for medical cannabis product packaging.

(5) Claims about recyclable or recycled content packaging shall comply with Title 16 of the Code of Federal Regulations relating to Commercial Practices, Part 260 regarding Guides for the Use of Environmental Marketing Claims.

(k) Medical Cannabis Product Packaging Prohibitions.

(1) A medical cannabis product package shall not:

- (i) be opened or the original seal be broken except for quality testing at an approved laboratory, for adverse event investigations, by the Office, by the certified patient or designated caregiver, designated caregiver facility, an authorized cannabis research license holder, or by the registered organization for internal quality control testing or disposal, unless otherwise approved by the Office;
- (ii) contain any pictures, images, or graphics, other than what may be required by the Office;
- (iii) contain any features that emit scent or sound;
- (iv) contain any features that change or alter a package's appearance through technology, other than for anti-counterfeiting purposes;
- (v) be made attractive to individuals under twenty-one (21) by using or including:
 - (a) Cartoons;
 - (b) Bubble-type or other cartoon-like font;
 - (c) Bright colors that are "neon" in appearance;
 - (d) Similarities to products or words that refer to products that are commonly associated with or marketed in a manner so as to be attractive to individuals under twenty-one (21), including but

not limited to, any imitation of food, candy, soda, drinks, cookies, or cereal, in labeling, packaging, advertising, or marketing;

(e) Terms “candy” or “candies” or variants in spelling such as “kandy” or “kandeez”;

(f) Symbols, images, characters, public figures, phrases, toys, or games that are commonly used to market products to individuals under the age of twenty-one (21); or

(g) Images of individuals who could reasonably appear to be under the age of twenty-one (21).

(vi) use any term or variants in the spelling of any term describing a medical condition;

(vii) be made of single-use plastic, unless containing a minimum 25% post-consumer recycled content. The Board may waive this requirement upon good cause shown; and

(viii) violate any additional requirements as set out by the Office.

(l) Cannabis Product Labeling Minimum Standards

(1) Registered organizations shall ensure that the principal packaging display panel shall have a white background with black text containing the following information:

- (i) the medical cannabis product form_u and brand designation;
- (ii) a list of all ingredients in descending order of predominance by weight in the medical cannabis product – both active and inactive. The ingredient list must include and separately list, in bold, any major allergens set forth in the Food Allergen Labeling and Consumer Protection Act of 2004, Title 21, as it relates to Food and Drugs, of the U.S. Code § 343, for misbranded food.
- (iii) milligrams per dose of total THC (THC + THCA x 0.877), total CBD (CBD + CBDA x 0.877) content;
- (iv) milligrams per package of total THC (THC + THCA x 0.877) and total CBD (CBD + CBDA x 0.877)
- (v) any other marketed phytocannabinoids in milligrams per dose and milligrams per package;
- (vi) the amount of total THC (THC + THCA x 0.877) and any other marketed phytocannabinoids as a percentage of volume, unless otherwise exempted by the Office;
- (vii) the total quantity or volume included in the package;
- (viii) the medical cannabis product lot unique identifier (lot number or bar code);

(ix) the date of expiration of the unopened medical cannabis product based on stability studies in accordance with paragraph 113.12(p)(2) of this section;

(x) use by date once the medical cannabis product is opened if not included on the dispensing label pursuant to 113.12(p)(1) of this section;

(xi) the proper storage conditions;

(xii) the name, address and registration number of the registered organization;

(xiii) language stating:

(a) “Keep secured at all times.”;

(b) “May not be resold or transferred to another person.”;

(c) “This product might impair the ability to drive.”;

(d) “Medical cannabis products must be kept in the original container in which they were dispensed and removed from the original container only when ready for use by the certified patient.”;

(e) “KEEP PRODUCT AWAY FROM CHILDREN (unless the medical cannabis product is being given to the child under a practitioner's care). In case of accidental ingestion or overconsumption, contact the poison control hotline 1-800-222-1222 or call 9-1-1.”

(f) “This product is for medicinal use only. This product should not be consumed during pregnancy or while nursing except on the advice of the certifying practitioner, and in the case of a nursing parent, including the infant’s pediatrician.”; and

(g) For topical products: “For external use only”.

(xiv) a scannable bar code or QR code linked to a downloadable certificate of analysis for the medical cannabis product or linked to a website where the certificate of analysis can be downloaded. A registered organization shall provide a physical or paper certificate of analysis which includes, but is not limited to, the quality, safety and clinical strength of the medical cannabis product manufactured or dispensed by the registered organization directly to certified patients or their designated caregivers upon their request, in accordance with section 34 of the Cannabis Law;

(xv) any solvent used to produce the medical cannabis product, if applicable; and

(xvi) any other information required by the Board.

(2) Required labeling on the medical cannabis package must be:

- (i) in text no smaller than 6-point font;
 - (ii) clearly written or printed and visible to consumers;
 - (iii) in Times New Roman, Calibri, Arial, or Helvetica; and
 - (iv) in the English language. In addition to the required labeling in English, licensees may include an additional, accurate foreign language translation on the package that otherwise complies with this Part.
- (3) The information required pursuant to section 113.12(1)(1) of this Part must be unobstructed and conspicuous. A registered organization may include the required information by printing the information directly onto the medical cannabis package or by affixing multiple labels with the information to the package, provided none of the information is obstructed. For example, and not by means of limitation, the information may appear on labels that may be accordion, expandable, extendable, or layered to accommodate labeling of small packages.
- (4) Any research licensee conducting research approved by the Office involving human subjects shall comply with all packaging and labeling requirements, unless the licensee receives prior written approval for a waiver of specific packaging or labeling requirements in connection with any research approved by the Office. The waiver may extend to a registered organization providing medical cannabis or medical cannabis products for an approved research study.

(m) Medical Cannabis Product Labeling Prohibitions; No medical cannabis product package shall display any content or be labeled in any manner that:

(1) is made attractive to individuals under twenty-one (21) as set forth in section 113.12(k)(1)(v) of this Part;

(2) includes any false or misleading statements;

(3) includes the term “organic”;

(4) includes the term “craft”;

(5) causes a reasonable consumer confusion as to whether the medical cannabis product is trademarked, marked or labeled in a manner that violates any federal trademark law or regulation;

(6) depicts cannabis, cannabis products, or paraphernalia;

(7) promotes overconsumption or consumption contrary to a certifying practitioner or pharmacist’s recommendation;

(8) depicts a child or other person reasonably appearing to be under the age of twenty-one (21);
and

(9) violates additional prohibitions as set out by the Office.

(n) For each lot of medical cannabis product produced by the registered organization, a predetermined number of final medical cannabis products shall be collected and submitted, in a manner approved by the Office, for final product testing to an independent laboratory/laboratories permitted by the Office. The registered organization must review the testing results provided by the independent laboratory/laboratories to verify that the concentration of cannabinoids is consistent with the form of medical cannabis and verify that contaminants do not exceed limits, as defined by the Office, prior to the medical cannabis product being released from the manufacturer to any dispensing site.

(o) Any lot not meeting the minimum testing standards for contaminants, shall be rejected and destroyed by the registered organization in accordance with section 113.25 of this Part, notwithstanding a medical cannabis flower product lot that has not met the minimum testing standards for microbial testing and has passed all remaining contaminant testing. A registered organization may remediate and repurpose medical cannabis flower products provided that;

(1) the lot must be resubmitted for laboratory testing in a manner set forth in section 113.12(n) of this Part;

(2) after completing the required analyses of a representative sample obtained from a

remediated or repurposed medical cannabis lot, the laboratory shall report the results to the Office within two (2) business days;

(3) a medical cannabis flower product lot may only be remediated or repurposed for extraction once. If the lot fails to meet minimum testing standards for contaminants after the remediation or repurposing process, the entire lot shall be destroyed by the registered organization in accordance with section 113.25 of this Part;

(4) when a failed medical cannabis flower lot is not remediated or reprocessed in any way it cannot be retested. Any subsequent testing results produced without remediation of the failed batch will not supersede the initial regulatory testing results.

(5) Any lot not meeting the minimum standards or specifications for product consistency shall be reported to the Office and not dispensed by a registered organization without prior written approval from the Office.

(6) The registered organization shall keep and maintain records documenting submission of medical cannabis products to approved laboratories as required herein, and the results of the laboratory testing. The registered organization shall provide the Office with such records upon request.

(p) The registered organization shall demonstrate the stability of each medical cannabis product produced by testing both the unopened and opened product in accordance with section 113.15(i) of this Part:

(1) the stability of opened products shall be validated under the conditions (light, temperature and humidity), specified for storage of the product and an expiration date for opened product shall be determined;

(2) the stability of unopened products (e.g., sealed packages or vials) shall be validated by ongoing stability testing and an expiration date for unopened products shall be determined;

(3) specifications regarding storage conditions must address storage at the manufacturing facility once the package is sealed, during transport, at the dispensing site, in the patient's home and for samples retained for future testing.

(q) Registered organization shall not prepare or produce any medical cannabis products that contains:

(1) synthetic cannabis additives;

(2) artificially derived phytocannabinoid; or

(3) phytocannabinoid not produced by a registered organization by extraction in an approved manufacturing facility.

(r) In the manufacturing of medical cannabis products, a registered organization may use hemp grown pursuant to the New York State Department of Agriculture and Markets, or hemp extracts derived from hemp, processed or manufactured in accordance with the Office's cannabinoid hemp program, in accordance with applicable federal, state and local laws and regulations;

(s) The registered organization's approved standard operating procedure for the aforementioned activities must be followed, unless otherwise approved by the Office.

Section 113.13 Requirements for Dispensing Sites.

(a) Medical cannabis products at a dispensing site shall only be dispensed by authorized employees, twenty-one (21) years of age or older, of the registered organization, under the in-person supervision of an individual with an active New York State pharmacist license as defined in Article 137 of the Education Law, who has completed at minimum a two (2) hour course pursuant to this Part.

(b) Dispensing sites 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.

(c) Dispensing sites may display, in secure, locked cases, samples of each medical cannabis product offered for sale. Authorized employees may remove samples from the display case and provide it to the medical cannabis certified patient or designated caregiver for inspection, provided the patient or caregiver may not consume or otherwise use or remove the sample from the dispensing site.

(d) No medical cannabis products shall be vaporized or consumed on the premises of a dispensing site.

(e) Dispensing sites shall not dispense medical cannabis products to anyone other than a certified patient, designated caregiver, research license holder, or unless such registered organization, pursuant to Article 4 of the Cannabis Law, is authorized by the Office to sell cannabis for adult use for retail sale.

(f) When dispensing medical cannabis, the dispensing site shall:

(1) not dispense any medical cannabis to a certified patient, unless the certified patient presents the dispensing site with:

(i) a valid certification from a practitioner, as defined in Article 1 of the Cannabis Law, and issued in accordance with, Article 3 of the Cannabis Law, which shall also serve as the certified patient's registry card; and

(ii) a valid government-issued photo identification, which the dispensing site shall use to validate that such patient is eighteen (18) years of age or older and capable of consent as documented on the certification, provided that, such government-issue photo identification, is issued by:

(a) the New York State commissioner of motor vehicles;

(b) the federal government of the United States;

(c) any United States territory;

(d) the District of Columbia;

(e) a state, commonwealth, or local government within the United States;

(f) a post-secondary educational institution regulated by the New York State Department of Education or another state; or

(g) or a provincial government of the dominion of Canada;

(2) use the patient certification number as the registry identification when a registry identification number is required;

(3) not dispense any medical cannabis product to a designated caregiver, unless such caregiver presents a certification in accordance with section 113.3 of this Part and a form of photo identification of such caregiver issued pursuant to this section.

(4) not dispense an amount greater than a sixty (60) day supply to a certified patient, and not until the patient has exhausted all but a seven (7) day supply provided pursuant to any previously dispensed medical cannabis by any registered organization;

(5) ensure that medical cannabis product packaging shall not be opened by dispensing site staff;

(6) provide a patient-specific log of medical cannabis products (brand, administration form, and dosage, and dates dispensed and any return of product) to the patient, the patient's designated caregiver, if applicable, or the patient's practitioner upon request;

(7) ensure the prescription monitoring program registry is consulted pursuant to 3343-a Public Health Law and section 34 Article 3 of the Cannabis Law prior to any sales transactions and dispensing of any medical cannabis products by the facility.

(g) The registered organization shall be responsible for maintaining the confidentiality of patients and the integrity of the security of the facility at all times. Access to medical cannabis storage areas and areas within the dispensing site where security equipment and recordings are stored shall be restricted to:

- (1) registered organization employees;
 - (2) employees of the Office or its authorized representatives;
 - (3) emergency personnel responding to an emergency, and;
 - (4) other persons authorized by a manager of the registered organization for the sole purpose of maintaining the operations of the facility.
- (h) The dispensing site shall maintain a visitor log of all persons, other than registered organization employees or emergency personnel responding to an emergency, that access these secured areas, which shall include the name of the visitor, date, time and purpose of the visit. The visitor log shall be available to the Office at all times during operating hours and upon request.
- (i) The dispensing site shall affix to the medical cannabis product package a patient specific dispensing label, that is easily readable, and firmly affixed and includes the following information:
- (1) the name and registry identification number of the certified patient and designated caregiver, if any;
 - (2) the certifying practitioner's name;

- (3) the dispensing site name, address and phone number;
 - (4) the dosing and administration instructions;
 - (5) the quantity and date dispensed;
 - (6) any recommendation or limitation by the practitioner as to the use of medical cannabis;
- and
- (7) the expiration date of the product once opened pursuant to section 113.12(p)(2) of this Part, if not included on the cannabis product label pursuant to section 113.12 of this Part.
- (j) The dispensing site shall include with each product package dispensed to a patient, a package safety insert. Information provided shall include but not be limited to:
- (1) the medical cannabis product;
 - (2) contraindications;
 - (3) specific dosage directions and instructions for administration based on the medical cannabis product form, including but not limited to onset of effect and duration of action;

- (4) warning of adverse events and/or any potential dangers stemming from the use of medical cannabis;
- (5) instructions for reporting adverse events as may be determined by the Office;
- (6) a warning about driving, operation of mechanical equipment, or making important decisions while taking medical cannabis;
- (7) information on tolerance, dependence and withdrawal and substance abuse, how to recognize what may be problematic usage of medical cannabis and obtain appropriate services or treatment;
- (8) language stating that the medical cannabis product must be kept secure at all times, and out of sight and reach of children and pets;
- (9) language stating that the certified patient may not distribute any medical cannabis product to anyone else;
- (10) language stating that unwanted, excess, or contaminated medical cannabis product must be disposed of in accordance with the requirements set forth in section 113.21 of this Part; and
- (11) language stating that “This product has not been analyzed by the FDA. There is limited information on the side effects of using this product and there may be associated health risks.”

(k) The dispensing site shall store the medical cannabis product in a manner to ensure that there is no contamination or deterioration of the medical cannabis product or its packaging.

(l) If a medical cannabis product is returned to the dispensing site, the dispensing site shall:

(1) dispose of such product pursuant to section 113.25 of this Part;

(2) retain the following information for at least five (5) years and make available to the Office upon request:

(i) the name and registry identification number of the certified patient for whom the product was dispensed;

(ii) the date of the return;

(iii) the product being returned;

(iv) the quantity and/or weight being returned;

(v) the reason for the return;

(vi) the name of the dispensing site employee accepting the return; and

(vii) any other information required by the Office;

(3) ensure the returned medical cannabis product is securely stored, separate from working inventory while awaiting disposal.

§ 113.14 Security Requirements for Manufacturing and Dispensing Sites.

(a) All facilities operated by a registered organization, including any manufacturing facility and dispensing site, shall have a security system to prevent and detect diversion, theft or loss of cannabis and/or medical cannabis products, utilizing commercial grade equipment, which shall, at a minimum, include:

(1) a perimeter alarm that communicates with an internal designee and a third-party commercial central monitoring station when intrusion is detected;

(2) video cameras in all areas that may contain cannabis or medical cannabis products, all surveillance areas or rooms and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The manufacturing facility or dispensing site shall direct cameras at all areas where cannabis or medical cannabis product is being handled, stored or disposed. At entry and exit points, the manufacturing facility or dispensing site shall angle cameras to allow for the capture of clear and certain identification of any person entering or exiting the facility;

(3) continuous recordings during hours of operation and at any time that cannabis or medical cannabis product, in any form is handled, and motion activated recordings at all other times, from all video cameras, which the manufacturing facility or dispensing site shall make available via remote access or login credentials for immediate viewing by the Office or the Office's authorized representative upon request and shall be retained for at least sixty (60) days. The registered organization shall provide the Office with an unaltered copy of such recording upon request. If a registered organization is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the registered organization shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the registered organization that it is not necessary to retain the recording, but in no event for less than sixty (60) days;

(4) failure notification system that provides an audible text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the registered organization's designated representative(s) within five (5) minutes of the failure, either by telephone, e-mail, or text message;

(5) the ability to immediately produce a clear color still photo from any camera image (live or recorded);

(6) a date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

(7) the ability for the security alarms and video surveillance system to remain operational during a power outage for a minimum of eight (8) hours.

(b) A registered organization shall limit access to any surveillance areas and keep all on-site surveillance rooms locked. A registered organization shall make available to the Office or the Office's authorized representative, upon request, a current list of authorized employees who have access to any surveillance room.

(c) A registered organization shall keep illuminated the outside perimeter of any manufacturing facility and dispensing site that is operated under the registered organization's registration.

(d) All video recordings shall allow for the exporting of still images in an industry standard image format (including .jpeg, .bmp, and .gif). Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A registered organization, after receiving approval of the Office, shall erase all recordings prior to disposal or sale of the facility.

(e) A registered organization shall keep all security equipment in full operating order and shall test such equipment no less than semi-annually at each manufacturing facility and dispensing site

that is operated under the registered organization's registration. Records of security tests must be maintained for five (5) years and made available to the Office upon request.

(f) The manufacturing facility of the registered organization must be securely locked and protected from unauthorized entry at all times.

(g) All cannabis and medical cannabis products must be stored in a secure area or location within the registered organization manufacturing or dispensing site accessible to the minimum number of employees essential for efficient operation, to prevent diversion, theft or loss.

(h) All medical cannabis must be stored in such a manner as to protect against physical, chemical and microbial contamination and deterioration.

(i) All 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.

(j) Keys shall not be left in the locks or stored or placed in a location accessible to individuals who are not authorized access to cannabis or manufactured medical cannabis products.

(k) Security measures, such as combination numbers, passwords or biometric security systems, shall not be accessible to individuals other than those specifically authorized to access cannabis or manufactured medical cannabis products.

(l) A registered organization shall ensure the safe and secure transport of any medical cannabis, including the safety of those transporting medical cannabis, and shall:

(1) prior to transporting any medical cannabis, shipping manifest data must be provided to the Office in a manner determined by the Office;

(2) maintain all shipping manifests and make them available to the Office for inspection upon request, for a period of five (5) years;

(3) transport all medical cannabis products in a secure manner that will not compromise the integrity of the products for the duration of the transport;

(4) transport all medical cannabis products directly to the destination(s) and the employee(s) shall not make any unnecessary stops in between;

(5) ensure that all medical cannabis product delivery times are randomized;

(6) ensure transport team members have the ability to communicate with employees at the registered organization at all times that the vehicle contains medical cannabis products; and

(7) ensure transport team members possess a copy of the shipping manifest at all times when transporting or delivering medical cannabis products and shall produce it to the Office, the Office's authorized representative or law enforcement official upon request.

§ 113.15 Laboratory Testing Requirements for Medical Cannabis.

(a) Medical cannabis products produced by a registered organization shall be examined by an independent laboratory physically located in New York State that is permitted by the Office and approved for the analysis of medical cannabis in accordance Article 3 of the Cannabis Law, and this Part. A laboratory licensed by the New York State Department of Health to conduct medical cannabis testing shall be deemed a "permittee" and must continue to comply with all applicable sections set forth in Subpart 55-2 of Title 10 NYCRR, in addition to this Part.

(b) No board member, officer, manager, owner, partner, principal stakeholder or member of a registered organization, or such persons' immediate family member, shall have an interest or voting rights in the independent laboratory performing medical cannabis testing.

(c) For final product testing, a statistically significant number of samples from the registered organization containing the final medical cannabis product equivalent to the sealed medical cannabis product dispensed to the patient (e.g., liquid extract in a sealed bottle or intact sealed bottle of capsules) shall be collected and submitted for final product testing in a manner approved by the Office.

(d) Testing of the final medical cannabis product is mandatory. However, at the option of the registered organization, testing may be performed on components used for the production of the final medical cannabis product, including but not limited to water or growing materials. Testing may also be performed on intermediate cannabis extract (e.g. for phytocannabinoid profile verification or contaminant testing).

(e) Sampling and testing of each lot of final medical cannabis product shall be conducted with a representative sample of a cannabis product batch by collecting a minimum number of sample increments relative to the batch size as set forth in guidance provided by the Office.

(f) Testing of the phytocannabinoid profile shall include, at a minimum, those analytes specified in section 113.12(b)(1) of this Part.

(g) Testing for contaminants in the final medical cannabis product shall include analytes, pesticides, or growth regulators determined by the Office. The Office shall make available a list of required analytes, pesticides or growth regulators for final product testing and the acceptable limits as determined by the Office.

(h) Independent laboratories performing final medical cannabis product testing pursuant to this section must report all results, which includes, but is not limited to, a certificate of analysis, to the Office, in a manner and timeframe prescribed by the Office.

(i) Stability testing shall be performed by a registered organization or permitted independent laboratory on each medical cannabis product as follows:

(1) For testing of open products, stability testing shall be performed, at time zero when opened and then, at a minimum, at sixty (60) days from the date of first analysis. This shall establish use of the product within a specified time once opened.

(2) For testing of unopened products, until stability studies have been completed, a registered organization may assign a tentative expiration date based on available stability information. The registered organization must concurrently have stability studies conducted to determine the actual expiration date of an unopened product.

(3) For stability testing of both opened and unopened cannabis products, each cannabis product shall retain a total THC and CBD concentration in milligrams per single serving that is consistent with paragraph 113.12(b)(2) of this Part. If the product no longer retains a consistent concentration of THC and CBD pursuant to paragraph 113.12(b)(2) of this Part, the product shall be deemed no longer suitable for consumption and destroyed by the registered organization in accordance with section 113.25 of this Part. The Registered Organization shall demonstrate the ongoing stability over time of any product form produced as deemed necessary by, but not limited to, product stability concerns or complaints, new stability information about cannabis, for internal audit, or as requested by the Office and shall provide such documentation whenever requested from the Office.

(4) The Office may waive any of the requirements of this subsection upon good cause shown.

(j) The laboratory shall track and use an approved method to dispose of any quantity of medical cannabis product that is not consumed in samples used for testing. Disposal of medical cannabis shall mean that the medical cannabis has been rendered unrecoverable and beyond reclamation.

(k) Any submitted medical cannabis products that are deemed unsuitable for testing shall be returned to the registered organization under chain of custody.

§ 113.16 Pricing.

(a) Registered organizations shall submit documentation to the Office at least fifteen (15) days prior to sale of each new medical cannabis product, a price per dose for each form of medical cannabis to be sold.

(b) The registered organization shall submit to the Office any change in pricing per dose for medical cannabis products within fifteen (15) days of such change. Prior approval by the Office is not required to change a price.

(c) The Office may modify the price per dose for any medical cannabis product if necessary to maintain access for certified patients.

(d) Examination of Records for Determination of Price. The registered organization shall grant the Office or the Office's authorized representative the right to examine records that formed the basis for their medical cannabis pricing, including the registered organization's books, records, documents and other types of factual information that will permit an adequate evaluation of the price charged by the registered organization.

(e) Correction of Insufficient Price Data. If the Office determines that the cost or pricing data provided pursuant to subdivision (d) of this section is inaccurate or incomplete, the registered organization shall submit new data or provide clarification as requested by the Office until such data is to the satisfaction of the Office.

§ 113.17 Medical Cannabis Marketing and Advertising.

(a) General Requirements.

(1) Medical cannabis marketing and advertising shall only include true and accurate statements relating to effectiveness, side effects, consequences or contraindications, regardless of marketing or advertising form. It shall present a fair balance between information relating to effectiveness, side effects, consequences, and contraindications in that the information relating to effectiveness may not be presented in greater scope, depth, or detail than is the information relating to side effects, consequences and contraindications, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(2) A registered organization may engage in reasonable advertising practices that are not otherwise prohibited in this Part, provided the marketing and advertising does not jeopardize public health or safety, promote youth use, or be attractive to individuals under twenty-one (21) as set forth in section 113.12(k)(1) of this Part.

(3) A registered organization shall ensure that an official translation of a foreign language advertisement is accurate.

(4) Any marketing or advertisement of medical cannabis or medical cannabis products shall include the following statements, in a conspicuous manner on the face of the marketing material or advertisement or be read aloud clearly at the same volume and pace as the rest of the advertisement:

(i) “Keep out of reach of children and pets.”;

(ii) “In case of accidental ingestion or overconsumption, contact the National Poison Control Center hotline 1-800-222-1222 or call 9-1-1.”;

(iii) “Please consume responsibly.”; and

(iv) any other statements or warnings as directed by the Office.

(5) statements or warnings in print or digital advertisements pursuant to this section shall be displayed as follows:

(i) in the English language;

(ii) in Times New Roman, Calibri, Arial, or Helvetica;

(iii) in text no smaller than size six (6) font;

(iv) bolded;

(v) be legible, unobscured, and visible to the consumer; and

(vi) in a bright yellow text box so as to stand out from the surrounding advertisement. The use of a bright yellow color for the warning shall not render the advertisement attractive to individuals under twenty-one (21) as prohibited by section 113.12 of this Part. If the surrounding advertisement is yellow in color, the text box shall be offset with a distinctive border so as to differentiate it from the surrounding advertisement.

(6) A registered organization shall only advertise medical cannabis products, cannabis paraphernalia, or goods or services related to medical cannabis or cannabis products by means of television, radio, print, internet, mobile applications, social media, other electronic communication, or print publication if the registered organization has reliable

evidence that at least 90%, unless otherwise determined by the Office, of the audience for the advertisement is reasonably expected to be twenty-one (21) years of age or older. The burden of proof of the audience composition lies with the registered organization.

(7) A registered organization shall maintain records and documentation to establish that its advertising and marketing meet the requirements of this section.

(8) A registered organization may sponsor a charitable, sports, or similar event provided however, a registered organization shall not engage in advertising at, or in connection with, such an event unless the registered organization has reliable evidence that at least 90%, unless otherwise determined by the Office, of the audience at the event and/or viewing advertising in connection with the event is reasonably expected to be twenty-one (21) years of age or older. Advertising and marketing at eligible events must comply with this Part.

(9) A registered organization shall limit the apparel displaying its brand and trademark used in connection with the sale of apparel displaying its brand to only adult sizes. Such apparel shall only be sold by the registered organization within its registered premises.

(10) A registered organization shall accurately and legibly include its name and registration number on all advertising and marketing for its products.

(11) A registered organization who advertises via a website or digital application shall have a mechanism designed to keep those under the age of twenty-one (21) from visiting the website or

digital application, notwithstanding a certified patient or designated caregiver who is at least eighteen years of age and visiting the website to purchase medical cannabis.

(12) A registered organization who has entered into an intellectual property licensing agreement, marketing or advertising agreement or any other agreement in which a registered organization authorizes the use of its intellectual property, or allows a third party to market or advertise on its behalf, the registered organization is responsible to ensure that such agreement, intellectual property use, marketing or advertising shall comply with this Part.

(13) A registered organization shall comply with requests from the Office to change any marketing and advertisements that are determined to be false, misleading, or deemed necessary to protect public health and safety.

(14) A registered organization shall comply with any additional requirements as set forth by the Office.

(b) No marketing or advertising of medical cannabis products shall:

(1) depict medical cannabis not otherwise permitted by section 113.12 of this Part or paraphernalia;

(2) use or display images designed in any manner to be attractive to individuals under twenty-one (21);

- (3) use audio that may be attractive to individuals under twenty-one (21), including but not limited to using children's voices or cartoon voices;
- (4) be on or in the form of a billboard;
- (5) use or display colloquial references to marijuana and cannabis or depictions or digital images or icons, whether animated or static, of cannabis, cannabis products, medical cannabis products, paraphernalia, or the imagery or action of smoking or vaping, including but not limited to "stoner", "chronic", "weed", "pot", or "sticky buds";
- (6) assert that medical cannabis or medical cannabis products are safe or effective because they are regulated by the Board or Office;
- (7) permit the use of their trademarks, brands, names, locations, or other distinguishing characteristics for third-party use on advertising in a manner that does not comply with this Part or any other statute, rule or regulation;
- (8) contain any statement, design, representation, picture or illustration related to the safety or efficacy of medical cannabis, unless supported by substantial evidence or substantial clinical data which shall be referenced in the advertisement and provided to the Office upon request;

- (9) contain favorable information or opinions about a medical cannabis product previously regarded as valid but which have been rendered invalid by contrary and more credible recent information;
- (10) use a quote or paraphrase out of context or without citing conflicting information from the same source, to convey a false or misleading idea;
- (11) contain favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;
- (12) use data favorable to a medical cannabis product derived from patients treated with a different product or form;
- (13) disparage cannabis or medical cannabis products from another registered organization or licensed entity;
- (14) fail to provide adequate emphasis for the fact that two (2) or more facing pages are part of the same advertisement when only one (1) page contains information relating to side effects, consequences and contraindications;
- (15) disseminate any advertisement if the registered organization has received information that has not been widely publicized in medical literature that the use of any medical cannabis product may cause fatalities or serious damage to a patient;

- (16) correct false or misleading information in any part of the advertisement by including a true statement in another distinct part of the advertisement;
- (17) use the term “organic”;
- (18) contain any statement, design, representation, picture or illustration that encourages or represents the use of medical cannabis that does not comport with Article 3 of the Cannabis Law or promotes overconsumption;
- (19) falsely portray medical cannabis or cannabis products as being in compliance with Article 4 and Article 5 of the Cannabis Law;
- (20) contain any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by any New York State employee or any person or entity associated with New York State provided that this shall not preclude a factual statement that an entity is a registered organization;
- (21) encourage the transportation of medical cannabis across state lines or otherwise encourage illegal activity;
- (22) contain any offer of a prize, award or inducement to a certified patient, designated caregiver or practitioner related to the purchase of a medical cannabis product or a certification

for the use of medical cannabis, provided, however, that, this shall not be construed as to prohibit a registered organization from offering discounts or a discount program to certified patients and designated caregivers, for the purchase of medical cannabis product;

(23) advertise through the marketing of free promotional items including, but not limited to, gifts, giveaways, except for the provision of branded exit packages or items that assist with public safety efforts, such as a lock box or safety storage bag which may be provided by a registered organization for the benefit of certified patients;

(24) produce any items for sale or promotional gifts, such as T-shirts or novelty items, bearing a symbol of or references to medical cannabis. This prohibition shall not pertain to cannabis paraphernalia sold to certified patients or designated caregivers;

(25) depict a child or other person under the age of twenty-one (21) or reasonably appearing to be under the age of twenty-one (21). Talent portrayed in medical cannabis advertising should be a minimum of twenty-five years old, substantiated by proper identification, and an actual certified patient, designated caregiver or health care practitioner and not a model or actor;

(26) contain any obscene or indecent statement, design, or representation, picture, or illustration;

(27) be within or be readily observed within 500 feet of an elementary or secondary school grounds as defined in Education Law, recreation center or facility, childcare center, playground, public park, or library;

(28) be on or through handbills that are passed out in public areas including but not limited to parking lots and publicly owned property;

(29) utilize unsolicited pop-up or banner advertising on the internet other than on age-restricted websites for people twenty-one (21) and over who consent to view cannabis-related material, notwithstanding a certified patient or designated caregiver who is at least eighteen years of age and visiting the website to purchase medical cannabis;

(30) cooperate, directly or indirectly, in any advertising if such advertising has the purpose or effect of steering or influencing patient or caregiver choice with regard to the selection of a practitioner. Nothing contained within this section prevents a registered organization from educating practitioners about medical cannabis products offered by the registered organization;
or

(31) violate any additional prohibitions determined by the Board or Office.

(c) A registered organization shall not use false or misleading information in any part of the advertisement. An advertisement is false, lacking in fair balance, or otherwise misleading if it:

(1) contains a representation or suggestion that one medical cannabis product, brand, or form is better, more effective, useful in a broader range of conditions or patients or safer than other drugs or treatments including other medical cannabis products or forms, unless such a claim has been demonstrated by substantial scientific evidence or clinical experience;

(2) contains favorable information or opinions about a medical cannabis product previously regarded as valid but which have been rendered invalid by contrary and more credible recent information;

(3) uses a quote or paraphrase out of context or without citing conflicting information from the same source, to convey a false or misleading idea;

(4) uses data favorable to a medical cannabis product derived from patients treated with a different product or form;

(5) contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; or

(6) fails to provide adequate emphasis for the fact that two (2) or more facing pages are part of the same advertisement when only one (1) page contains information relating to side effects, consequences and contraindications.

(d) Outdoor Marketing and Advertising.

(1) Outdoor dispensing site signage for the purpose of alerting individuals to the location of a medical cannabis dispensing site is permitted provided such signs:

(i) are limited to the following information:

(a) business or trade name,

(b) business location, and

(c) the nature of the business;

(ii) are affixed to a building or permanent structure;

(iii) are not illuminated by neon lights;

(iv) are not on vehicles owned, leased, or utilized by registered organizations;

(v) do not total more than two (2) in number per dispensing site; and

(vi) do not depict cannabis, cannabis products, or the imagery or action of smoking or vaping.

(2) Outdoor marketing or advertising is prohibited on signs and placards in arenas, stadiums, shopping malls, fairs that receive state allocations, and video game arcades, whether any of the foregoing are open air or enclosed, but does not include any such sign or placard located at an adult only facility or as further set out by the Office in guidance.

(3) Use of a commercial mascot is prohibited.

(4) A registered organization shall remove the outdoor signage if the Office determines the outdoor signage violates the provisions of Cannabis Law and this Part or if the registered organization fails to provide records to the Office upon request that establishes the outdoor signage meets the requirements of Cannabis Law and this Part.

(5) Outdoor dispensing site signage must comply with any additional requirements as set out by the Office.

(e) Marketing and Advertising Violations and Penalties.

(1) A registered organization shall immediately remove or discontinue advertising or marketing if the Board determines the advertising, marketing, or outdoor signage violates the provisions of the Cannabis Law and this Part or if the registered organization fails to provide records to the Office upon request that establishes the advertising and marketing meets the requirements of the Cannabis Law and this Part.

(2) In the event a third-party has used a registered organization's trademarks, brands, names, locations, or other distinguishing characteristics in an advertisement that does not comply with this Part or any other statute, rule or regulation, the registered organization must immediately notify the Office, issue a cease-and-desist notification to the third-party, and may pursue appropriate legal action.

(3) The Office may take any action against any registered organization who fails to comply with this Part, including but not limited to recommendations to the Board for suspension, cancellation, or revocation of a registration, imposition of any fees or fines, requiring a registered organization to cease by a date determined by the Office the non-compliant marketing and advertising and requiring removal by a date determined by the Office of any marketing material or advertising still being published or displayed, and any other penalties set forth in Cannabis Law and this Part 113.

§ 113.18 Reporting Dispensed Medical Cannabis Products.

(a) A record of all medical cannabis products that have been dispensed shall be filed electronically to the prescription monitoring program registry established pursuant to section 3343-a of Article 33 of the Public Health Law, utilizing a transmission format acceptable to the Office, not later than twenty-four (24) hours after the cannabis was dispensed to the certified patient or designated caregiver.

(b) The information filed to the prescription monitoring program registry for each medical cannabis product dispensed shall include but not be limited to:

- (1) a serial number that will be generated by the dispensing site for each medical cannabis product dispensed to the certified patient or designated caregiver;
- (2) an identification number which shall be populated by a number provided by the Office, to identify the registered organization's dispensing site;
- (3) the patient's name, date of birth and gender;
- (4) the patient's address, including street, city, state, zip code;
- (5) the patient's certification identification number;
- (6) if applicable, designated caregiver's name and registry identification number;
- (7) the date the medical cannabis product was dispensed by the dispensing site;
- (8) the metric quantity for the medical cannabis product;
- (9) the medical cannabis product identifier code number, which shall be populated by a number provided by the Office, to represent the medical cannabis product that was dispensed to the certified patient or designated caregiver, as applicable;

- (10) the number of days supply dispensed;
- (11) the certifying practitioner's Drug Enforcement Administration number;
- (12) the date the written certification was issued by the certifying practitioner; and
- (13) the payment method.

(c) When applicable, a registered organization shall file a zero report to the prescription monitoring program registry, in a format acceptable to the Office. For the purposes of this section, a zero report shall mean a report that no medical cannabis product was dispensed by a registered organization during the relevant period of time. A zero report shall be submitted no later than fourteen (14) days following the most recent previously reported dispensing of a medical cannabis product or the submission of a prior zero report.

§ 113.19 Prohibition on the use of Medical Cannabis Products in Certain Places.

(a) In no event shall medical cannabis products be consumed through smoking or vaporization in any location in which smoking is prohibited under Article 13-E of the Public Health Law, except where the consumption through smoking or vaporization is authorized by the research license issued pursuant to Article 3 of the Cannabis Law.

(b) Consumption of medical cannabis products shall not be permitted in any motor vehicle, either public or private, as defined in section 125 of the Vehicle and Traffic Law.

Section 113.20 Reporting Requirements for Registered Practitioners, Certified Patients and Designated Caregivers.

(a) A practitioner shall report to the Office, in a manner determined by the Office, the death of a certified patient or change in status of a condition involving a certified patient for whom the practitioner has issued a certification if such change may affect the patient's continued eligibility for certification for use of medical cannabis products. A practitioner shall report such death or change of status not more than five (5) business days after the practitioner becomes aware of such fact.

(b) If a practitioner issues a new certification for a certified patient, then the existing certification and associated registration shall expire upon issuance of the new certification and a new registration expiration date, equivalent to the certification expiration date, shall be established.

(c) A practitioner shall report patient adverse events to the Office, in a manner determined by the Office, not more than five (5) business days after the practitioner becomes aware of such adverse event, except that serious adverse events shall be reported not more than one (1) business day after the practitioner becomes aware of such adverse event.

(d) A certified patient or designated caregiver, who has been issued a registration shall notify the Office of any change in the information provided to the Office not later than ten (10) business days after such change. A certified patient or designated caregiver shall report changes that include, but are not limited to, a change in the certified patient's name, address, contact information, or

medical status. A certified patient or designated caregiver shall report such changes on a form, and in a manner, determined by the Office. Should a certified patient cease to have the condition noted on their certification, the certified patient or designated caregiver shall notify the Office of such within ten (10) days and the certified patient's and designated caregiver's registration shall be considered void.

(e) If a certified patient has a designated caregiver, that designated caregiver may notify the Office of any changes on behalf of the certified patient using the same forms and process prescribed for certified patients.

(f) A certified patient or designated caregiver shall notify the Office of any change in demographic information that results in information on the certification being inaccurate.

(g) If a certified patient or designated caregiver becomes aware of the loss, theft or destruction of the registry identification card of such certified patient or designated caregiver, the certified patient or designated caregiver shall notify the Office, on a form and in a manner prescribed by the Office, not later than ten (10) days of becoming aware of the loss, theft or destruction. The Office shall inactivate the initial registry identification card upon receiving such notice and issue a replacement registry identification card provided the applicant continues to satisfy the requirements of Article 3 of the Cannabis Law and section 113.4 of this Part.

(i) If a certified patient wishes to change or terminate their designated caregiver, the certified patient shall notify the Office, in a manner determined by the Office, and shall notify their designated caregiver as soon as practicable.

(1) The Office shall issue a notification, in a format determined by the Office, to the designated caregiver and the certified patient that the designated caregiver's registration is invalid.

(2) In the event that the certified patient has selected another designated caregiver, the proposed designated caregiver must register with the Office as defined in section 113.5 of this Part.

(j) If a designated caregiver wishes to terminate their relationship with a certified patient, the designated caregiver shall notify the Office, in a manner determined by the Office, and shall notify the certified patient, as soon as practicable.

(1) The Office shall issue a notification, in a format determined by the Office to the certified patient and the designated caregiver that the designated caregiver has terminated their relationship with the certified patient.

(2) In the event that the designated caregiver has no other active certified patients, the designated caregiver's registration will be inactivated.

Section 113.21 Proper Disposal of Medical Cannabis Products by Certified Patients or

Designated Caregivers.

(a) A certified patient or designated caregiver shall dispose of all medical cannabis product in the certified patient's or designated caregiver's possession no later than ten (10) calendar days after the expiration of the patient's certification, if such certification is not renewed, or sooner should the patient no longer wish to possess medical cannabis.

(b) A certified patient or designated caregiver shall complete disposal of medical cannabis products by one of the following methods:

(1) rendering the medical cannabis product unusable in accordance with the Department of Environmental Conservation's guidance;

(2) in the case of whole flower or ground flower, on-site composting is an acceptable alternative to rendering the product unusable; or

(3) returning the medical cannabis product to the dispensing site from which it was purchased, or any dispensing site associated with the registered organization which manufactured the medical cannabis product, to the extent that the registered organization accepts product returns.

Section 113.22 General Prohibitions.

(a) No person, except for a certified patient, designated caregiver, designated caregiver facilities, an approved laboratorian, or an approved research license holder shall open or break the

seal placed on a medical cannabis product packaged by a registered organization and provided to the certified patient.

(b) No person associated with a registered organization shall enter into any agreement with a registered practitioner or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the dispensing site at which the certified patient or designated caregiver will purchase medical cannabis products.

(c) No registered organization shall employ, or permit to be employed, or shall allow to work, on any premises registered, any person under the age of eighteen (18) years in any capacity where the duties of such person require or permit such person to sell, dispense or handle cannabis. Any employee eighteen (18) years of age or older and under twenty-one (21) years of age may not have direct interaction with patients inside a dispensing site.

(d) No employee of a registered organization shall counsel a certified patient or designated caregiver on the use, administration of, and the risks associated with medical cannabis products, unless the employee is a practitioner as defined in Article 1 of the Cannabis Law, with an active New York State license, registration or certification who has completed at minimum a two (2) hour course pursuant to section 113.2 of this Part, or the employee is, twenty-one (21) years of age or older and under the direct supervision of, and in consultation with, such practitioner, or the pharmacist working at the dispensing site.

(e) No certified patient or designated caregiver shall be in possession of medical cannabis products without having in their possession:

(1) Patient's valid certification; and

(2) Other forms of identification or documentation as provided by this Part or as determined by the Office to verify that the certified patient or designated caregiver is authorized to possess medical cannabis products.

(f) No certified patient or designated caregiver shall transport medical cannabis product unless such products remain in the original package as dispensed by the registered organization and the patient or designated caregiver is in possession of patient's valid certification.

(g) The certified patient or designated caregiver, upon request by the officer or law enforcement, shall present such certification to verify that the certified patient or designated caregiver is authorized to possess medical cannabis products.

§ 113.23 Practitioner Prohibitions.

(a) A practitioner shall not:

(1) directly or indirectly accept, solicit, or receive any item of value from a registered organization. However, free or discounted products or services may be provided for use in

research, provided such research is conducted by a cannabis research licensee pursuant to section 38 Article 3 of the Cannabis Law;

(2) offer a discount or any other item of value to a certified patient based on the patient's agreement or decision to use a particular practitioner, registered organization, brand or specific form of medical cannabis product produced by a registered organization. However, free or discounted products or services may be provided for use in research, provided such research is conducted by a cannabis research licensee pursuant to section 38 Article 3 of the Cannabis Law;

(3) examine a patient for purposes of issuing a certification at any location owned or operated by a registered organization, except where such examination is being conducted in accordance with a cannabis research license pursuant to section 38 Article 3 of the Cannabis Law; or

(4) directly or indirectly benefit from a patient obtaining a written certification. Such prohibition shall not prohibit a practitioner from conducting research pursuant to section 38 of Article 3 of the Cannabis Law, or charging an appropriate fee for the patient visit.

(b) A practitioner that issues certifications, and such practitioner's co-worker, employee, spouse, parent, child, or sibling shall not have a direct or indirect financial interest in a registered organization or any other entity that may benefit from a certified patient's or designated caregiver's acquisition, purchase or use of medical cannabis products, including any formal or informal agreement whereby a registered organization provides compensation if the practitioner issues a written certification for a certified patient or steers a certified patient to a specific dispensing site.

- (c) A practitioner shall not issue a certification for themselves.
- (d) A practitioner shall not receive or provide product samples containing cannabis.

§ 113.24 Designated Caregiver Prohibitions and Protections.

- (a) An individual shall not serve as a designated caregiver for more than four (4) certified patients at any given time, not including designated caregiver facilities and employees of such facilities, and research license holders acting as designated caregivers.
- (b) A designated caregiver may only obtain payment from the certified patient to be used for the cost of home cultivation activities in accordance with section 115.2 of Part 115 of this Title and medical cannabis product purchased for the certified patient in the actual amount charged by the registered organization; provided, however, that a designated caregiver may charge the certified patient for reasonable costs incurred in the transportation, delivery, storage and administration of medical cannabis products.
- (c) Designated caregivers, including employees of designated caregiver facilities acting within their scope of employment, and research license holders shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for an action or conduct in accordance with this Part.

(d) A designated caregiver shall not purchase medical cannabis product for the certified patient, unless such caregiver presents the following documentation to a registered organization:

(1) the patient's certification from a practitioner, as defined in Article 1 of the Cannabis Law, and issued in accordance with Article 3 of the Cannabis Law, which shall also serve as the patient/designated caregiver registry identification card; and

(2) a valid government-issued photo identification, in accordance with subdivision (f) of section 113.13 of this Part.

§ 113.25 Registered Organizations; Disposal of Medical Cannabis.

(a) The disposal of medical cannabis shall mean that the medical cannabis has been rendered unusable, except for stalks, stems, fan leaves, root balls, and soil media.

(b) Registered organizations shall dispose of any medical cannabis that is outdated, damaged, deteriorated, contaminated or otherwise deemed not appropriate for manufacturing or dispensing, or any plant-based waste created as a by-product of the manufacturing processes. Registered organizations shall dispose of liquid and chemical waste in accordance with applicable federal, state and local laws and regulations.

(c) For registered organizations generating more than a half ton of organic waste per week and within 25 miles of an organic recycling facility, the waste shall not be landfilled or combusted but must either be:

- (1) composted on-site or at an organic recycling facility;
 - (2) used to produce energy through the process of anaerobic digestion; or
 - (3) used as input by the licensee or a third party in the manufacture of other products, such as paper, packaging, or pet bedding.
- (d) Registered organizations shall maintain records of disposal, which shall include:
- (1) the type of plant material being disposed, if the material is a by-product of the manufacturing process;
 - (2) the medical cannabis product being disposed, if a finished product;
 - (3) the weight of the disposed material, the number of plants, or in the case of a finished product, the quantity of the disposed product;
 - (4) the signatures of at least two (2) registered organization staff members who witnessed the disposal; and
 - (5) the methods and destination/location of disposal, by waste type and weight, for each method of disposal.

(d) All records of disposal shall be retained for at least five (5) years and be made available for inspection by the Office.

§ 113.26 Energy and Environmental Standards and Regulations.

(a) Annual benchmarking of energy and water usage is required, using either EPA Energy Portfolio Manager or the Resource Innovation Institute's Cannabis PowerScore, with the first report to be completed and submitted to the Office no later than one year after registration and with subsequent reports to be submitted annually to the Office thereafter.

(b) Lighting Standards for indoor cultivation areas.

(1) All horticultural lighting used in a manufacturing facility shall be listed on the current design lights consortium solid-state horticultural lighting qualified products list ("Horticultural QPL") or other similar list as determined by the Office and lighting Photosynthetic Photon Efficacy (PPE) must be at least 2.2 $\mu\text{mol}/\text{J}$ (micromoles per joule).

(2) Registered organizations with existing manufacturing facilities will have one year from the date of adoption of the regulations to comply with this subdivision, unless otherwise approved by the Office with good cause shown.

(3) A facility seeking to use horticultural lighting not included on the Horticultural QPL or other similar list, as determined by the Office, shall seek a waiver pursuant to a third-party certification of the energy efficiency features of the proposed lighting.

(c) Dehumidification. Dehumidification equipment for all new construction shall include one of the following:

(1) stand-alone dehumidifiers that have a minimum integrated energy factor of 1.77 L/kWh for product case volumes of 8.0 cubic feet or less, and a minimum integrated energy factor of 2.41 L/kWh for product case volumes greater than 8.0 cubic feet;

(2) integrated HVAC system with on-site heat recovery designed to fulfill at least 75 percent of the annual energy for dehumidification reheat;

(3) chilled water system with on-site heat recovery designed to fulfill at least 75 percent of the annual energy for dehumidification reheat; or (iv) solid or liquid desiccant dehumidification system for system designs that require dewpoint of 50°F or less; or

(4) any other equipment as determined by the Office.

§ 113.27 Registered Organizations; Inspections and Audits.

(a) Licensed, registered or permitted premises, regardless of the type of premises, and all records including but not limited to financial statements and corporate documents, shall be subject to inspection by the Office, by the duly authorized representatives of the Office, by any peace officer acting pursuant to his or her special duties, or by a law enforcement officer.

(b) A registered organization must make themselves, or an agent thereof, available and present for any inspection required by the Office. Such inspection may include, but is not limited to, ensuring compliance by the registered organization with all requirements of the regulations pursuant thereto, and other applicable state and local building codes, fire, health, safety, and other applicable regulations.

(c) Any deficiencies identified by the inspection shall be documented in a statement of findings by the Office and require that the registered organization submit a written plan of correction in a format acceptable to the Office within fifteen (15) calendar days of the issue date of the statement of findings. A plan of correction shall address all deficiencies or areas of noncompliance cited in the statement of findings and shall:

(1) contain an assessment and analysis of the events and/or circumstances that led to the noncompliance;

(2) contain a procedure addressing how the licensee intends to correct each area of noncompliance;

(3) contain an explanation of how proposed corrective actions will be implemented and maintained to ensure noncompliance does not recur;

(4) contain the proposed date by which each area of noncompliance shall be corrected;

- (d) Any inspection finding which the Office determines jeopardizes the immediate health, safety, or well-being of the public shall be deemed a critical deficiency and shall require immediate corrective action to remove the immediate risk. The registered organization shall submit a preliminary corrective action plan to the Office within twenty-four (24) hours of notification by the Office of the critical deficiency.

- (e) If the Office determines that the corrective action plan needs modification, the registered organization shall modify the plan until it is in its final form, as accepted by the Office;

- (f) Upon written approval of the Office, the registered organization shall implement the plan of correction.

- (g) Failure by the registered organization to comply with these requirements may result in suspension, revocation, and or a civil penalty in accordance with all applicable rules and regulations of the Office and pursuant to Section 133 of the Cannabis Law.

- (h) Nothing herein shall limit the application of any other remedies or sanctions that are available through local, state, and federal laws, and these rules.

§ 113.28 Referenced Material.

- (a) Regulations included in Part 113 of this Title contain references to documents for information as to the standards to be met or guidelines and methodologies to be used in meeting the requirements of specific regulations. In addition, copies of referenced materials are available

for public inspection and copying at the Albany office of the New York State Department of State.

Table 1

<u>Regulation</u>	<u>Referenced Material</u>	<u>Availability</u>
<u>9 NYCRR</u>		
<u>Part/sec./etc.</u>	<u>CFR (Code of Federal Regulations) or other</u>	
113.12(d)(5)	6 NYCRR, Section 325.2(b) (eff. Jan. 21, 2000)	*
113.1(j) 113.12(j)(2)	16 CFR §1700.15 and §1700.20 (eff. July 22, 1996)	**
113.6(b)(5)	21 CFR, Parts 111 (eff. August 24, 2007) or 21 CFR Part 117 (eff. November 16, 2015)	**
113.12(j)(5)	16 CFR Part 260 (eff. October 11, 2012)	**
113.12(a)(2)(iii)	21 USC § 321 (eff. July 17, 2022)	***
113.12(l)(1)(ii)	21 USC § 343 (eff. July 17, 2022)	***
113.1(z)	Public Health Law § 3306 Schedule I (eff. March 31, 2021)	****
113.3(a)(7)(ii)	Public Health Law § 2782 (eff. Dec. 2, 2020)	****
113.3(k); 113.13(f)(7); 113.18 (a)	Public Health Law § 3343-a (eff. Aug. 27, 2013)	****
113.8(c)(2)(ii)	Public Health Law § 3306 (eff. March 31, 2021)	****

113.5(c)(3); 113.5(d)(4); 113.5(e)(4)	Penal Law § 210.45 (eff. 1965)	****
113.21(b)(1)	Department of Environmental Conservation's guidance for "Safe Medication Disposal for Households"	*****

* Electronic copies of New York Codes, Rules and Regulations (NYCRR) sections can be searched directly at:

https://govt.westlaw.com/nycrr/index?_lrTS=20190327201930309&transitionType=Default&contextData=%28sc.Default%29

** Any printed editions of the *Code of Federal Regulations* (CFR) can be obtained by calling the Superintendent of Documents, U.S. Government Printing Office, at (202) 512-

1800. Electronic copies of CFR sections may also be obtained at Government Printing Office (GPO) which contains the most recent revisions, can be searched directly

at: <https://www.ecfr.gov/>

*** Any printed editions of the *United States Code* (USC) can be obtained by calling the Superintendent of Documents, U.S. Government Printing Office, at (202) 512-1800. Electronic

copies of CFR sections may also be obtained at Government Printing Office (GPO) which contains the most recent revisions, can be searched directly at: <https://uscode.house.gov/>

**** Electronic copies of New York State Law, including but not limited to, Public Health Law, Vehicle and Traffic Law, Education Law, Mental Hygiene Law, Social Services Law may be

searched directly under the Laws tab (which drops down to “Laws of New York”) at:

<http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO>:

***** Electronic copies of the New York State Department of Environmental Conservation

Guidance for “Safe Medication Disposal for Households” can be searched directly at:

<https://www.dec.ny.gov/chemical/67720.html>