

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**

**§ 113.1 Definitions.**

**§ 113.2 Practitioner Eligibility.**

**§ 113.3 Practitioner Issuance of Certification.**

**§ 113.4 Application for Registration as a Certified Patient.**

**§ 113.5 Designated Caregiver Registration.**

**§ 113.6 Application for Initial Registration as a Registered Organization.**

**§ 113.7 Consideration of Registered Organization Applications.**

**§ 113.8 Applications for Renewal of Registration as Registered Organization.**

**§ 113.9 Registrations Non-Transferable.**

**§ 113.10 Failure to Operate.**

**§ 113.11 Registered Organizations; General Requirements.**

**§ 113.12 Manufacturing Requirements for Medical Cannabis Products.**

**§ 113.13 Requirements for Dispensing Facilities.**

**§ 113.14 Security Requirements for Manufacturing and Dispensing Facilities.**

**§ 113.15 Laboratory Testing Requirements for Medical Cannabis.**

**§ 113.16 Pricing.**

**§ 113.17 Medical Cannabis Marketing and Advertisings.**

**§ 113.18 Reporting Dispensed Medical Cannabis Products.**

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

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

**§ 113.21 Proper Disposal of Medical Cannabis Products by Certified Patients or Designated Caregivers.**

**§ 113.22 General Prohibitions.**

**§ 113.23 Practitioner Prohibitions.**

**§ 113.24 Designated Caregiver Prohibitions and Protections.**

**§ 113.25 Registered Organizations; Disposal of Medical Cannabis.**

### **Section 113.1 Definitions**

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

(a) *Applicant* means a person applying for a medical cannabis license or permit issued by the office pursuant to Article 3 of the Cannabis Law that: has a significant presence in New York state, either individually or by having a principal corporate location in the state; is incorporated or otherwise organized under the laws of this state; or a majority of the ownership are residents of this state. For the purposes of this subdivision, "person" means an individual, institution, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(b) *Brand* means a medical cannabis product that has a determined homogenous and uniform phytocannabinoid concentration (total THC and total CBD) and product quality, produced according to an approved and stable processing protocol and shall have the same inactive ingredients as are defined for that form of the brand.

(c) *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.

(d) *Certified medical use* includes the acquisition, cultivation, manufacture, delivery, harvest, possession, preparation, transfer, transpiration, 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.

(e) *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 113.2 of this Part.

(f) *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.

(g) *Designated caregiver facility* means a facility that registers with the office to assist one 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.

(h) *Form* shall be a type of a medical cannabis product approved by the office and shall refer to the final preparation of an approved medical cannabis brand; for example, an extract in oil for sublingual administration, an extract for vaporization or an extract in a capsule for ingestion.

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

(j) *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.

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

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

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

(n) *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 plant, including but not limited to tetrahydrocannabinol and cannabidiol, .....and does not include synthetic cannabinoids as that term is defined in subdivision (g) of schedule I of section thirty-three hundred six of the public health law.

(o) *Practitioner* means a practitioner 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 eight 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 eight of the education law.

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

(q) *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.

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

### **Section 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 office, to treat patients with one or more of the conditions set forth in paragraph 113.3(a)(8) 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 eight of the education law and is in good standing as determined by the office; and

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

(b) The office shall approve at least one, if not more, courses for practitioners seeking to certify patients for medical cannabis, which shall be a minimum of two 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.

### **Section 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 (e) 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 from the patient consent for disclosure of this information that meets the requirements set forth in sections twenty-seven hundred eighty and twenty-seven hundred eighty-two 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; and

(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.

(b) 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.

(c) Expiration of Certification.

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

(d) 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.

(e) Record Retention. The practitioner shall date and place their signature upon the certification, and provide the signed certification to the patient. The practitioner shall also maintain a copy of the signed certification, which shall include all information required in subdivision (a) of this section, for a period of five years, in the patient's medical record.

(f) 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.

#### **Section 113.4 Application for Registration as a Certified Patient.**

(a) A person applying for issuance or renewal of a registration as a certified patient shall:

(1) be a resident of New York State, or be receiving care and treatment in New York State; and

(2) possess a certification issued by an eligible practitioner.

(b) New York State residents. An applicant shall demonstrate their New York State residency by submitting to the office a copy or electronic submission of information concerning their New York State Driver's License or New York State Identification Card. If the applicant does not possess or cannot obtain a valid New York State Driver's License or New York State Identification Card, the applicant shall submit a copy of one or more of the following forms of documentation to establish that he or she is a New York resident:

(1) a copy or electronic submission of a government-issued identification card that contains the applicant's name and New York State address;

(2) a copy or electronic submission of a utility bill or other document indicating an applicant's residency issued within the previous two months that contains the applicant's name and address;

(3) a copy or electronic submission of a current lease or similar document indicating an applicant's residency within New York State; or

(4) such other documentation as approved by the office containing sufficient information to show proof of residency in New York State.

(c) Non-New York State Residents. An applicant applying for registration who is not a resident of New York State but is temporarily residing in New York State and receiving care and treatment in this state from a practitioner, as defined in Article 1 of the Cannabis Law and in accordance with this Part, may qualify for registration as a certified patient if the applicant otherwise meets the requirements of Article 3 of the Cannabis Law and this Part.

(1) The applicant shall submit a copy or electronic submission of the following forms of documentation along with the application for registration:

(i) a copy or electronic submission of a state or government issued identification card that contains the applicant's name and permanent address;

(ii) proof of temporary residence in New York State, including, but not limited to a copy or electronic submission of a lease, utility bill, hospital bill, or such other documentation as approved by the office containing sufficient information to show proof of temporary residency in New York State. If the applicant is under the age of eighteen, the parent or legal guardian applying on behalf of the applicant shall submit a copy or electronic submission of such documentation to show sufficient proof of the applicant's temporary residency in New York State.

(2) Nothing in this Part shall be construed to grant to the applicant authorization to transport medical cannabis outside of New York State.

(d) For new applicants, if the applicant does not have a current valid New York State Driver's license, New York State Identification Card, or government issued identification containing a photograph, the applicant shall provide a recent passport-style color photograph of the applicant's face, taken against a white background or backdrop. The photograph shall be a true likeness of the applicant's actual appearance on the date the photograph was taken and shall not be altered to change any aspect of the applicant's physical appearance. The photograph shall have been taken not more than thirty (30) days prior to the date of the application. The photograph shall be submitted in a form and manner described by the office, including as a digital file (.jpeg) when appropriate, provided, however, the office may waive the requirements of this paragraph upon good cause shown. For amendments and renewal applications, the office may utilize a previously submitted photograph if the applicant attests it is a true likeness of the applicant on the date the amendment or renewal application is submitted.

(e) The applicant shall acknowledge that a false statement in the application is punishable under section 210.45 of the penal law.

(f) If the applicant for a registry identification card is under the age of eighteen or a person who is otherwise incapable of consenting to medical treatment, the application shall be made by an appropriate person over eighteen years of age. In preparing the application, the applicant may designate up to five proposed designated caregivers, not including designated caregiver facilities, designated caregiver facility employees, or applicable cannabis research license holders who shall be either:

- (1) a parent or legal guardian of the certified patient;
  - (2) a person designated by a parent or legal guardian of the certified patient;
  - (3) an employee of a designated caregiver facility, including a cannabis research license holder; or
  - (4) an appropriate person approved by the office upon a sufficient showing, as determined by the office, that no parent or legal guardian is appropriate or available.
- 
- (i) As a condition of registration of a certified patient who is under the age of eighteen or is incapable of medical decision-making, the applicant shall consent, in a manner determined by the office to the certified patient's use of medical cannabis product(s), and shall acknowledge that the proposed designated caregiver(s) will control the acquisition and possession of the medical cannabis product(s) and any device used for its administration.
  - (ii) Once the certified patient who is under the age of eighteen or is incapable of medical decision-making is registered, the proposed designated caregiver(s) may apply for and, if approved, receive a designated caregiver registration in accordance with the requirements of Article 3 of the Cannabis Law and section 113.5 of this Part.
  - (g) Prior to issuing or renewing a registry identification card, the office may verify the information submitted by the applicant. The applicant shall provide, at the office's request, such information and documentation that may be necessary for the office to verify the information.

(h) The office shall approve, deny, or determine incomplete or inaccurate an application to issue or renew a registry identification card as soon as is reasonably practicable.

(i) The office shall notify the 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.

(j) An 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 applicant fails to submit the required materials within such thirty-day time period, the application shall be denied by the office.

(k) Applicants whose applications are denied may submit a new application for an initial or renewal of a registry identification card.

(l) A certified patient may designate up to five 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.

**Section 113.5 Designated Caregiver Registration.**

(a) A certified patient's designation of a designated caregiver shall not be valid unless and until the proposed designated caregiver successfully applies for and receives a designated caregiver registry identification card.

(b) A natural person selected by a certified patient as a designated caregiver shall apply to the office for a registry identification card or renewal of such card 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) for a proposed designated caregiver that is a natural person, the individual shall submit:

(i) the applicant's full name, address, date of birth, telephone number, email address if available, and signature;

(ii) if the applicant has a designated caregiver registry identification card, the registry identification number;

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

(iv) acknowledgement that a false statement in the application is punishable under section 210.45 of the penal law;

(v) proof that the applicant is a New York State resident, consisting of a copy of either:

(a) a New York State issued driver's license; or

(b) a New York State non-driver identification card;

(vi) if the documentation submitted by the applicant in accordance with paragraph (v) of this subdivision does not contain a photograph of the applicant or the photograph on the documentation is not a true likeness of the applicant, the applicant shall provide one recent passport-style color photograph of the applicant's face taken against a white background or backdrop. The photograph shall be a true likeness of the applicant's appearance on the date the photograph was taken and shall not be altered to change any aspect of the applicant's physical appearance. The photograph shall have been taken not more than thirty (30) days prior to the date of the application. The

photograph shall be submitted in a form and manner as directed by the office, including as a digital file (.jpeg); and

(vii) identification of all certified patients for which the applicant serves, has served or has an application pending to serve as a designated caregiver and a statement that the applicant is not currently a designated caregiver for more than four current certified patients, and that they have not submitted an application which is pending and, if approved, would cause the applicant to be a designated caregiver for more than four current certified patients;

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

(i) 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;

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

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

(iv) an acknowledgement that a false statement in the application is punishable under section 210.45 of the penal law;

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

(i) 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;

(ii) if the research license holder already has a designated caregiver registry identification card, the registry identification number;

(iii) a statement that the research license holder agrees to secure and ensure proper handling of all medical cannabis products;

(iv) names of the principal investigator(s) and key personnel;

(v) an acknowledgement that a false statement in the application is punishable under section 210.45 of the penal law; and

(vi) any other identifying information as determined by the office;

(c) Prior to issuing or renewing a designated caregiver registry identification card, the office may verify the information submitted by the applicant. The applicant 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.

(d) The office shall approve, deny, or determine incomplete or inaccurate an application to issue or renew a designated caregiver registry identification card as soon as is reasonably practicable.

(e) The office shall notify the 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.

(f) An 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 applicant fails to submit the required materials within such thirty-day time period, the application shall be denied by the office.

(g) Applicants whose applications are denied pursuant to subdivision (f) of this section may submit a new initial or renewal application for a designated caregiver registry identification card.

(h) The office shall deny a designated caregiver registry identification card for an applicant who:

(1) is already a designated caregiver for four 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 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.

**Part 113.6 Application for Initial Registration as a Registered Organization.**

(a) No person or entity 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 office.

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

(1) the name, address, phone and email address of the 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 office 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 applicant. In addition, the plan shall include a description detailing how the 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 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 products and devices to be offered or sold;

(iv) services to be offered by the 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 activities involving medical cannabis including, as applicable, methods used from cultivation of the medical cannabis through packaging, sealing and labeling of each lot of medical cannabis product. 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 product being manufactured and as otherwise determined appropriate by the office. All procedures must conform to all applicable federal and state rules, regulations, and laws as amended;

(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) policies and procedures to document and investigate medical cannabis product returns, complaints and adverse events, and to provide for rapid voluntary or involuntary recalls of any lot

of medical cannabis product. Such policies and procedures shall include a plan for any retesting of returned medical cannabis products, storage and disposal of cannabis and any manufactured medical cannabis products not passing requirements, and a requirement that the office is notified within 24 hours of the following;

(i) any adverse events that the registered organization is made aware of;

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

(iii) any suspected or known security breach or other facility event that may compromise public health or safety, or which requires response by public safety personnel or law enforcement; (iv) any vehicle accidents or incidents occurring during transport of medical cannabis.

(8) description of policies, procedures, and systems to be used for tracking, record keeping, record retention and reporting surveillance relating to all activities involving medical cannabis;

(9) an attestation that the applicant will submit seed to sale data from their system of record to the office in a format as determined by the office;

(10) copies of the organizational and operational documents of the 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;

(11) 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 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 years of a ten percent or greater interest in any other cannabis business, or 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 applicant or entity that is a member of the 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;

(12) documentation that the applicant has entered into a labor peace agreement, as required by section thirty five of Article 3 of the Cannabis Law, with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees. The maintenance of such a labor peace agreement shall be an ongoing material condition of registration;

(13) a statement that the applicant is able to comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the registration;

(14) 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 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 applicant shall post a bond of not less than two million dollars; provided, however, that if the applicant posts a bond in lieu of providing the documentation requested herein, the applicant's submission of the applicable executed deeds, leases and rental agreements shall be required prior to the issuance of a registration to the applicant, if selected; In accordance with the social-equity plan established pursuant to section 87 of the Cannabis Law, the office may waive such requirements when the applicant is a social and economic equity applicant, provided, however, that prior to issuance of the registration, the 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 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:

(i) "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 dispossession proceedings or that the lease is due to expire, at least 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 60 days before expiration of the lease.";

(15) 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;

(16) a proposed construction timetable;

(17) a statement as to whether the applicant, any controlling person of the applicant, any manager, any sole proprietor 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;

(18) if any controlling person of the applicant maintains a ten percent interest or greater in any firm, association, foundation, trust, partnership, corporation, or other entity or if such entity maintains a ten percent interest or greater in the 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 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;

(19) if the 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 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;

(20) the most recent certified financial statement of the 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 applicant's last fiscal year and income statements for the past two fiscal years, or such shorter period of time as the applicant has been in operation;

(21) if construction, lease, rental or purchase of the manufacturing or dispensing facility 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;

(22) 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 years of age or older and under twenty-one years of age may not have direct interaction with customers inside a registered organization's dispensing facility;

(iv) a requirement that all staff involved in the manufacturing 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 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; 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 office, if approved by the office upon good cause shown.

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

### **Section 113.7 Consideration of Registered Organization Applications**

(a) 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.

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

(2) The registration fee for the registration period, as well as any renewal registration period, shall be \$200,000, unless the office determines otherwise due to the nature and scope, or size of the activities for which the registered organization is applying. Applicants shall submit any registration fee by certified check, or another method approved by the office, at the time of submission of the application. The registration fee shall be returned to the applicant if the applicant is not granted a registration under this Part.

(3) Only applications completed in accordance with this Part as determined by the office and for which the application and registration fees have been submitted shall be considered if submitted in a timely manner. The office shall return the registration fee to all applicants who are not granted a registration.

(b) In deciding whether to grant an application, or amendment to a registration, the board shall consider whether:

(1) the 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 brand) and each able to pass the required quality control testing;

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

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

(4) the applicant will be able to comply with all applicable state and local laws and regulations;

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

(6) the 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 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 office;

(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.

(8) the moral character and competence of board members, officers, managers, owners, partners, principal stakeholders, directors, and members of the applicant's organization;

(9) the applicant has entered into a labor peace agreement with a bona-fide labor organization, as defined in Article 1 of the Cannabis Law, that is actively engaged in representing or attempting to represent the applicant's employees; and

(10) evaluation of the applicant's proposed business plan and suitability of the proposed manufacturing and dispensing facilities, including but not limited to the suitability of the location and construction timeline for the proposed facilities.

(c) The 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 facilities.

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

(e) Upon application to the office, 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 office shall consider whether to grant or deny the application for amendment of the registration utilizing the criteria set forth in subdivision (b) of this section. The fee for such amendment shall be \$250.

(f) Registrations issued shall be valid for two 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 months nor less than four months prior to the expiration thereof. If a renewal application is not filed at least four months prior to the expiration thereof, the office 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 office 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 applicant if the 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 office may require, including but not limited to:

(1) any material change 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 applicant with local or state laws, or regulations of the board, including but not limited to, with respect to any substance listed in section thirty-three hundred six of the Public Health Law;

(3) information concerning the 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; and

(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 brand and form passing all required testing, the percentage of lots failing contaminant testing, the percentage of lots failing brand requirements, all recalls of product lots and all adverse events reported.

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

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

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

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

### **Section 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 office and prior written

approval of the office. Failure to notify the office 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 office, 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 organization's assets, a merger or consolidation, a change in ownership or control, liquidation, dissolution of an organization, or other events as determined by the office.

(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 office at least 60 days prior to the proposed date of execution, acquisition or change. In determining whether to approve such application, the office may set terms or conditions under which it may allow the continued operation of the registered organization. The office 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 \$250.

### **Section 113.10 Failure to Operate**

(a) A registration shall be surrendered to the office upon written notice and demand if the registered organization fails to begin operations, to the satisfaction of the office, of a manufacturing or dispensing facility within the six 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.

### **Section 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) Except for the operating plan which must be onsite and readily accessible at each facility, make its books, records, operating plan, manufacturing and dispensing facility 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 facilities, available to the office or its authorized representatives 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;

(i) Any deficiencies documented in a statement of findings by the office shall require that the registered organization submit a written plan of correction in a format acceptable to the office within 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:

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

(b) contain a procedure addressing how the registered organization intends to correct each area of noncompliance;

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

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

(e) address any inspection finding which the office determines jeopardizes the immediate health, safety, or well-being of certified patients, designated caregivers or the public. Such a finding shall be deemed a critical deficiency and shall require immediate corrective action to remove the immediate risk, followed by the submission of a preliminary corrective action plan within 24 hours of notification by the office of the critical deficiency. The office will acknowledge receipt within 24 hours and respond as soon as practicable to notify if the plan is accepted or needs modification. If 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;

(ii) Upon written approval of the office, the registered organization shall implement the plan of correction. Failure by the registered organization to implement a plan of correction as directed by the office may result in a civil penalty.

(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;

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

(ii) retained samples must be readily identifiable as belonging to its specific lot;

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

(6) implement policies and procedures to notify the office within 24 hours of the following:

(i) any 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.

(7) Within ten 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 facility; and

(12) amend its operating plan as directed by the office.

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

(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 and 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 facility without prior written approval of the office;

(5) modify, remodel, expand, reduce or make other physical, non-cosmetic alternations to a registered facility, or change the location of a registered facility, without receipt of prior written approval of the office;

(6) materially modify or revise its operating plan, including its policies and procedures related to cultivation, processing, manufacturing, distributing or dispensing policies or procedures, without prior written approval of the office;

(7) locate a dispensing facility on the same street or avenue and 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. 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 facility to the center of the nearest entrance of such school 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 to surrender its registration, the following provisions shall apply:

(1) The registered organization shall notify the office in writing at least 120 days prior to the anticipated date of closure of the manufacturing and each dispensing facility.

(2) Such written notice shall include a proposed plan for closure. 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 years; and

(iv) maintain compliance with these regulations and any other conditions required by the office until the approved closure date.

(3) A registered organization shall take no action to close a manufacturing or dispensing facility prior to office approval of the plan for closure.

(4) A 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 office to revoke the registration of the registered organization under such terms as the office 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.

(d) 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 this section.

### **Section 113.12 Manufacturing Requirements for Medical Cannabis Products**

(a) A registered organization shall use either carbon dioxide (CO<sub>2</sub>), and/or alcohol for phytocannabinoid extraction. A registered organization shall only use carbon dioxide that is of a supply equivalent to food or beverage grade of at least 99.5% purity; and alcohol 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). A registered organization shall obtain prior written approval from the office if it seeks to use any other extraction method.

(b) A registered organization shall only produce such brands and forms of medical cannabis as approved by the office and according to the following requirements:

(1) Each medical cannabis product brand, 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 90 percent, nor more than 110 percent, of the concentration of total THC or total CBD as indicated on the label for the brand.

However:

(i) Where the total THC concentration is less than 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 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 brand lot submitted for testing must be within 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 brands with a specified total THC and CBD concentration less than 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 brand 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 brand that has approximately equal amounts of THC and CBD.

(5) For each brand offered, the registered organization shall only utilize a distinct name which has been approved by the office. No reference shall be made to any specific medical condition.

(6) Each registered organization shall have a manufacturing schedule that ensures the ability to produce adequate supply of any offered brand, unless otherwise allowed by the office, to ensure continuity of care for certified patients.

(c) The registered organization shall not add any additional ingredients or excipients to medical cannabis products outside of the ingredients or excipients approved by the office for the brand unless it has first obtained prior written approval of the office.

(1) Excipients for all forms of administration must be demonstrated safe for use in the proposed form and approved by the office.

(2) All vaporized and inhaled medical cannabis products shall meet the following additional requirements:

(i) unless prior written approval of the office is received, medical cannabis vaporization devices shall be a closed system with a pre-filled disposable cartridge that attaches to a rechargeable battery, or a single-use product that cannot be recharged;

(ii) 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;

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

(a) synthetic terpenes;

(b) polyethylene glycol (PEG); 26

(c) vitamin E acetate;

(d) medium chain triglycerides (MCT oil);

(e) medicinal compounds;

(f) illegal or controlled substances;

(g) artificial food coloring;

(h) benzoic acid;

(i) diketones; and

(j) any other compound or ingredient as determined by the office;

(iv) 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);

(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) upon prior written notice to the office, 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 section 325.2(b) of title 6 of the NYCRR;

(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 office.

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

(h) 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.

(i) The registered organization shall package the medical cannabis product such that it is child-resistant, unless otherwise approved by the office, tamper-proof/tamper-evident, and in a resealable package that minimizes oxygen exposure. Packaging must be in a manner that prevents the degradation of the medical cannabis product.

(1) No packaging or labeling shall imitate a candy label or use cartoons or other images popularly used to advertise to children or otherwise be marketed to anyone under 18 years of age.

(2) Registered organizations may implement a recycling program for medical cannabis product packaging with prior written approval of the office.

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

(k) Each medical cannabis product shall be affixed with a product label that has been approved by the office prior to use. Each product label shall be applied at the manufacturing facility, be easily readable, firmly affixed and include:

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

(2) the medical cannabis product form and brand designation;

(3) the single dose total THC (THC + THCA x 0.877) and total CBD (CBD + CBDA x 0.877) content for the product, and the individual THC, THCA, CBD and CBDA content for the product, each set forth in milligrams (mg);

(4) any other marketed phytocannabinoids;

(5) the medical cannabis product lot unique identifier (lot number or bar code);

(6) the quantity included in the package;

(7) a list of all ingredients in descending order of predominance by weight in the product;

(8) the date packaged;

(9) the date of expiration of the unopened product, based on stability studies in accordance with paragraph 113.11(m)(2) of this Part, or a tentative expiration date approved by the office;

(10) the proper storage conditions;

(11) language stating:

(i) “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”;

(ii) “Keep secured at all times”;

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

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

(v) “KEEP PRODUCT AWAY FROM CHILDREN (unless medical cannabis product is being given to the child under a practitioner’s care”); and

(vi) “This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the certifying practitioner, and in the case of breastfeeding mothers, including the infant’s pediatrician.”

(l) 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 brand and verify that contaminants do not exceed limits, as defined in guidance provided by the office, prior to the medical cannabis product being released from the manufacturer to any dispensing facility.

(1) Unless prior written approval is received from the office, based on a sufficient showing by the registered organization that there is no risk to public health or safety, 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.

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

(3) 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.

(m) The registered organization shall demonstrate the stability of each medical cannabis product produced (each brand in each form) by testing both the unopened and opened product in accordance with section 113.15(h) 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 facility, in the patient's home and for samples retained for future testing.

(n) No synthetic cannabis additives nor any phytocannabinoid preparation not produced by a registered organization in an approved manufacturing facility shall be used in the production of any medical cannabis product; provided, however, that a registered organization may, in accordance with guidance provided by the office, use hemp, or extracts derived from hemp, grown or processed under the authority of the New York State Department of Agriculture and Markets hemp grower program or the office's cannabinoid hemp program, or cannabis purchased from entities licensed by the office of cannabis management to supply cannabis, cannabis product or cannabis extracts to registered organizations, in the manufacturing of medical cannabis products.

(o) 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 Facilities**

(a) Medical cannabis products at a dispensing facility shall only be dispensed by authorized employees of the registered organization, under the in-person or remote supervision of an individual with an active New York State pharmacist license who is physically located in New York State, provided a pharmacist shall not remotely supervise more than one dispensing facility

at a time, as defined in Article 137 of the Education Law, who has completed at minimum a two-hour course pursuant to this Part.

(b) Dispensing facilities shall only sell approved medical cannabis products, related products necessary for the administration of medical cannabis, and items that promote health and well-being subject to disapproval of the office.

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

(d) Dispensing facilities shall not dispense medical cannabis products to anyone other than a certified patient or designated caregiver 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.

(e) When dispensing medical cannabis, the dispensing facility shall:

(1) 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-day supply provided pursuant to any previously dispensed medical cannabis by any registered organization;

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

(3) 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;

(4) 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.

(f) 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 facility 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.

(i) The dispensing facility 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.

(g) The dispensing facility shall affix to the medical cannabis product package a patient specific dispensing label approved by the office, 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 facility 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 113.2 of this Part.

(h) The dispensing facility shall include with each product package dispensed to a patient, a package safety insert approved by the office. Information provided shall include but not be limited to:

(1) the medical cannabis product and brand;

(2) a list of any excipients used;

(3) a warning if there is any potential for allergens in the medical cannabis product;

(4) contraindications;

(5) more specific dosage directions and instructions for administration;

(6) warning of adverse effects and/or any potential dangers stemming from the use of medical cannabis;

(7) instructions for reporting adverse effects as may be determined by the office;

(8) a warning about driving, operation of mechanical equipment, or making important decisions while under the influence of medical cannabis;

(9) 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;

(10) language stating that the medical cannabis product must be kept secure;

(11) language stating that the certified patient may not distribute any medical cannabis product to anyone else;

(12) 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 thisP; and

(13) 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.”

(i) The dispensing facility 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.

(j) If a medical cannabis product is returned to the dispensing facility, the dispensing facility shall:

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

(2) provide the following information to the office:

(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 brand and form being returned;

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

(v) the reason for the return;

(vi) the name of the dispensing facility 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.

### **Section 113.14 Security Requirements for Manufacturing and Dispensing Facilities**

(a) All facilities operated by a registered organization, including any manufacturing facility and dispensing facility, 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 facility 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 facility 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 facility 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 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 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 minutes of the failure, either by telephone, email, 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 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 facility 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 facility

that is operated under the registered organization's registration. Records of security tests must be maintained for five 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 facility 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 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.

### **Section 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, 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. Upon prior written approval of the office, a registered organization may submit to the laboratory the final medical cannabis product sample packaged in a quantity less than that which would be provided to the patient if the sample is prepared and packaged in the identical manner as the product provided to the patient.

(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 paragraph 113.12(b)(2) 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 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 brand and form of 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 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 products, each brand shall retain a total THC and total CBD concentration in milligrams per single dose that is consistent with paragraph 113.12(b)(3) of this Part. If stability testing demonstrates that a product no longer retains a consistent concentration of THC and CBD pursuant to paragraph 113.12(b)(3) of this Part, the product shall be deemed no longer suitable for dispensing or consumption. The office may request further stability testing of a brand to demonstrate the ongoing stability of the product produced over time.

(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.

**Section 113.16 Pricing.**

(a) Registered organizations shall submit documentation to the office at least fifteen 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 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) All physical structures owned, leased or otherwise utilized by a registered organization shall:

(1) Not advertise cannabis or utilize graphics related to cannabis or devices for the administration of cannabis on the exterior of the physical structures unless prior written approval is received from the office; and

(2) Not display cannabis products and devices for the administration of cannabis so as to be clearly visible on the exterior of a physical structure.

(b) All restrictions listed in subdivision (a) of this section shall apply to any item located on any real property on which a registered organization's physical structures is located.

(c) All restrictions listed in subdivision (a) of this section shall apply to all vehicles owned, leased or utilized by a registered organization.

(d) All advertisements, regardless of form, for cannabis that make a statement relating to effectiveness, side effects, consequences or contraindications shall present a true and accurate statement of such information.

(e) An advertisement does not satisfy the requirement that it presents a "true and accurate statement" of information relating to effectiveness, side effects, consequences, and

contraindications if it fails to present a fair balance between information relating to effectiveness, side effects, consequences, and contraindications in that the information relating to effectiveness is 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.

(f) 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 brands 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 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 or more facing pages are part of the same advertisement when only one page contains information relating to side effects, consequences and contraindications.

(g) False or misleading information in any part of the advertisement shall not be corrected by the inclusion of a true statement in another distinct part of the advertisement.

(h) An advertisement for cannabis shall not contain:

(1) any statement that is false or misleading;

(2) any statement that falsely disparages a competitor's products;

(3) any statement, design, or representation, picture or illustration that is obscene or indecent;

(4) any statement, design, representation, picture or illustration that encourages or represents the recreational use of cannabis or promotes overconsumption;

(5) 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;

(6) any picture or illustration portraying anyone under the age of 18, objects suggestive of the presence of anyone under the age of 18, or containing the use of a figure, symbol or language that is customarily associated with anyone under the age of 18;

(7) 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 products; or

(8) any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the executive director, any member of the cannabis control board, office, chief equity officer, New York State 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.

(i) An advertisement for cannabis shall not be permitted:

(1) within or is readily observed within five hundred feet of the perimeter of school grounds, as that term is defined in the education law;

(2) on or inside public transit vehicles and stations;

(3) in the form of an unsolicited internet pop-up; or

(4) in the form of a billboard.

(j) Any advertisement or marketing for cannabis or medical cannabis must accurately and legibly identify the party or other business responsible for its content;

(k) Any advertisement for medical cannabis, which makes any claims or statements regarding efficacy, shall be submitted to the office at least 60 days prior to the public dissemination of the advertisement.

(l) The submitter of the advertisement shall provide the following information to the office in addition to the advertisement itself:

(1) A cover letter that:

(i) provides the following subject line: Medical cannabis advertisement review package for a proposed advertisement;

(ii) provides a brief description of the format and expected distribution of the proposed advertisement; and

(iii) provides the submitter's name, title, address, telephone number, fax number, and email address;

(2) an annotated summary of the proposed advertisement showing every claim being made in the advertisement and which references support for each claim;

(3) verification that a person identified in an advertisement as an actual patient or health care practitioner is an actual patient or health care practitioner and not a model or actor;

(4) verification that a spokesperson who is represented as an actual patient is indeed an actual patient;

(5) verification that an official translation of a foreign language advertisement is accurate;

(6) annotated references to support disease or epidemiology information, cross-referenced to the advertisement summary; and

(7) a final copy of the advertisement, including a video where applicable, in a format acceptable to the office.

(m) Advertising packages that are missing any of the elements in subdivision (k) of this section, or that fail to follow the specific instructions for submissions, shall be considered incomplete. If the office receives an incomplete package, it shall so notify the submitter.

(n) No advertisement may be disseminated if the submitter of the advertisement 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.

(o) A registered organization, its officers, managers and employees shall not 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.

(p) The office may:

(1) require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the office determines that the advertisement would be false or misleading without such a disclosure; or

(2) require that changes be made to the advertisement that are:

(i) necessary to protect the public health, safety and welfare; or

(ii) consistent with dispensing information for the product under review.

**§ 113.18 Reporting Dispensed Medical Cannabis Products**

(a) A record of all medical cannabis products that have been dispensed shall be filed electronically with the office, utilizing a transmission format acceptable to the office, not later than 24 hours after the cannabis was dispensed to the certified patient or designated caregiver.

(b) The information filed with the office for each medical cannabis product dispensed shall include but not be limited to:

(1) a serial number that will be generated by the dispensing facility 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 facility;

(3) the patient name, date of birth and gender;

(4) the patient address, including street, city, state, zip code;

(5) the patient's registry identification card number;

(6) if applicable, designated caregiver's name and registry identification card number;

(7) the date the medical cannabis product was filled by the dispensing facility;

(8) the metric quantity for the medical cannabis product;

(9) the medical cannabis product drug code number, which shall be populated by a number provided by the cannabis, to represent the medical cannabis brand 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 with the office, 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 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 section thirteen hundred ninety-nine 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 129 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 re-issues a patient's certification to terminate the certification on an earlier date, then the registry identification card shall expire on such earlier date and shall be promptly returned to the office by the certified patient or designated caregiver.

(c) a practitioner shall report patient adverse events to the office, in a manner determined by the office, not more than five business days after the practitioner becomes aware of such adverse event,

except that serious adverse events shall be reported not more than one business day after the practitioner becomes aware of such adverse event.

(d) A certified patient or designated caregiver, who has been issued a registry identification card, 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, 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 10 days and the certified patient's and designated caregiver's registry identification cards shall be considered void and shall be returned promptly to the office.

(e) If a certified patient's or designated caregiver's appearance has substantially changed such that the photograph submitted to the office does not accurately resemble such certified patient or designated caregiver, such person shall submit, in a timely manner, an updated photograph that meets the requirements set forth by the office.

(f) 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.

(g) If a certified patient, designated caregiver notifies the office of any change that results in information on the registry identification card being inaccurate or the photograph needing to be replaced, the certified patient or designated caregiver shall obtain a replacement registry identification card. The office shall thereafter issue the certified patient or designated caregiver a new registry identification card. Upon receipt of a new registry identification card, the certified patient or designated caregiver shall destroy in a non-recoverable manner the registry identification card that was replaced.

(h) 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 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 card is invalid.

(2) In the event that the designated caregiver has no other active certified patients, the designated caregiver's registration card must be returned to the office within 10 business days.

(3) 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 card must be returned to the office within ten business days.

### **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 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 non-recoverable beyond reclamation in accordance with the Department of Environmental Conservation's guidance; or;

(2) returning the medical cannabis product to the dispensing facility from which it was purchased or any dispensing facility 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 facility at which the certified patient or designated caregiver will purchase medical cannabis products.

(c) 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 hour course pursuant to section 113.2 of this Part, or the employee is under the direct supervision of, and in consultation with, such practitioner, or the pharmacist working at the dispensing facility.

(d) No certified patient or designated caregiver shall be in possession of medical cannabis products without having in their possession their registry identification card, except where the certified patient or designated caregiver is 21 years of age or older and has in their possession no more than three ounces of cannabis or twenty-four grams of concentrated cannabis. The certified patient or designated caregiver, upon request by the office or law enforcement, shall present such card 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 facility.

(c) A practitioner shall not issue a certification for themselves.

(d) A practitioner shall not receive or provide product samples containing cannabis.

(e) A practitioner shall not be a designated caregiver for any patients that he or she has certified under section 113.2 of this Part. However, this shall not prohibit a facility or a research license holder from being a designated caregiver pursuant to section 113.5 of this Part.

#### **§ 113.24 Designated Caregiver Prohibitions and Protections**

(a) An individual shall not serve as a designated caregiver for more than five 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 115.3 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 facilities registered as designated caregivers facility and 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.

#### **§ 113.25 Registered Organizations; Disposal of Medical Cannabis**

(a) The disposal of medical cannabis shall mean that the medical cannabis has been rendered unrecoverable and beyond reclamation, 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:

(1) obtain office approval of disposal methods; and

(2) dispose of liquid and chemical waste in accordance with applicable federal, state and local laws and regulations.

(c) 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 brand and form of 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; and

(4) the signatures of at least two registered organization staff members who witnessed the disposal.

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