Pursuant to the authority vested in the Cannabis Control Board by Sections 10, 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, to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

Section 113.1 is amended to read as follows:

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

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

(b) *Advertising* means [disseminating communications in any manner or by any means, for the purpose of causing, directly or indirectly, the purchase or use of a medical cannabis product brand or medical cannabis product, including but not limited to websites, social media, brochures, prints ads, TV, radio, streaming, our of home, and digital advertisements]<u>advertising as defined in Part 128 of this Title.</u>[,]

([b]<u>c</u>) <u>*Advertisement* means advertisement as defined in Part 128 of this Title.</u>

<u>(d) *Aggregate ownership* means aggregate ownership as defined in Part 118 of this Title.</u>

([c]e) *Artificially derived phytocannabinoid* means artificially derived phytocannabinoid[that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from cannabis sativa. Artificially derived phytocannabinoid does not include: a naturally-occurring chemical substance that is separated from cannabis sativa by a chemical or mechanical extraction process; phytocannabinoids that are produced by decarboxylation of the phytocannabinoid's respective naturally-occurring carboxylic acid form without the use of a chemical catalyst; any other chemical substance identified by the Board] as defined in Part 118 of this Title.

([d]f) *Board* means the New York State Cannabis Control Board as defined in Article 1 of the Cannabis Law.

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

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

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

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

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

([j]l) *Child-Resistant* means child-resistant as defined in Part 128 of this Title. [a resealable package for dispensing any cannabis product intended for more than a single use or containing multiple doses, that is designed or constructed to be significantly difficult for children under five (5) years of age to open and not difficult for adults to use properly as defined by 16 C.F.R. §1700.15 and 16 C.F.R. §1700.20.]

([k]m) *Condition* means having one (1) of the following conditions: cancer, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord

with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, post-traumatic stress disorder, pain that degrades health and functional capability (where the use of medical cannabis is an alternative to opioid use), substance use disorder, Alzheimer's, muscular dystrophy, dystonia, rheumatoid arthritis, autism or any other condition certified by the practitioner.

([l]n) *Control or controlling interest* means [the power, from a business organization and ownership perspective, to order or direct the management, managers, or policies of a person] control or controlling interest as defined in Part 118 of this Title.

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

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

([o]q) *Designated caregiver facility* means a facility that registers with the [O]office to assist one (1) or more certified patients with the acquisition, possession, delivery, transportation or administration of medical cannabis and is a: general hospital or residential health care facility operating pursuant to Article 28 of the Public Health Law; an adult care facility operating pursuant to Title 2 of Article 7 of the Social Services Law; a community mental health residence

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

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

([q]s) *Financial Interest* means [any actual or future right to ownership, investment or compensation arrangement with another person, either directly or indirectly, through business, investment, spouse, parent or child. Person with a] financial interest [does not include a passive investor] as defined in Part 118 of this Title.

([r]t) *Form of medical cannabis or f*[*F*]*orm* means ["]form of medical cannabis["] as defined by Article 1 of the Cannabis Law.

(u) *Goods and services agreement* means goods and services agreement as described in Part 124 of this Title.

(v) *House of worship* means house of worship as defined in Part 118 of this Title.

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

([t]x) *Lot unique identifier or* [*(L*]*lot number or bar code*[*)*] means lot unique identifier or lot number or bar code as defined in Part 118 of this Title[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].

(y) *Marketing* means marketing as defined in Part 128 of this Title.

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

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

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

[([x]ab) *Office* means the New York State Office of Cannabis Management as defined in Article 1 of the Cannabis Law.

(ac) *Passive Investor* means passive investor as defined in Part 118 of this Title.

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

([z]ae) Phytocannabinoid[s refers to] means phytocannabinoid as defined in Part 128 of this Title[any of the chemical compounds, excluding terpenes or any other compounds determined by the [O]office, that are the active principles of the cannabis sativa, including but not limited to tetrahydrocannabinol (THC) and CBD, and does not include synthetic cannabinoids as that term is defined in subdivision (g) of schedule I of section 3306 of the Public Health Law].

(af) *Plastic* means plastic as defined in Part 128 of this Title.

(a[a]g) *Post-consumer recycled*[*material*] *content* means post-consumer recycled content as defined in Part 128 of this Title[new material produced using material resulting from the recovery, separation, collection and reprocessing of material that would otherwise be disposed of or processed as waste and that was originally sold for consumption. It does not include post-industrial material, or material generated by means of combustion, incineration, pyrolysis, gasification, solvolysis, chemical recycling and any high-heat or conversion process].

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

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

(a[d]j) *Registered organization* means an organization registered as defined under Article [section] 3 of the Cannabis Law.

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

(al[f]) *Registry application* means an application properly completed and filed with the [O]office by a certified patient in accordance with Article 3 of the Cannabis Law and this Part.

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

(an[h]) *Resealable* means resealable as defined in Part 128 of this Title[a package that maintains its child-resistant effectiveness, as well as preserving the integrity of cannabis products for multiple doses].

(ao) *School grounds* means school grounds as defined in Part 118 of this Title.

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

(aq[j]) *Significant presence* means significant presence as defined in Cannabis Law section 3(1).

(ar) *Sole Control* means sole control as defined in Part 118 of this Title.

(as) *Special branding material* means a visual or audio element which shall only be for use in packaging, labeling, marketing, and advertising by certain registered organizations or on certain medical cannabis products including, but not limited to, a designation that a licensee is a social and economic equity licensee. All special branding materials and the brands or products authorized to use such materials shall be defined, made available, and designated for use in guidance.

(at[k]) *Synthetic cannabis additives* means [refer to] any chemical substances that do not naturally occur in cannabis sativa.

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

(av[m]) *Tamper-evident* means tamper-evident as defined in Part 128 of this Title[, with respect to a device or process, bearing a seal, a label or a marking that makes unauthorized access to or tampering with a package, product or container easily detectable].

(aw) *True Party of Interest* means true party of interest as defined in this Part 118 of this Title.

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

Subdivision (k) of section 113.3 is repealed.

Paragraph (1) of subdivision (a) of section 113.6 is amended to read as follows:

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

Paragraph (2) of subdivision (b) of section 113.6 is amended to read as follows:

(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] shall comply with all measuring requirements as described in section 119.4 of this Title, as applicable.

Paragraphs (3) through (20) of subdivision (b) of Section 113.6 are renumbered to paragraphs (4) through (21) and a new paragraph (3) is added to read as follows:

(3) identification of cultivation tier and type, pursuant to section 120.3, as applicable;

Newly created paragraphs (4) and (5) of subdivision (b) of Section 113.6 are amended to read as follows:

([3]4) identification of equipment, as determined by the [B]board in the application, that will be used to carry out any manufacturing, processing, transportation, distributing, sale [and]or dispensing activities;

([4]5) a business plan that includes a description of the activities, authorized by Article 3 of the Cannabis Law, to be conducted by the registered organization applicant. In addition, the plan shall include a description detailing how the registered organization applicant proposes to provide services to areas of the state, unserved or underserved as, in accordance with section 35 of the Cannabis Law; a description containing details of how the registered organization applicant proposes: to be reflective of the demographics of the state, to be representative of communities disproportionally impacted by cannabis prohibition, as set forth in guidance by the [O]office. Unless waived by the [B]board, the plan shall include, to the satisfaction of the [Office]board, the following information, in a format specified on the application;

(i) executive summary;

(ii) entity description;

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

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

(v) market analysis demonstrating a need for the dispensing sites proposed; and

(vi) [implementation strategy; and

(vii)] any other information requested by the [O]office[:].

Subparagraph (vi) of newly created paragraph (6) of subdivision (b) of Section 113.6 is renumbered to subparagraph (vii) of newly created paragraph (6) of subdivision (b) of Section 113.6 and a new subparagraph (vi) is added to read as follows:

(vi) sampling and transport to a permitted cannabis laboratory for testing; and

Newly created paragraph (11) of subdivision (b) of section 113.6 is amended to read as follows:

(1[0]1) 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]true parties of interest of the registered organization applicant, with the exception of any passive investors of a publicly traded company with less than or equal to 5% current ownership or future right to ownership, or shareholders in a privately-held company with less than or equal to 10% current ownership or future right to ownership. Each such person (if an individual, or lawful representative, if a legal entity) shall submit an affidavit with the application setting forth:

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

(ii) whether such person or any such business has been convicted of a felony or had a registration or license suspended or revoked in any administrative or judicial proceeding, and if applicable, the history of violations or administrative penalties with respect to any license to cultivate, manufacture, distribute or sell adult-use cannabis or medical cannabis. In addition, any true parties of interest, not including passive investors, and managers who are a member of the registered organization applicant or entity that is a member of the registered organization applicant who may come in contact with or handle medical cannabis, including medical cannabis products, shall be subject to a fingerprinting process as part of a criminal history background

check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee; and

(iii) any other disclosure so required by the office.

Newly created paragraph (14) of subdivision (b) of section 113.6 is amended to read as follows:

(14[3]) copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts related to the organization's real property interests, that shows that the registered organization applicant possesses or has the right to use sufficient land, buildings, and other premises as specified in the application and equipment to properly carry on the activities for which registration is sought. In the alternative, the registered organization applicant shall post a bond of not less than [two (]$2[)] million[dollars]; provided, however, that if the registered organization applicant posts a bond in lieu of providing the documentation requested herein, the registered organization applicant's submission of the applicable executed deeds, leases and rental agreements shall be required prior to the issuance of a registration to the registered organization applicant, if selected; In accordance with the social-equity plan established pursuant to section 87 of the Cannabis Law, the [B]board may waive such requirements when the registered organization applicant is a social and economic equity applicant, provided, however, that prior to issuance of the registration, the registered organization applicant must submit to the [O]office, copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts related to the

organization's real property interests, and, provided further that whenever any registered organization applicant proposes to lease a premises for the activities described in its operating plan, the lease agreement shall clearly set forth as a purpose the manufacturing and/or dispensing of medical cannabis, as applicable, and include the following language:

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

Newly created paragraphs (18) and (19) of subdivision (b) of section 113.6 are amended to read as follows:

(18[7]) [if any controlling person of the registered organization applicant maintains a ten (10) percent interest or greater in any firm, association, foundation, trust, partnership, corporation, or other entity or if such entity maintains a ten (10) percent interest or greater in the registered organization applicant, and such entity will or may provide goods, leases, or services to the registered organization, the value of which is or would be five hundred dollars or more within any one (1) year, the name and address of the entity shall be disclosed together with a description of the goods, leases or services and the probable or anticipated cost to the registered

organization;] all proposed or executed contracts, term sheets, agreements, or side letters between the applicant or its true parties of interest of the applicant and a goods and services provider, other than those agreements delineated as exempt agreements under section 124.3 of this Title and any non-exempt goods and services agreement for a flat fee.

(19[8]) if the registered organization applicant is a [corporate subsidiary or affiliate of]true party of interest of another corporation, disclosure of the parent or affiliate corporation including the name and address of the parent or affiliate, the primary activities of the parent or affiliate, the interest in the registered organization applicant held by the parent or affiliate and the extent to which the parent will be responsible for the financial and contractual obligations of the subsidiary;

Paragraph (21) of subdivision (b) of section 113.6 is repealed.

Paragraph (22) and (23) of subdivision (b) of section 113.6 are renumbered to (21) and (22) of subdivision (b) of section 113.6 and newly renumbered (22) of subdivision (b) of section 113.6 is amended to read as follows:

(22[3]) any other information as may be required by the [O]office, including by not limited to, information relating to any holder of any shares or interest in the applicant.

Subdivision (g) of section 113.6 is amended to read as follows:

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

Subdivision (d) of section 113.7 is amended to read as follows:

(d) Registered organization applicants granted a registration shall immediately submit the registration fee by certified check, or another method approved by the [B]board. The board shall deliver such registration upon receipt of the registration fee. For renewal purposes, the renewal period shall be calculated from the date the registration was granted.

Subdivisions (g) and (h) of section 113.7 is amended to read as follows:

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

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

* * *

Paragraphs (4) and (5) of subdivision (c) of Section 113.8 is amended and a new paragraph (6) of subdivision (c) of Section 113.8 is added to read as follows:

(4) a summary of quality assurance testing for all medical cannabis products produced in the prior year, including but not limited to, the percentage of lots of each product passing all required testing, the percentage of lots failing contaminant testing, the percentage of lots failing product requirements, all recalls of product lots and all adverse events reported; [and]

(5) an updated environmental sustainability packaging program plan and a report of key metrics including, but not limited to, the total amount of packaging material, by weight, sold, offered for sale, or distributed into the state by the registered organization during the renewal period and the total costs of packaging material[.]; and

(6) disclosure of true parties of interest, as required by the board.

Subdivision (d) of Section 113.9 is repealed and subdivision (c) is amended to read as follows:

(c) [A r] Registered organizations shall have a continuing duty to provide the office with up-to-date contact information and shall notify the office in writing of any amendments or changes in compliance with the provisions set forth in Part 120.18 of this Title[not change its composition, including but not limited to, a change in ownership, structure or control, without notification to the Board and without prior written approval of the Board. Failure to notify the Board and receive prior written approval of such changes may result in civil penalties or revocation of the registered organization's registration. For purposes of this subdivision, a change shall include, but not be limited to:

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

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

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

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

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

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

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

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

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

(4) a change of ownership, or roles and responsibilities of any individual or entity, such that the net effect would cause a change in the power to direct, or cause the direction of, the management and policies of the organization].

Paragraph (1) of subdivision (a) of section 113.11 is amended to read as follows:

(1) make its books, records, manufacturing and dispensing site architectural and engineering design drawings, including a description of energy sources, type and location of engineering systems in use for heating, cooling, ventilation and electrical distribution, water supply and sewage, policies and procedures, and manufacturing and dispensing sites, available to the [O]ffice or its authorized representatives within 48 hours of notice, <u>except during unannounced inspections where such information shall be available to the Office immediately upon request during the unannounced inspection,</u> for monitoring, on-site inspection, and audit purposes, including but not limited to periodic inspections or evaluations of facilities, methods, procedures, materials, staff and equipment to assess compliance with requirements set forth in Article 3 of the Cannabis Law and this Part. The operating plan <u>and inventory tracking data</u> must be onsite and readily accessible at each facility at all times;

Subparagraph (iii) of paragraph (5) of subdivision (a) of section 113.11 is amended to read as follows:

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

Subparagraph (iii) and (iv) of paragraph (6) of subdivision (a) of section 113.11 is amended and a new subparagraph (v) of paragraph (6) of subdivision (a) of section 113.11 is added to read as follows:

(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 recalls; and

(v) any vehicle accidents or incidents occurring during transport of medical cannabis products[; and].

Subparagraph (i) of paragraph (10) of subdivision (a) of section 113.11 is amended, and new paragraphs (15) and (16) are added to read as follows:

(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 any hemp or hemp extract used, soil, soil amendment, nutrients, hydroponic materials, fertilizers, growth promoters, pesticides, fungicides, and herbicides;

* * *

(15) implement policies and procedures for off-line dispensing of medical cannabis to patients in the event of a technological failure.

(16) maintain 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) at each cultivation facility;

(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 18 years of age or older. Any employee 18 years of age or older and under 21 years of age may not have direct interaction with certified patients inside a registered organization's dispensing site;

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

(v) policies and procedures to ensure that the registered organization shall not be managed by or employ anyone who has been convicted within three 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 subdivision 7 of section 34 of article 3, or section 137 of the Cannabis Law;

Subdivision (b) of section 113.11 is amended to read as follows:

(b) Registered organizations registered under article 3 of the Cannabis Law shall not:

(1) concurrently hold a license under article 4 of the Cannabis Law;

(2) sell adult-use cannabis or cannabis products to any licensee under article 4 of the Cannabis Law;

[(1)](3) dispense medical cannabis products from the same location where the cannabis is grown or manufactured, except for the operation of home delivery services where the operation of such services is conducted in compliance with the requirements of section 113.13 of this Part;

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

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

(4)] (5) make substantial alterations to the structure or architectural design of a manufacturing or dispensing site, for which the office authorized to issue guidance to further clarify what substantial alterations may mean, without prior written approval of the [O]office;

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

(i) change the location without prior approval of the [B]board; or

(ii) expand or reduce the size of a registered facility without prior written approval of the [O]office;

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

(7) locate a dispensing site in violation of Part 119.4 of this Title[on the same street or avenue and within five hundred (500) feet of school grounds as such term is defined in the Education Law or two hundred (200) feet from a house of worship. The measurements in this paragraph of this subdivision are to be taken in straight lines from the center of the nearest entrance of the

premises sought to be used as a dispensing site used by certified patients or designated caregivers to enter to the nearest point of the school grounds or house of worship]in violation of Part 119.4 of this Title; 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 [O]office.

A new subdivision (d) of section 113.11 is added to read as follows:

(d) Registered organizations shall comply with all requirements for worker health and safety standards in accordance with Part 125.6 of this Title.

Subparagraph (vi) of paragraph (1) of subdivision (a) of section 113.12 is amended to read as follows:

(vi) evidence the purity of any chemical solvents used and make any [certificate of analysis]laboratory testing results or other documentation evidencing such purity and shall make such evidence readily available to employees and to the [O]office upon request.

Clause *(b)* of subparagraph (iv) of paragraph (2) of subdivision (a) of section 113.12 is amended to read as follows:

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

Paragraph (5) of subdivision (a) of section 113.12 is amended to read as follows:

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

Subparagraph (vii) of paragraph (1) of subdivision (b) of Section 113.12 is amended to read as follows:

(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].

Subparagraph (iii) of paragraph (2) of subdivision (b) of Section 113.12 is renumbered to paragraph (3) and is amended to read as follows:

([iii]) except for flower products, be homogenous, with phytocannabinoid content evenly distributed throughout the cannabis product; [u]Unless otherwise approved by the Office, the concentration of total THC and CBD in milligrams per single dose for any sample of a product submitted for testing must be within twenty-five (25) percent of the mean concentration of total THC and CBD in milligrams per single dose for that submitted lot with the exception that, for products with a specified total THC and CBD concentration less than two (2) milligrams per single dose, the concentration of each sample for that low concentration phytocannabinoid shall be within 0.5 milligrams per dose of the mean concentration.

Paragraph (3) through (6) of subdivision (b) of section 113.12 is renumbered to paragraphs (4) through (7) of subdivision (b) of section 113.12 and newly renumbered paragraph (6) of subdivision (b) of section 113.12 is amended to read as follows:

(6[5]) for each medical cannabis product offered, the registered organization shall utilize a name that complies with the requirements of section 113.12(j[k]) of this Part; and

Paragraphs (1) through (5) of subdivision (f) of section 113.12 are repealed and new paragraphs (1) through (5) of subdivision (f) of section 113.12 are added to read as follows:

(1) cannabis concentrates, including, but not limited to, shatters, waxes, resins and any other concentrates (not gel-based or water soluble);

(2) cannabis edibles, including, but not limited to, capsules, beverages, tablets, tinctures, baked goods, gummies, chocolates and any other edibles;

(3) cannabis flower products, including, but not limited to, whole flower, ground flower, shake, pre-rolls, and any other flower;

(4) vaporization cartridges or single use pens;

(5) topicals; or

Subdivisions (g) and (m) of section 113.12 are repealed and subdivisions (h) through (l) of section 113.12 are renumbered as paragraph (g) through (k) and newly renumbered subdivision (h) of section 113.12 is amended to read as follows:

(h[i]) The registered organization shall package the final form of the medical cannabis product at the manufacturing site.

(1) The original seal shall not be broken except for:

(i) quality testing at an approved laboratory,

(ii) for [adverse event] investigations or as part of an inspection[,] by the [O]office,

(iii) 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, or

(iv) by a registered organization for dispensing smaller quantities of medical cannabis product to certified patients. The office may issue future guidance regarding the parameters of how a registered organization may dispense smaller quantities of medical cannabis products to certified patients.

Paragraphs (2) through (5) of newly renumbered subdivision (i) of section 113.12 are repealed and paragraph (1) of newly renumbered subdivision (i) section 113.12 is amended to read as follows:

(1) A medical cannabis product [package]shall:

(i) be used to package a product [packaged and labeled]in its final form at the manufacturing facility;

(ii) [be easily readable and firmly affixed to the package]in addition to the packaging and labeling requirements under section 34 of the Cannabis Law, conform with all packaging and labeling requirements set forth in Part 128 of this Title, except that a "serving" shall be referenced as a "dose";

(iii) be child-resistant unless otherwise approved by the [O]office;

(iv) notwithstanding the requirements of section 128.6 of this Title, contain the message "for medicinal use only" for those dosage forms that are not authorized for adult-use pursuant to article 4 of the Cannabis Law, and applicable regulations[be tamper-evident]; and

(v) be allowed, where the cannabis product may be used as an adult-use cannabis product or a medical use product, to use a safety insert to comply with packaging and labeling requirements in addition to those requirements in Part 128, as required by section 34 of the Cannabis Law or in

section 113.13 of this Part. [fully enclose the product, minimize oxygen exposure and prevent the contamination and/or degradation of the medical cannabis product; and

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

Paragraph (1) of newly renumbered subdivision (j) of section 113.12 is amended to read as follows:

(1) A medical cannabis product [package] shall not:

(i) be opened or the original seal be broken except for quality testing at an approved laboratory, for adverse event investigations, by the [O]office, by the certified patient or designated caregiver, designated caregiver facility, an authorized cannabis research license holder, or by the registered organization for internal quality control testing or disposal, unless otherwise approved by the [O]office; or

(ii) [contain any pictures, images, or graphics, other than what may be required by the Board;

(iii) contain any features that emit scent or sound;

(iv) contain any features that change or alter a package's appearance through technology, other than for anti-counterfeiting purposes;

(v) be made attractive to individuals under 21, by using or including:

(a) Cartoons;

(b) Bubble-type or other cartoon-like font;

(c) Bright colors that are "neon" in appearance ;

(d) Similarities to products or words that refer to products that are commonly associated with, or marketed in a manner so as to be attractive to, individuals under twenty-one (21), including but not limited to, any imitation of food, candy, soda, drinks, cookies, or cereal, in labeling, packaging, advertising, or marketing;

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

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

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

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

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

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

Paragraph (1) of newly renumbered subdivision (k) of section 113.12 is amended to read as follows:

(1) Registered organizations shall ensure that the principal packaging display panel or safety insert shall [have a white background with black text] conform with all packaging and labeling requirements set forth in Part 128 of Title 9 and contain[ing] the following information:

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

(ii) [a list of all ingredients in descending order of predominance by weight in the medical cannabis product – both active and inactive. The ingredient list must include and separately list, in bold, any major allergens set forth in the Food Allergen Labeling and Consumer Protection Act of 2004, Title 21, as it relates to Food and Drugs, of the U.S. Code § 343, for misbranded food.

(iii) milligrams per dose of total THC (THC + (THCA x 0.877)), total CBD (CBD + (CBDA x 0.877)) content;

(iv) milligrams per package of total THC (THC + (THCA x 0.877)) and total CBD (CBD + (CBDA x 0.877))

(v)] any other marketed phytocannabinoids in milligrams per dose and milligrams per package shall be calculated the same way as total THC and total CBD using its acid form and 0.877 as part of the calculation;

([v]iii) the amount of total THC (THC + (THCA x 0.877)) and any other marketed phytocannabinoids as a percentage of volume, unless otherwise exempted by the [O]office;

[(vii) the total quantity or volume included in the package;

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

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

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

(xi) the proper storage conditions;

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

(xiii) language stating:

(a) “Keep secured at all times.”;

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

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

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

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

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

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

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

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

(xvi) any other information required by the Board.

Paragraphs (2) and (4) of newly renumbered subdivision (k) of section 113.12 is repealed and paragraph (3) of subdivision (k) of section 113.12 is renumbered as paragraph (2) and is amended to read as follows:

(3) The information required pursuant to section 113.12([l]k)(1) of this Part must be unobstructed and conspicuous. A registered organization may include the required information by printing the information directly onto the medical cannabis package or by affixing multiple labels with the information to the package, provided none of the information is obstructed. For example, and not by means of limitation, the information may appear on labels that may be accordion, expandable, extendable, or layered to accommodate labeling of small packages.

Paragraph (n) through (s) of section 113.12 is renumbered as subdivision (l) through (q) of section 113.12 and newly renumbered subdivision (m) of section 113.12 is amended to read as follows:

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

(1) the registered organization must notify the office their intention to remediated or repurposed a medical cannabis product prior to initiating remediation or repurposing process;

(2[1]) the lot must be resubmitted for laboratory testing in a manner set forth in section 113.12(l[n]) of this Part;

(3[2]) after completing the required analyses of a representative sample obtained from a remediated or repurposed medical cannabis lot, the laboratory shall report the results to the [O]office within [two (]2[)] business days;

(4[3]) a medical cannabis[flower] product lot may only be remediated or repurposed for extraction once. If the lot fails to meet minimum testing standards for contaminants after the remediation or repurposing process, the entire lot shall be destroyed by the registered organization in accordance with section 113.25 of this Part;

(5[4]) when a failed medical cannabis product [flower] lot is not remediated or reprocessed in any way it cannot be retested. Any subsequent testing results produced without remediation of the failed batch will not supersede the initial regulatory testing results.

(6[5]) Any lot not meeting the minimum standards or specifications for product consistency shall be reported to the [O]office and not dispensed by a registered organization without prior written approval from the [O]office.

(7[6]) The registered organization shall keep and maintain records documenting submission of medical cannabis products to approved laboratories as required herein, and the results of the laboratory testing. The registered organization shall provide the [O]office with such records upon request.

Newly renumbered subdivision (n) of section 113.12 is amended to read as follows:

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

New subdivisions (c) and (d) of section 113.13 are added to read as follows:

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

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

Subdivisions (c) through (l) are renumbered as (e) through (n) of section 113.13.

Paragraphs (4) and (7) of newly renumbered subdivision (h) of section 113.13 are repealed and paragraphs (5) and (6) of newly renumbered subdivision (h) of section 113.13 are renumbered as paragraph (4) and (5).

Paragraph (7) of newly renumbered subdivision (k) of section 113.13 is amended to read as follows:

(7) the expiration date of the product once opened pursuant to section 113.12(n[p])(2) of this Part, if not included on the cannabis product label pursuant to section 113.12 of this Part.

A new paragraph (12) of newly renumbered subdivision (k) of section 113.13 is added to read as follows:

(12) language stating, in bold:

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

(b) “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.”; and

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

Subdivision (n) of section 113.13 is amended to read as follows:

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

A new subdivision (o) of section 113.13 is added to read as follows:

(o) A registered organization shall provide a physical or paper certificate of analysis which includes, but is not limited to, the quality, safety and clinical strength of the medical cannabis product manufactured or dispensed by the registered organization directly to certified patients or their designated caregivers upon their request, in accordance with section 34 of the Cannabis Law.

Subdivision (a) of section 113.15 is amended to read as follows:

(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 [O]office and approved for the analysis of medical cannabis in accordance Article 3 of the Cannabis Law, and[this] Part 130.[A laboratory licensed by the New York State Department of Health to conduct medical cannabis testing shall be deemed a "permittee" and must continue to comply with all applicable sections set forth in Subpart 55-2 of Title 10 NYCRR, in addition to this Part.]

Subdivision (c) of section 113.15 is amended to read as follows:

(c) For final product testing, a[statistically significant] representative 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)] in the respective product packaging shall be [collected and submitted]sampled and transported for final product testing in a manner approved by the [O]office.

Subdivisions (h) and (j) of section 113.15 are repealed and subdivisions (i) and (k) of section 113.15 are renumbered as subdivisions (h) and (i) and paragraph (3) of newly created subdivision (h) is amended to read as follows:

(3) For stability testing of both opened and unopened cannabis products, each cannabis product shall retain a total THC and total CBD concentration in milligrams per single serving that is consistent with paragraph 113.12(b)(2) of this Part. If the product no longer retains a

consistent concentration of total THC and total CBD pursuant to paragraph 113.12(b)(2) of this Part, the product shall be deemed no longer suitable for consumption and destroyed by the registered organization in accordance with section 113.25 of this Part. The [R]registered [O]organization shall demonstrate the ongoing stability over time of any product form produced as deemed necessary by, but not limited to, product stability concerns or complaints, new stability information about cannabis, for internal audit, or as requested by the [O]office and shall provide such documentation whenever requested from the [O]office.

Paragraphs (1) through (10) of subdivision (a) of section 113.17 are amended to read as follows:

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

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

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

(4) Any [marketing or] advertisement of medical cannabis or medical cannabis products shall, unless otherwise approved by the office, include [the following statements, in a conspicuous manner on the face of the marketing material or advertisement or be read aloud clearly at the same volume and pace as the rest of the advertisement:]a required warning statement that depends on that advertisement's form:

(i) If the advertisement contains only visual elements, or a combination of audio and visual elements, then the following statements shall be included in a conspicuous manner on the face of the advertisement or be read aloud clearly at the same volume and pace and in the same language as the rest of the advertisement: "For use only by certified registered patients.

[(i) "] Keep out of reach of children and pets.["

(ii) "] In case of accidental ingestion or overconsumption, contact your Poison Center at 1-800-222-1222 or call 9-1-1.["

(iii) "] Please consume responsibly.";

(ii) If the advertisement contains only auditory elements, then the following statements shall be clearly read aloud at the same volume and pace and in the same language as the rest of the advertisement: "For use only by certified patients. Keep out of reach of children and pets. In case of accidental ingestion or overconsumption, contact [the National Poison Control Center hotline 1-800-222-1222 or call 9-1-1.";

(iii) "Please consume responsibly] your Healthcare Provider or Poison Center."; and

(iii[v]) any other statements or warnings as directed by the [B]board.

(5) [s]Statements or warnings in print or digital advertisements pursuant to this section shall be displayed as follows:

(i) in the same language as the advertisement[English language];

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

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

(iv) bolded;

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

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

(6) A registered organization shall only advertise medical cannabis products, cannabis paraphernalia, or goods or services related to medical cannabis or cannabis products by means of television, radio, print, internet, mobile applications, social media, other electronic communication, or other print publication if the registered organization has reliable evidence that at least 90%, unless otherwise determined by the [O]office, of the audience for the advertisement is reasonably expected to be [twenty-one (]21[)] years of age or older. The burden of proof of the audience composition lies with the registered organization.

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

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

(i) any advertisements consist only, at a maximum, of the registered organization's logo and the following text:

(a) the registered organization's name, entity name, or doing business as name or ;

(b) the registered organization's website URL, email address, and phone number;

(c) if the registered organization is authorized to conduct retail sales, the registered organization retail dispensary's location; and

(d) the nature of the business; and

(e) the location(s) of the registered organization's dispensing site(s); and

(ii) that the advertising and marketing at eligible events shall comply with this Part.

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

(10) A registered organization shall accurately and legibly include its name and registration number [on all advertising and marketing for its products]in all advertisements, unless the form of the advertisement has been exempted from this requirement by the office.

Subdivision (b) of Section 113.17 is amended to read as follows:

(b) No marketing,[or] advertising, or advertisement of medical cannabis products shall:

* * *

Paragraph (5) of subdivision (b) of section 113.17 is amended to read as follows:

(5) use or display colloquial references to marijuana and cannabis or depictions [or digital images or icons, whether animated or static,]of cannabis, cannabis products, medical cannabis products, paraphernalia, or the imagery or action of smoking or vaping, including but not limited to the words "stoner", "chronic", "weed", "pot", or "sticky buds" unless such reference is used in the registered organization's name, entity name, doing business as name, or logo;

Paragraphs (22) through (24) of subdivision (b) of section 113.17 are repealed and paragraphs (25) through (30) renumbered to (22) through (27) and newly renumbered paragraph (27) of subdivision (b) of section 113.17 is amended to read as follows:

(27[30]) cooperate, directly or indirectly, in any advertising if such advertising has the purpose or effect of steering or influencing patient or caregiver choice with regard to the selection of a practitioner. Nothing contained within this section prevents a registered

organization from educating practitioners about medical cannabis products offered by the registered organization; [or]

Paragraph (31) of subdivision (b) of section 113.17 is renumbered to (29) and a new paragraph (28) is added to read as follows:

(28) use a commercial mascot; or

Subdivision (d) of section 113.17 is amended to read as follows:

(d) Outdoor [Marketing and Advertising]Signs.

(1) [Outdoor dispensing site signage for the purpose of alerting individuals to the location of a medical cannabis dispensing site is permitted]A registered organization may advertise outdoors using signs provided such signs:

(i) are for the purpose of alerting individuals to the location of a dispensing site;

(ii) are limited to the following information:

(*a*) business or trade name,

(*b*) business location, and

(*c*) the nature of the business;

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

[(iii) are not illuminated by neon lights;]

(iv) are not on vehicles[owned, leased, or utilized by registered organizations] except where a registered organization name and address are required on a vehicle to comply with any other state or local laws or regulations; and

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

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

(2) [Outdoor m]Marketing or advertising is prohibited on signs and placards, regardless of their size or purpose, in arenas, stadiums, other sport venues, shopping malls unless alerting individuals to the location of a dispensing site located within that mall, fairs that receive state allocations, and video game arcades, regardless of whether any of the foregoing are open air or enclosed, but this does not include any such sign or placard located at an adult only facility or as further set out by the [O]office in guidance.

[(3) Use of a commercial mascot is prohibited.]

(3[4]) A registered organization shall remove an[the] outdoor sign[age] if the [O]office determines the outdoor sign[age] violates the provisions of Cannabis Law and this Part or if the registered organization fails to provide records to the [O]office upon request that establishes the outdoor sign[age] meets the requirements of Cannabis Law and this Part.

(4[5]) Outdoor dispensing site signs[age] must comply with any additional requirements as set out by the [O]office.

Paragraph (2) of subdivision (e) of section 113.17 is amended to read as follows:

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

Subdivisions (a), (b) and (c) of section 113.18 are amended to read as follows:

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

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

* * *

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

Subdivision (i) and (j) of section 113.20 are renumbered to (h) and (i) and subdivision (g) of section 113.20 is amended to read as follows:

(g) If a certified patient or designated caregiver becomes aware of the loss, theft or destruction of the registry identification[card] of such certified patient or designated caregiver, the certified patient or designated caregiver shall notify the [O]office, on a form and in a manner prescribed by the [O]office, not later than [ten (]10[)] days of becoming aware of the loss, theft or destruction. The [O]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 [A]article 3 of the Cannabis Law and section 113.4 of this Part.

Subdivisions (a), (b), (d), (e), (f) and (g) of section 113.22 are amended to read as follows:

(a) No person, except for a certified patient, designated caregiver, designated caregiver facilities, an approved laboratorian, pharmacist, or an approved research license holder shall open or break the seal placed on a medical cannabis product packaged by a registered organization and provided to the certified patient.

(b) No person associated with a registered organization shall enter into any agreement with a registered practitioner or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the dispensing site at which the certified patient or designated caregiver will purchase medical cannabis products. Nothing in this subdivision shall prohibit a practitioner employed by a registered organization from providing services at a registered organization.

* * *

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

(e) No certified patient or designated caregiver shall be in possession of medical cannabis products above the possession limits as defined in Penal Law or at any time medical cannabis products are possessed by a patient or designated caregiver under 21 years of age without having in their possession:

* * *

(f) No certified patient or designated caregiver shall transport medical cannabis product unless such products remain in the original package as dispensed by the registered organization and the patient or designated caregiver is in possession of patient's valid certification in accordance with 113.22(e).

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

Paragraphs (2) and (3) of subdivision (a) of section 113.23 and subdivision (b) of section 113.23 are repealed, paragraph (4) of subdivision (a) of section 113.23 is renumbered to (2), and subdivisions (c) and (d) of section 113.23 are renumbered to (b) and (c).

Subparagraph (2) of subdivision (d) of section 113.24 is amended to read as follows:

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

The second subdivision (d) of section 113.25 is renumbered to (e).

Subdivision (a) of section 113.26 is amended to read as follows:

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

Paragraphs (1) and (2) of subdivision (b) of section 113.26 is amended to read as follows:

1) All horticultural lighting used in [a manufacturing facility]cultivation shall be compliant with standards that are [listed on the current design lights consortium solid-state horticultural lighting qualified products list ("Horticultural QPL") or other similar list as] determined by the [O]office and lighting Photosynthetic Photon Efficacy (PPE) must be at least 2.2 μmol/J (micromoles per joule). The office is authorized to establish such standards in guidance.

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

Paragraph (4) of subdivision (c) of section 113.26 is renumbered as (5) and paragraph (3) is amended to create a new paragraph (4) of subdivision (c) of section 113.26 to read as follows:

(3) chilled water system with on-site heat recovery designed to fulfill at least 75 percent of the annual energy for dehumidification reheat; or

([iv]4) solid or liquid desiccant dehumidification system for system designs that require dewpoint of 50°F or less; or

New paragraphs (5) and (6) of subdivision (c) of section 113.27 are added to read as follows:

(5) additional information in compliance with Part 133 of this Title; and

(6) any other information as determined by the office.

The Title and table in Section 113.28 are amended to read as follows:

§ 113.28 Reverenced Materials.

* * *

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

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

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