SUMMARY OF EXPRESS TERMS

As required by section 3369-a of the Public Health Law ("PHL"), Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register. A new subpart 80-1 is added to read as follows:

§**80-1.1 Practitioner registration.** Establishes a process for practitioners who have completed an educational course approved by the Commissioner on the use of medical marihuana under Title V-A of the Public Health Law to register with the department to issue patient certification.

§**80-1.2 Practitioner issuance of certification.** Establishes a process for registered practitioners to issue a certification to patients with certain severe debilitating or life-threatening conditions, with certain clinically associated conditions or complications, that are likely to receive therapeutic or palliative benefit from the treatment of medical marihuana to be able to receive approved medical marihuana products from a registered organization.

§**80-1.3 Application for registration as a certified patient.** Provides the criteria by which a person may obtain a registration as a certified patient and receive a registry identification card.

§**80-1.4 Designated caregiver registration.** Caregivers designated to handle approved medical marihuana products on behalf of certified patients are required to register with the department according to the procedures detailed in this section and to obtain a registry identification card.

§**80-1.5 Application for initial registration as a registered organization.** Establishes the application process for registered organizations interested in manufacturing and dispensing approved medical marihuana products. Provides that no person or entity shall manufacture or dispense medical marihuana without such registration.

§**80-1.6 Consideration of registered organization applications.** Requires potential registered organizations to submit an application fee of $10,000, accompanied by a check for an additional $200,000, the latter of which will be refunded to applicants not selected as registered organizations. Provides that the department shall initially register up to five applicants as registered organizations according to enumerated factors. Requires that the applicant allow for reasonable access to its facilities for inspection by the department. Provides that registrations shall be valid for two years, except that initial registrations may be extended up to eleven months by the commissioner.

§80-1.7 Application for renewal of registered organization registrations. Establishes the process by which registered organizations renew their registration. Requires an application fee of $10,000, accompanied by a check for an additional $200,000, the latter of which will be refunded to applicants not granted renewal registration. Provides an opportunity to submit additional information or to demand a hearing for applicants not granted renewal registration.

§80-1.8 Registrations non-transferable. Prohibits the transfer or assignment of registrations issued under this subpart.

§**80-1.9 Failure to operate.** Provides that a registration shall be surrendered to the department if a registered organization fails to begin operations to the satisfaction of the department within six months of the issuance of a registration.

§**80-1.10 Registered organizations; general requirements.** Lists requirements for registered organizations, including making its books and facilities available for monitoring by the department; submitting medical marihuana product samples to the department for quality assurance testing; implementing policies and procedures to investigate complaints and adverse events; as well as closure procedures.

§80-1.11 Manufacturing requirements for approved medical marihuana product(s). Contains requirements for the manufacturing of medical marihuana products. Provides the brands, forms and routes of administration of medical marijuana products authorized for manufacturing, as well as product labeling requirements. Provides that no synthetic marihuana additives shall be used in the production of any medical marihuana product.

§**80-1.12 Requirements for dispensing facilities.** Details the requirements for the operation of dispensing facilities as well as the required patient specific label required to be affixed to each medical marihuana product dispensed. Provides that no medical marihuana product shall be consumed or vaporized on the premises of such facilities.

§80-1.13 Security requirements for manufacturing and dispensing facilities. Details the minimum security requirements for manufacturing and dispensing facilities and for the transportation of medical marihuana products.

§80-1.14 Laboratory testing requirements for medical marihuana. Details the minimum laboratory testing requirements for medical marihuana products. Testing shall be performed by a DOH approved laboratory located within NYS.

§80-1.15 Pricing. Requires registered organizations submit proposed prices for medical marihuana products to the department for approval. The department may approve the proposed price, refuse approval of a proposed price, or modify or reduce the proposed price.

§**80-1.16 Medical marihuana marketing and advertising by registered organizations.** Restricts the marketing and advertising of medical marihuana.

§**80-1.17 Reporting dispensed medical marihuana products.** Details reporting requirements for dispensed medical marihuana products.

§**80-1.18 Prohibition of the use of medical marihuana in certain places.** Restricts the vaporization of medical marihuana in certain places.

§**80-1.19 Reporting requirements for practitioners, patients and designated caregivers.** Details reporting requirements for practitioners related to changes in circumstances affecting the

patient's certification. Defines reporting requirements for patients and designated caregivers for scenarios where certain information contained on the patient certification changes or if the certified patient or designated caregiver loses his or her registry identification card.

§**80-1.20 Proper disposal of medical marihuana products by patients or designated caregivers.** Details the required disposal procedures for medical marihuana products.

§**80-1.21 General prohibitions.** Contains general prohibitions.

§**80-1.22 Practitioner prohibitions.** Lists prohibitions on practitioners.

§80-1.23 Designated caregiver prohibitions. Lists prohibitions on designated caregivers.

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Subpart 55-2 is amended as follows:

§55-2.2 Certificates of approval. Paragraph 5 is renumbered paragraph 6 and a new paragraph 5 is added to provide for certification of laboratories to test medical marihuana.

§55-2.15 Requirements for laboratories performing testing for medical marihuana. Adds requirements for laboratories.

Pursuant to the authority vested in the Commissioner of Health by section 3369-a of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register.

A new subpart 80-1 is added to read as follows:

Subpart 80-1

MEDICAL USE OF MARIHUANA

§80-1.12 Requirements for dispensing facilities.

§80-1.13 Security requirements for manufacturing and dispensing facilities.

§80-1.14 Laboratory testing requirements for medical marihuana.

§80-1.15 Pricing.

§80-1.16 Medical marihuana marketing and advertising by registered organizations

§80-1.17 Reporting dispensed medical marihuana products.

§80-1.18 Prohibition of the use of medical marihuana in certain places.

§80-1.19 Reporting requirements for practitioners, patients and designated caregivers.

§80-1.20 Proper disposal of medical marihuana products by patients or designated caregivers.

§80-1.21 General prohibitions.

§80-1.22 Practitioner prohibitions.

§80-1.23 Designated caregiver prohibitions.

§80-1.1 Practitioner registration.

(a) No practitioner shall be authorized to issue a patient certification as set forth in §80-1.2 unless the practitioner:

(1) is qualified to treat patients with one or more of the serious conditions set forth in subdivision seven of section thirty-three hundred sixty of the public health law or as added by the commissioner;

(2) is licensed, in good standing as a physician and practicing medicine, as defined in article one hundred thirty one of the Education Law, in New York State;

(3) has completed a four hour course approved by the commissioner as set forth in subdivision (b) of this section;

(4) has applied to the department for a registration or a renewal of registration to issue patient certifications in a manner and format determined by the commissioner; and

(5) has been granted such registration by the department.

(b) The commissioner shall approve at least one, if not more, courses for practitioners seeking to become registered, which shall be four hours in duration. The educational content of such course shall include: the pharmacology of marihuana; 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 commissioner.

§80-1.2 Practitioner issuance of certification.

(a) Requirements for Patient Certification. A practitioner who is registered pursuant to 80-1.1 of this subpart may issue a certification for the use of an approved medical marihuana product by a qualifying patient. 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;

(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;

(5) a statement that the practitioner is registered with the department to issue the certification;

(6) a statement that the practitioner is caring for the patient in relation to the patient's serious condition;

(7) the patient's name, date of birth, address, telephone number and email address if available;

(8) the patient's diagnosis, limited solely to the specific severe debilitating or life-threatening condition(s), as defined in subdivision seven of section thirty-three hundred sixty of the public health law and listed below as the following;

(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; or

(xi) any other condition added by the commissioner.

(9) The condition or symptom that is clinically associated with, or is a complication of the severe debilitating or life-threatening condition listed in paragraph (8) of this subdivision. Clinically associated conditions, symptoms or complications, as defined in subdivision seven of section thirty-three hundred sixty of the public health law are limited solely to:

(i) Cachexia or wasting syndrome;

(ii) severe or chronic pain resulting in substantial limitation of function;

(iii) severe nausea;

(iv) seizures;

(v) severe or persistent muscle spasms or

(vi) such other conditions, symptoms or complications as added by the commissioner.

(10) a statement that by training or experience, the practitioner is qualified to treat the serious condition, which encompasses the severe debilitating or life-threatening condition listed pursuant

to paragraph (8) and the clinically associated condition, symptom or complication listed pursuant to paragraph (9) of this subdivision;

(11) 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 marihuana for the serious condition;

(12) any recommendations or limitations the practitioner makes to the certified patient and/or the patient's designated caregiver concerning:

(i) the authorized brand, authorized form, administration method, dosage and any limitations in the use of the approved medical marihuana product; and

(ii) the total amount of usable approved medical marihuana product that may be dispensed to the patient, in measurable controlled doses, which shall not exceed a thirty (30) day supply, if used as directed;

(13) a statement that the practitioner has explained the potential risks and benefits of the use of medical marihuana to the qualifying patient and has documented in the patient's medical record that such explanation has been provided to the patient.

(14) to the extent that a practitioner is seeking to authorize the use of an approved medical marihuana product by a patient who is under the age of eighteen or a person who is otherwise

incapable of consenting to medical treatment, the practitioner shall explain the potential risks and benefits of medical marihuana to the patient's parent or legal guardian, and if appropriate, to the minor patient. The practitioner shall document in the patient's medical record that such explanation has been provided as required herein; and

(15) a statement that the patient, or the patient's parent or legal guardian if applicable, has provided informed consent, if required by law;

(b) 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 revokes the certification.

(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.

(c) Submission of Certification to the Department. Practitioners shall utilize a form, which may be in an electronic format, developed by the department for the certification required in

subdivision (a) of this section. The practitioner shall submit to the department, the information required by subdivision (a) of this section, in a manner determined by the department, including by electronic transmission through a secure website. In the instance that a practitioner submits this information to the department electronically, the practitioner shall retain, for a period of 5 years, a printed copy of the electronic certification that shall contain the information required in subdivision (a).

(d) Medical Record Retention. The practitioner shall date and place his or her handwritten signature upon the printed certification, and provide the printed certification to the patient. The practitioner shall also maintain a copy of the signed certification in the patient's medical record.

§80-1.3 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 a registered practitioner.

(b) New York State residents. An applicant shall demonstrate his or her New York State residency by submitting to the department a copy of information concerning his or her 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 of a government-issued identification card that contains the applicant's name and New York State address. If the applicant is under the age of eighteen, the parent or legal guardian applying on behalf of the applicant shall submit a copy of the parent or legal guardian's state or government issued identification and a copy of the applicant's birth certificate;

(2) a copy 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 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 department containing sufficient information to show proof of temporary 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 receiving care and treatment in this state, may qualify for registration as a certified patient if the applicant otherwise meets the requirements of article thirty-three of the public health law and this subpart, and is temporarily residing in New York State for the purpose of receiving care and treatment from a practitioner registered with the department.

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

(i) a copy of a state or government issued identification card that contains the applicant's name and permanent address. If the applicant is under the age of eighteen, the parent or legal guardian applying on behalf of the applicant shall submit a copy of the parent or legal guardian's state or government issued identification and a copy of the applicant's birth certificate;

(ii) proof of temporary residence in New York State, including, but not limited to a copy of a lease, utility bill, hospital bill, or such other documentation as approved by the department 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 of such documentation to show sufficient proof of the applicant's temporary residency in New York State; and

(iii) a statement included in the applicant's patient certification indicating that the applicant is temporarily receiving care and treatment in New York.

(2) Nothing in this subpart shall be construed to grant to the applicant authorization to transport approved medical marihuana products outside of New York State.

(d) Application for a registry identification card. To obtain, amend or renew a registry identification card, a certified patient shall file a registry application with the department, on a form or in a manner determined by the department, which shall include:

(1) the documentation required in subdivisions (b) and (c) of this section, as applicable;

(2) the information required in section thirty-three hundred sixty-three of the public health law;

(3) 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 department, including as a digital file (.jpeg) when appropriate, provided, however, the department may waive the requirements of this paragraph upon good cause shown. For amendments and renewal applications, the department 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;

(4) a nonrefundable application fee of fifty dollars; provided, however, that the department may waive or reduce the fee in cases of financial hardship as determined by the department; and

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

(e) 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 twenty-one years of age. In preparing the application, the applicant may designate up to two proposed designated caregivers who shall be either: (i) a parent or legal guardian of the certified patient; (ii) a person designated by a parent or legal guardian, or (iii) an appropriate person approved by the department upon a sufficient showing that no parent or legal guardian is appropriate or available.

(1) As a condition of registration of a certified patient who is a minor or is incapable of medical decision-making, the applicant shall consent, in a manner determined by the department, to the certified patient's use of an approved medical marihuana product, and shall acknowledge that the parent, legal guardian or other appropriate person, as applicable, will control the acquisition and possession of the medical marihuana and any device used for its administration.

(2) Once the certified patient who is a minor 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 section thirty-three hundred sixty-three of the public health law and section 80-1.4 of this subpart.

(f) Prior to issuing or renewing a registry identification card, the department may verify the information submitted by the applicant. The applicant shall provide, at the department's request, such information and documentation, including any consents or authorizations to contact treating practitioners that may be necessary for the department to verify the information.

(g) The department shall approve, deny, or determine incomplete or inaccurate an application to issue or renew a registry identification card within thirty (30) days of receipt of the application. If the application is approved within the 30 day period, the department shall issue a registry identification card as soon as is reasonably practicable.

(h) The department shall notify the applicant in writing, by email, by telephone, or in another manner as determined appropriate by the department, if an application is incomplete or factually inaccurate, and shall explain what documents or information is necessary for the department to consider the application complete and accurate.

(i) 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 department.

(j) Applicants whose applications are denied may submit a new application for an initial or renewal of a registry identification card, together with the applicable fee as set forth herein.

(k) A certified patient may designate up to two designated caregivers either on the application for issuance or renewal of a registry identification card or in another manner determined by the department. The application 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);

(4) any other individual identifying information concerning the proposed designated caregiver(s) required by the department.

§80-1. 4 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 person selected by a certified patient as a designated caregiver shall apply to the department for a registry identification card or renewal of such card on a form or in a manner

determined by the department. The proposed designated caregiver shall submit an application to the department which shall contain the following information and documentation:

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

(2) if the applicant has a registry identification card, the registry identification number;

(3) a nonrefundable application fee of fifty ($50) dollars, provided, however that the department may waive or reduce the fee in cases of financial hardship as determined by the department;

(4) a statement that the applicant is not the certified patient's practitioner;

(5) a statement that the applicant agrees to secure and ensure proper handling of all approved medical marihuana products;

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

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

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

(ii) a New York State identification card;

(8) If the documentation submitted by the applicant in accordance with paragraph (7) 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 department, including as a digital file (.jpeg).

(9) 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 five current certified patients, and that he/she has not submitted an application which is pending and, if approved, would cause the applicant to be a designated caregiver for a total of five current certified patients;

(c) Prior to issuing or renewing a registry identification card, the department may verify the information submitted by the applicant. The applicant shall provide, at the department's request, such information and documentation, including any consents or authorizations that may be necessary for the department to verify the information.

(d) The department shall approve, deny or determine incomplete or inaccurate an initial or renewal application within thirty (30) days of receipt of the application. If the application is approved within the 30 day period, the department shall issue a registry identification card as soon as is reasonably practicable.

(e) The department shall notify the applicant in writing, by email, by telephone, or in another manner as determined appropriate by the department if an application is incomplete or factually inaccurate, and shall explain what documents or information is necessary for the department 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 department.

(g) Applicants whose applications are denied pursuant to subdivision (f) of this section may submit a new initial or renewal application for a registry identification card, together with the applicable fee as set forth herein.

(h) The department shall deny a registry identification card for an applicant who:

(1) is already a designated caregiver for five 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 five currently certified patients; or

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

§80-1.5 Application for initial registration as a registered organization.

(a) No person or entity shall produce, grow or sell medical marihuana or hold itself out as a New York State registered organization unless it has complied with article 33 of the public health law and this subpart and is registered by the department.

(b) In order to operate as a registered organization, an entity shall file an application on forms or in a manner prescribed by the commissioner. 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 80-1.11 of this subpart, and dispensing of the medical marihuana products;

(3) identification of all equipment that will be used to carry out the manufacturing, processing, transportation, distributing, sale and dispensing activities described in the application and operating plan;

(4) an operating plan that includes a detailed description of the applicant's manufacturing processes, transporting, distributing, sale and dispensing policies or procedures. The operating plan shall also include:

(i) a detailed description of any devices used with approved medical marihuana products to be offered or sold by the registered organization;

(ii) policies and procedures related to security and control measures that will be in place to prevent diversion, abuse, and other illegal or unauthorized conduct relating to medical marihuana and are consistent with provisions set forth in this subpart;

(iii) a standard operating procedure manual for all methods used from cultivation of the medical marihuana through packaging, sealing and labeling of each lot of medical marihuana product. The procedures shall include use of good agricultural practices (GAPs) and must conform to all applicable laws and rules of New York State. Standard operating procedures shall be able to be validated to demonstrate that the applicant will be able to produce and dispense consistent and reproducible medical marihuana product such that, for each form of each brand produced, there

is homogeneity, absence of contamination and reproducibility of the brand profile in each lot as defined in section 80-1.11 of this subpart.

(iv) quality assurance plans, including but not limited to plans to detect, identify and prevent dispensing errors;

(v) policies and procedures to document and investigate approved medical marihuana product returns, complaints and adverse events, and to provide for rapid voluntary or involuntary recalls of any lot of medical marihuana product. Such policies and procedures shall include a plan for any retesting of returned approved medical marihuana products, storage and disposal of marihuana and any manufactured medical marihuana products not passing requirements, and a requirement that adverse events and total recalls are reported to the department within twenty-four hours of their occurrence;

(vi) a quality assurance program to track contamination incidences and document the investigated source of such incidences, and the appropriate corrective action(s) taken.

(vii) detailed description of plans, procedures and systems adopted and maintained for tracking, record keeping, record retention and surveillance systems, relating to all medical marihuana at every stage including cultivating, possessing of marihuana, and manufacturing, delivery, transporting, distributing, sale and dispensing by the proposed registered organization.

(viii) proposed hours of operation for the manufacturing and dispensing facilities;

(5) copies of the organizational and operational documents of the applicant, including but not limited to, as applicable: the certificate of incorporation, bylaws, articles of organization, partnership agreement, operating agreement and other applicable documents and agreements, and all amendments thereto;

(6) 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 or ownership during the preceding ten years of a ten percent or greater interest in any other business, located in or outside New York State, manufacturing or distributing drugs; 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. In addition, any managers who may come in contact with or handle medical marihuana, including medical marihuana 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;

(7) documentation that the applicant has entered into a labor peace agreement, as required by subdivision one of section thirty-three hundred sixty five of the public health 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;

(8) 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;

(9) 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; and, provided further that whenever any applicant proposes to lease 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 marihuana, 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 and/or dispense on the premises medical marihuana in accordance with article 33 of the Public Health Law and agrees to provide the New York State Department of Health, Mayor Erastus Corning 2nd Tower, The Governor Nelson A. Rockefeller

Empire State Plaza, Albany, N.Y. 12237, with notification by certified mail of its intent to reenter the premises or to initiate dispossess proceedings or that the lease is due to expire, at least 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."

(10) 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 and/or arranging for the assistance in preparing the application;

(11) architectural program and sketches of the applicant’s proposed manufacturing and dispensing facility(ies) including the following:

(i) site plans;

(ii) schematic architectural and engineering design drawings and single line sketches in an appropriate scale showing the relationship of various buildings to each other, room configurations, major exit corridors, exit stair locations, and circulation along with existing buildings if additions or alterations are part of the project;

(iii) outline specifications for the type of construction proposed including a description of energy sources, type and location of engineering systems proposed for heating, cooling, ventilation and electrical distribution, water supply and sewage;

(iv) a security plan indicating how the applicant will comply with the requirements of article 33 of the Public Health Law, this subpart and any other applicable law, rule, or regulation; and

(v) the registered organization shall submit detailed floor plans indicating the activities performed in each area and security plans (physical and cyber) consistent with the requirements of section 80-1.13 of this subpart.

(12) a construction timetable;

(13) a statement as to whether 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;

(14) if 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, or corporate general partner or a combination of such persons collectively, 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;

(15) 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;

(16) the most recent financial statement of the applicant prepared in accordance with generally accepted accounting principles (GAAP) applied on a consistent basis and certified by an independent certified public accountant, 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;

(17) 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;

(18) a staffing plan for staff involved in activities related to the cultivation of marihuana, the manufacturing and/or dispensing of approved medical marihuana products and/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 twenty-one (21) years of age or older;

(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 proposed registered organization shall not employ anyone who would come in contact with or handle medical marihuana who has been convicted of any felony of sale or possession of drugs, narcotics, or controlled substances in accordance with the requirements of section thirty-three hundred sixty-four of the public health law.

(19) any other information as may be required by the commissioner.

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

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

§80-1.6 Consideration of registered organization applications.

(a) Applicants for approval to operate as registered organizations shall submit an application to the department, containing the information required in §80-1.5, in a manner and format determined by the department.

(1) Applications shall be accompanied by a non-refundable application fee in the amount of $10,000.

(2) The registration fee for the registration period shall be $200,000. Applicants shall submit the registration fee by certified check 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 subpart.

(3) Only applications completed in accordance with this subpart as determined by the department and for which the application and registration fees have been submitted shall be considered if submitted in a timely manner. The department shall return the certified check for $200,000 to all applicants who are not granted a registration.

(b) The department shall initially register up to five applicants as registered organizations. In deciding whether to grant an application, or amendment to a registration, the department shall consider whether:

(1) the applicant will be able to manufacture approved medical marihuana products, each with a consistent cannabinoid 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 approved medical marihuana products as necessary to meet the needs of certified patients;

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

(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;

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

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

(10) the applicant has entered into a labor peace agreement with a bona-fide labor organization, as defined in section thirty-three hundred sixty of the public health law, that is actively engaged in representing or attempting to represent the applicant's employees; and

(11) evaluation of the applicant's proposed operating plan and suitability of the proposed manufacturing and dispensing facilities, including but not limited to the suitability of the location and architectural and engineering design of the proposed facilities. Department approval of the applicant's operating plan and architectural and engineering design of the proposed facilities shall be required for issuance of a registration.

(c) The applicant shall allow reasonable access to the department and/or its authorized representatives for the purpose of conducting an on-site survey or inspection of the applicant's proposed manufacturing and/or dispensing facilities.

(d) If the commissioner is not satisfied that the applicant should be issued a registration, he or she 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 commissioner or demand a hearing, or both.

(e) An application 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 department 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 two hundred fifty dollars.

(f) Registrations issued shall be valid for two years from the date of issuance. To facilitate renewals of registrations, the commissioner may upon the initial application for a registration, issue some registrations which may remain valid for a period of time greater than two years, but not exceeding an additional eleven months. The registration fee will be prorated for the additional time exceeding two years.

§80-1.7 Applications for renewal of registration as registered organization

(a) An application to renew any registration issued under this subpart shall be filed with the department 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 department 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 in the amount of $10,000. Applications shall also be accompanied by a registration fee in the amount of $200,000

made by certified check. Only applications completed in accordance with this subpart as determined by the department 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 commissioner may require, including but not limited to:

(1) any material change as determined by the department in the information, circumstances or factors listed in section 80-1. 5 of this subpart;

(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 marihuana manufactured, distributed, or dispensed by the registered organization; and

(ii) compliance by the applicant with local or state laws, or regulations of the department, 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 manufacturing and distributing activity for which it is registered, including but not limited to approved medical marihuana product shortages or wait lists occurring during the registration period; and

(4) a summary of quality assurance testing for all medical marihuana 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 department shall consider applications for renewal in accordance with the criteria set forth in section thirty-three hundred sixty-five of the public health law.

(e) If the department determines that the applicant's registration should not be renewed, the department shall serve upon the applicant or his or her attorney of record, in person or by registered or certified mail, an order directing the applicant to show cause why his or her application for renewal should not be denied. The order shall specify in detail the respects in which the applicant has not satisfied the department 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 department or demand a hearing, or both. If a hearing is demanded, the commissioner shall fix a date as soon as reasonably practicable.

(2) If the applicant fails to submit additional material to the department 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.

§ **80-1.8 Registrations non-transferable.**

(a) Registrations issued under this subpart 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.

§ **80-1.9 Failure to operate.**

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

§80-1.10 Registered organizations; general requirements

(a) In addition to the requirements in public health law and as otherwise set forth in this subpart, a registered organization shall:

(1) make its books, records and manufacturing and dispensing facilities available to the department or its authorized representatives for monitoring, on-site inspection, and audit purposes, including but not limited to periodic inspections and/or evaluations of facilities, methods, procedures, materials, staff and equipment to assess compliance with requirements set forth in article 33 of the public health law and this subpart;

(2) only manufacture and dispense approved medical marihuana products in New York State in accordance with article 33 of the public health law and this subpart;

(3) only manufacture and dispense approved medical marihuana products in an indoor, enclosed, secure facility located in New York State which may include greenhouses;

(4) submit approved medical marihuana product samples to the department upon request, including for quality assurance testing or investigation of an adverse event. A subset of each lot of medical marihuana product shall be retained by the registered organization to allow for testing in the future if requested by the department and shall be stored unopened as indicated on the label and in the original packaging. This subset of medical marihuana product must be readily identifiable as belonging to its specific lot. The quantity retained shall be a statistically representative number of samples to allow for complete testing of the product at least three times and shall be retained by the registered organization for at least two years following the date of expiration.

(5) implement immediately policies and procedures to document and investigate complaints and adverse events and report these events to the department within 24 hours of their occurrence. Such policies and procedures shall be set forth in the registered organization's operating plan.

(6) quarantine any lot of medical marihuana product as directed by the department, and not transport, distribute or dispense such lot unless prior approval is obtained from the department;

(7) dispose of unusable medical marihuana products that have failed laboratory testing or any marihuana used in the manufacturing process as per the registered organization's approved operating plan.

(8) maintain records required by article 33 of the public health law and this subpart for a period of five (5) years and make such records available to the department upon request. Such records shall include:

(i) documentation, including lot numbers where applicable, of all materials used in the manufacturing of the approved medical marihuana 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.

(b) Registered organizations shall not:

(1) dispense approved medical marihuana products from the same location where the marihuana is grown or manufactured;

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

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

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

(5) change the composition of the entity which is the registered organization, including but not limited to, a change in sole proprietor, partner, director, stockholder, member or membership interest of the registered organization without the prior written approval of the department; or

(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 department.

(7) locate a dispensing facility on the same street or avenue and within one thousand feet of a building occupied exclusively as a school, church, synagogue or other place 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, church, synagogue or other place of worship.

(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 department 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 department approval in accordance with department 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 medical marihuana and medical marihuana products;

(iii) maintain and make available to the department all records required to be maintained under this subpart for a period of five years; and

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

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

(4) A registered organization's failure to notify the department 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 department to revoke the registration of the registered organization under such terms as the department

determines is appropriate based on public health and safety considerations. In addition, the department 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.

§80-1.11 Manufacturing requirements for approved medical marihuana products

(a) Definitions. Wherever used in this subpart, the following terms shall have the following meanings:

(1) "Approved medical marihuana product" is the final manufactured product delivered to the patient that represents a specific brand with a defined cannabinoid content and active and inactive ingredients, prepared in a specific dosage and form, to be administered as recommended by the practitioner.

(2) "Brand" means a defined medical marihuana extraction product that has a homogenous and uniform cannabinoid concentration and product quality, produced according to an approved and stable processing protocol. The specified brand shall have a total THC and total CBD concentration that is within 95 – 105% of that specified in milligrams per dose for that brand and shall have the same composition and concentration of inactive ingredients as that defined for the brand.

(3) “Form” of medical marihuana shall be a type of a medical marihuana product approved by the commissioner and shall refer to the final preparation of an approved medical marihuana brand; for example, an extract in oil for sublingual administration, an extract for vaporization or an extract in a capsule for ingestion.

(4) “Lot” means a quantity of a medical marihuana extraction product that has a homogenous and uniform cannabinoid concentration and product quality, produced according to an approved and stable processing protocol specific to that brand and form of medical marihuana product, during the same cycle of manufacture.

(5) “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 marihuana product can be determined.

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

(b) A registered organization shall use either carbon dioxide (CO_2, super-critical) or alcohol for cannabinoid extraction and shall only perform extraction of the leaves and flowers of female marihuana plants. 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). 21 USC §321 is available for copying and inspection at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. A registered organization shall obtain prior written approval from the department if it seeks to use other extraction methods.

(c) A registered organization shall only produce such forms of medical marihuana as approved by the department according to the following requirements:

(1) Each registered organization may initially produce up to five brands of medical marihuana product with prior approval of the department. These brands may be produced in multiple forms as approved by the commissioner. Thereafter, additional brands may be approved by the department. However, in no case shall marihuana in unprocessed whole flower form be made available to certified patients.

(2) Each medical marihuana 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 cannabinoid profile. The concentration of the following cannabinoids, at a minimum, must be reported:

(i) Tetrahydrocannabinol (THC)

(ii) Tetrahydrocannabinol acid (THCA)

(iii) Tetrahydrocannabivarin (THCV)

(iv) Cannabidiol (CBD)

(v) Cannabinadiolic acid (CBDA)

(vi) Cannabidivarine (CBDV)

(vii) Cannabinol (CBN)

(viii) Cannabigerol (CBG)

(ix) Cannabichromene (CBC)

(x) Any other cannabinoid component at > 0.1%

(3) The final medical marihuana product shall not contain less than ninety-five percent (95%) or more than one hundred-five percent (105%) of the concentration of total THC or total CBD indicated on the label for this brand. Each brand shall have a maximum of 10mg total THC per dose.

(4) 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).

(5) The registered organization shall offer and make available at least one brand that has approximately equal amounts of THC and CBD.

(6) For each brand offered, the registered organization shall only utilize a distinct name which has been approved by the department, consisting of only letters and/or numbers. The name shall not be coined or fanciful, and may not include any "street", slang or other name. No reference shall be made to any specific medical condition.

(7) Each registered organization shall ensure the availability of at least a one year supply of any offered brand unless otherwise allowed by the department.

(d) The registered organization shall not add any additional active ingredients or materials to any approved medical marihuana product that alters the color, appearance, smell, taste, effect or weight of the product unless it has first obtained prior written approval of the department. Excipients must be pharmaceutical grade and approved by the department.

(e) A registered organization shall:

(1) use good agricultural practices (GAPs) and must conform to all applicable laws and rules of New York State;

(2) use water from a public water supply or present a plan, approved by the department, 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;

(3) use only pesticides, fungicides, and herbicides that are approved by the New York State Department of Agriculture and Markets;

(4) process the leaves and flowers of the female plant only, in a safe and sanitary manner;

(5) perform visual inspection of the harvested plant material to ensure there is no mold, mildew, pests, rot or gray or black plant material; and

(6) have a separate secure area for temporary storage of any medical marihuana or medical marihuana product that needs to be destroyed.

(f) Production of any approved medical marihuana 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 marihuana and medical marihuana 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.

(g) Approved medical marihuana products shall be limited to the following forms and routes of administration:

(1) liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube;

(2) metered liquid or oil preparations for vaporization;

(3) capsules for oral administration; or

(4) any additional form and route of administration approved by the commissioner. Smoking is not an approved route of administration.

(5) approved medical marihuana products may not be incorporated into edible food products by the registered organization, unless approved by the commissioner.

(h) The registered organization shall package the final form of the approved medical marihuana 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 department, or by the certified patient or designated caregiver.

(i) The registered organization shall package the approved medical marihuana product such that it is child-resistant, tamper-proof/tamper-evident, light-resistant, and in a resealable package that minimizes oxygen exposure.

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

(k) Each approved medical marihuana product shall be affixed with a product label. Medical marihuana product labels shall be approved by the department 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 marihuana product form and brand designation;

(3) the single dose THC and CBD content for the product set forth in milligrams (mg);

(4) the medical marihuana product lot unique identifier (lot number or bar code);

(5) the quantity included in the package;

(6) the date packaged;

(7) the date of expiration of the product;

(8) the proper storage conditions;

(9) language stating:

(i) "Medical marihuana 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 THIS PRODUCT AWAY FROM CHILDREN (unless medical marihuana 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 marihuana product produced, the registered organization shall submit a predetermined number of final medical marihuana products (e.g., sealed vials or capsules; with the number of samples submitted, based on statistical analysis, determined to be representative of the lot) to an independent laboratory/laboratories approved by the department. The laboratory verifying the cannabinoid content shall be approved for the analysis of medical marihuana product by the department in accordance with section five hundred two of the public health law and subpart 55-2 of this title. Such laboratory, or approved laboratories cumulatively, shall certify the medical marihuana product lot as passing all contaminant testing and verify that the content is consistent with the brand prior to the medical marihuana product being released from the manufacturer to any dispensing facility.

(1) Any lot not meeting the minimum standards or specifications for safety shall be rejected and destroyed by the registered organization in accordance with the registered organization's approved operating plan.

(2) Any lot not meeting the minimum standards or specifications for brand consistency shall be rejected and destroyed by the registered organization in accordance with the registered organization's approved operating plan.

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

(m) The registered organization shall demonstrate the stability of each approved medical marihuana product produced (each brand in each form) by testing at an approved laboratory in accordance with section 80-1.14 of this title:

(1) the stability and expiration date of the final distributed medical marihuana product shall be validated and shall be stable for a minimum of 60 days under the specified storage conditions (light, temperature and humidity) when opened;

(2) shelf-life of unopened medical marihuana products (e.g., packages or vials) shall be validated by ongoing stability testing according to a schedule determined by the department and an expiration date for unopened products shall be determined through the stability testing;

(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 marihuana additives shall be used in the production of any medical marihuana product.

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

§80-1.12 Requirements for dispensing facilities

(a) Dispensing facilities shall not be open or in operation unless an individual with an active New York State pharmacist license, as defined in article one hundred and thirty seven of the Education Law, is on the premises and directly supervising the activity within the facility. At all other times, the dispensing facility shall be closed and properly secured.

(b) Dispensing facilities shall not sell items other than approved medical marihuana products and related products necessary for the approved forms of administration of medical marihuana, without prior written approval from the department.

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

(d) No food or beverages shall be consumed by certified patients or designated caregivers on the premises of a dispensing facility, unless necessary for medical reasons.

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

(f) When dispensing approved medical marihuana products, the dispensing facility shall:

(1) not dispense an amount greater than a thirty (30) 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 marihuana product by any registered organization;

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

(3) provide a patient specific log of medical marihuana 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;

(g) Access to the dispensing facility shall be restricted as follows:

(1) Except as provided in paragraph (2) of this subdivision, no person, except a registered organization employee, shall be allowed on the premises of a dispensing facility without a certified patient or designated caregiver registry identification card issued by the department.

(2) Upon prior written request, the department may waive the provisions of paragraph (1) of this subdivision. All persons not permitted on the premises of a dispensing facility pursuant to paragraph (1) of this subdivision, but who have been authorized, in writing, to enter the facility by the department shall obtain a visitor identification badge from a dispensing facility employee prior to entering the dispensing facility. A dispensing facility employee shall escort and monitor the visitor at all times while the visitor is in the dispensing facility. The visitor identification

badge shall be visible at all times. The dispensing facility shall require the visitor to return the identification badge to a dispensing facility employee upon exiting the dispensing facility.

(i) The dispensing facility shall maintain a visitor log, which shall include the name of the visitor, date, time and purpose of the visit. The visitor log shall be available to the department at all times during operating hours and upon request.

(ii) If an unforeseen circumstance requires the presence of a visitor and makes it impractical for the dispensing facility to obtain a waiver pursuant to this subpart, the dispensing facility shall record in the visitor log, the name of the visitor, date, time, purpose of the visit and the facts upon which the access was granted.

(h) the dispensing facility shall affix to the approved medical marihuana product package a patient specific dispensing label approved by the department, that is easily readable, and firmly affixed and includes:

(1) the name and registry identification number of the certified patient and designated caregiver, if any;

(2) the ordering practitioner's name;

(3) the dispensing facility name, address and phone number;

(4) the dosing and administration instructions;

(5) the quantity and date dispensed; and

(6) any recommendation or limitation by the practitioner as to the use of medical marihuana.

(i) the dispensing facility shall place the approved medical marihuana product in a plain outer package when dispensing to the patient or designated caregiver.

(j) The dispensing facility shall ensure that each patient receives approved medical marihuana product from no more than two distinct lots for any 30-day supply dispensed.

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

(1) the medical marihuana product and brand;

(2) a list of any excipients used;

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

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

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

(9) information on tolerance, dependence and withdrawal and substance abuse, how to recognize what may be problematic usage of medical marihuana and obtain appropriate services or treatment;

(10) advice on how to keep the medical marihuana product secure;

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

(12) language stating that unwanted, excess, or contaminated medical marihuana product must be disposed of according to section 80-1.20 of this subpart; 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.”

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

(m) If an approved medical marihuana product is returned to the dispensing facility, the dispensing facility shall dispose of such product as per the registered organization’s approved operating plan.

§ **80-1.13 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 marihuana and/or medical marihuana products, utilizing commercial grade equipment, which shall, at a minimum, include:

(1) a perimeter alarm;

(2) motion detectors;

(3) video cameras in all areas that may contain marihuana 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 approved safes, approved vaults, dispensing areas, marihuana sales areas and any other area where marihuana is being produced, harvested, manufactured, stored, handled or dispensed. At entry and exit points, the manufacturing facility or dispensing facility shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;

(4) twenty-four hour recordings from all video cameras, which the manufacturing facility or dispensing facility shall make available for immediate viewing by the department or the department's authorized representative upon request and shall be retained for at least 90 days. The registered organization shall provide the department 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;

(5) a duress alarm, which for purposes of this section means a silent security alarm system signal generated by the entry of a designated code into an arming station in order to signal that the alarm user is being forced to turn off the system;

(6) a panic alarm, which for purposes of this section, means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;

(7) a holdup alarm, which for purposes of this section, means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;

(8) an automatic voice dialer, which for purposes of this section, means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;

(9) a 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 manufacturing facility or dispensing facility within five minutes of the failure, either by telephone, email, or text message;

(10) the ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);

(11) 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

(12) the ability to remain operational during a power outage.

(b) A registered organization shall ensure that any manufacturing facility and dispensing facility maintains all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction or alterations.

(c) In addition to the requirements listed in subdivision (a) of this section, each manufacturing facility and dispensing facility shall have a back-up alarm system approved by the department that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment, which shall not be the same company supplying the primary security system.

(d) A registered organization shall limit access to any surveillance areas solely to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, the department or the department's authorized representative, and others when approved by the department. A registered organization shall make available to the department or the department's authorized representative, upon request, a current list of authorized employees and service employees who have access to any surveillance room. A manufacturing facility and dispensing facility shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.

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

(f) 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 shall erase all recordings prior to disposal or sale of the facility.

(g) A registered organization shall keep all security equipment in full operating order and shall test such equipment no less than monthly 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 department upon request.

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

(i) All marihuana that is not part of a finished product must be stored in a secure area or location within the registered organization accessible only to the minimum number of employees essential for efficient operation.

(j) All medical marihuana products, approved or ready for testing, must be stored in a department approved safe or vault in such a manner as to prevent diversion, theft or loss.

(k) All approved safes, vaults or any other approved equipment or areas used for the manufacturing or storage of marihuana and approved medical marihuana products must be securely locked or protected from entry, except for the actual time required to remove or replace marihuana or approved medical marihuana products.

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

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

(n) Prior to transporting any approved medical marihuana product, a registered organization shall complete a shipping manifest using a form determined by the department.

(1) A copy of the shipping manifest must be transmitted to the dispensing facility that will receive the products and to the department at least two business days prior to transport.

(2) The registered organization shall maintain all shipping manifests and
make them available to the department for inspection upon request, for a period of 5 years.

(o) A registered organization shall only transport approved medical marihuana products from a manufacturing facility to dispensing facilities.

(1) the approved medical marihuana products must be transported in a locked, safe and secure storage compartment that is part of the vehicle transporting the marihuana; and

(2) in a storage compartment that is not visible from outside the vehicle.

(p) An employee of a registered organization, when transporting approved medical marihuana products, shall travel directly from the registered organization's manufacturing facility to the dispensing facility and shall not make any unnecessary stops in between.

(q) A registered organization shall ensure that all approved medical marihuana product delivery times are randomized.

(r) A registered organization shall staff all transport vehicles with a minimum of two employees. At least one transport team member shall remain with the vehicle at all times that the vehicle contains approved medical marihuana products.

(s) A transport team member shall have access to a secure form of communication with employees at the registered organization's manufacturing facility at all times that the vehicle contains approved medical marihuana products.

(t) A transport team member shall possess a copy of the shipping manifest at all times when transporting or delivering approved medical marihuana products and shall produce it to the

commissioner, the commissioner's authorized representative or law enforcement official upon request.

§80-1.14 Laboratory testing requirements for medical marihuana.

(a) Medical marihuana products produced by a registered organization shall be examined in a laboratory located in New York State that is licensed by the federal Drug Enforcement Administration (DEA) and approved for the analysis of medical marihuana by the department in accordance with article 5 of the public health law and subpart 55-2 of this title.

(b) No board member, officer, manager, owner, partner, principal stakeholder or member of a registered organization shall have an interest or voting rights in the laboratory performing medical marihuana testing.

(c) The registered organization shall submit to the laboratory, and testing shall only be performed on, the final medical marihuana product equivalent to the sealed medical marihuana product dispensed to the patient (e.g., in a sealed vial or intact capsule).

(d) Testing of the final medical marihuana 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 marihuana product including but not limited to water or growing materials. Testing

may also be performed on the final marihuana extract prior to packaging e.g. for cannabinoid profile verification or contaminant testing.

(e) Sampling and testing of each lot of final medical marihuana product shall be conducted with a statistically significant number of samples and with acceptable methodologies such that there is assurance that all lots of each medical marihuana product are adequately assessed for contaminants and the cannabinoid profile is consistent throughout.

(f) Testing of the cannabinoid profile shall include, at a minimum, those analytes specified in section 80-1.11(h)(2) of this subpart.

(g) Testing for contaminants in the final medical marihuana product shall include but shall not be limited to those analytes listed below. The department shall make available a list of required analytes and their acceptable limits as determined by the commissioner.

Analyte:

E. coli

Klebsiella

Pseudomonas (for products to be vaporized)

Salmonella

Streptococcus

Bile tolerant gram negative bacteria

Aspergillus

Mucor species

Penicillium species

Thermophilic Actinomycetes species

Aflatoxin

Ochratoxin

Antimony

Arsenic

Cadmium

Chromium

Copper

Lead

Nickel

Zinc

Mercury

Any pesticide/herbicide/fungicide used during production of the medical marihuana product

Any growth regulator used during production of the medical marihuana product

Any other analyte as required by the commissioner

(h) The laboratory shall track and destroy any quantity of medical marihuana product that is not consumed in samples used for testing.

§80-1.15 Pricing.

(a) Definitions. For purposes of this section, the following terms have the following meanings:

(1) “Cost analysis” shall mean the review and evaluation of the separate cost elements and profit of a proposed price and the application of judgment to determine how well the proposed costs represent what the price per unit for approved medical marihuana products should be, assuming reasonable economy and efficiency.

(2) “Price” shall mean the cost to manufacture, market and distribute approved medical marihuana products plus a reasonable profit.

(b) Department Approval Required. A registered organization shall only charge a price for an approved medical marihuana product that has been approved by the department.

(c) Determination of Price. The department shall set the per unit price of each form of approved medical marihuana product sold by any registered organization, as follows:

(1) Registered organizations shall submit a proposed price per unit for each form of medical marihuana indicated in its registration. Registered organizations shall submit such information and documentation, in a manner and format determined by the department, sufficient for the department to perform a cost analysis of the proposed price. In particular, the registered organization shall, in a manner and format determined by the department, provide a detailed breakdown of, and submit information and documentation concerning, all costs it factored to

arrive at its proposed price, including but not limited to its fixed and variable costs such as materials and services; direct labor; and indirect costs.

(2) The registered organization shall provide cost or pricing data that is accurate and reliable, and shall certify, at the time of submission of its price proposal, that to the best of its knowledge and belief, the cost or pricing data were accurate, complete, and current as of the date of submission.

(3) The department shall determine the reasonableness of the proposed costs. In making this determination, the department may consider whether the costs represent inefficient and uneconomical practices; are not costs appropriately attributable to the price; and/or are costs unsupported by sufficient documentation or information to justify their inclusion in the proposed price. If the registered organization has been granted a renewal of its registration, any relevant historical price, cost and/or sales data of the registered organization; and any other information the commissioner deems appropriate.

(4) The department may approve the proposed price, refuse approval of a proposed price, or modify or reduce the proposed price.

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

(e) Correction of Insufficient Price Data. If the registered organization or department determines that the cost or pricing data submitted is inaccurate, incomplete or noncurrent prior to the department's approval of the price, the registered organization shall submit new data to correct the deficiency, or consider the inaccuracy, incompleteness, or noncurrency of the data.

(f) Duration of Price Determination. The department's approved price shall be in effect for the entire period of the registered organization's registration; provided, however, that at the conclusion of the first year of the registration period, or prior to that time based upon documented exceptional circumstances, the registered organization may request that the price be modified based upon a material change in the registered organization's costs. The registered organization shall fully support its request with sufficient information and documentation, in a manner and format determined by the department, to justify its request. If the department denies such request, the registered organization shall only charge prices previously approved by the department.

(g) Adjustments to determined price. If the department has approved a price, the registered organization shall immediately notify the department of any cost or pricing data submitted that it determines was inaccurate, incomplete, or noncurrent as of the date of the department's approval of the price. If the registered organization provides such notice, or if the department independently learns of such inaccurate, incomplete or noncurrent data, the department may require the registered organization to provide new data to correct the deficiency, or consider the

inaccuracy, incompleteness, or noncurrency of the data. The department may adjust the price per dose if the defective data significantly increased the price approved by the department.

(h) Audits. The department may perform audits, which may include site visits. The registered organization shall provide reasonable access to the department of its facilities, books and records.

§80-1.16 Medical marihuana marketing and advertising by registered organizations

(a) All physical structures owned, leased or otherwise utilized by a registered organization, including any dispensing facility, shall:

(1) Restrict external signage to a single sign, with only black and white colors;

(2) Not illuminate, at any time, a sign advertising a marihuana product located on any physical structure;

(3) Not advertise medical marihuana brand names or utilize graphics related to marihuana or paraphernalia on the exterior of the physical structures; and

(4) Not display approved medical marihuana products and paraphernalia so as to be clearly visible from 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 approved medical marihuana products that make a statement relating to effectiveness, side effects, consequences, and 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 marihuana 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 marihuana brands or forms, unless such a claim has been demonstrated by substantial scientific or clinical experience;

(2) Contains favorable information or opinions about a marihuana 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 a study on persons without a debilitating medical condition without disclosing that the subjects were not suffering from a debilitating medical condition;

(5) Uses data favorable to a marihuana product derived from patients treated with a different product or dosages different from those recommended in New York State;

(6) 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

(7) 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 any approved medical marihuana product 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 use of marihuana for a condition other than a serious condition as defined in subdivision seven of section thirty-three hundred sixty of the public health law;

(5) any statement, design, representation, picture or illustration that encourages or represents the recreational use of marihuana;

(6) any statement, design, representation, picture or illustration related to the safety or efficacy of marihuana, unless supported by substantial evidence or substantial clinical data;

(7) any statement, design, representation, 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;

(8) any offer of a prize, award or inducement to a certified patient, designated caregiver or practitioner related to the purchase of marihuana or a certification for the use of marihuana; or

(9) any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the commissioner, department, 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) Any advertisement for an approved medical marihuana product shall be submitted to the department at least 30 business days prior to the public dissemination of the advertisement.

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

(1) A cover letter that:

(i) provides the following subject line: Medical marihuana 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 department.

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

(l) 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 approved medical marihuana product may cause fatalities or serious damage to a patient.

(m) 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, or approved medical marihuana product.

(n) The department may:

(1) require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the department 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.

§80-1.17 Reporting dispensed medical marihuana products.

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

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

(1) a serial number that will be generated by the dispensing facility for each approved medical marihuana product dispensed to the certified patient or designated caregiver;

(2) an identification number which shall be populated by a number provided by the department, to identify the registered organization's dispensing facility;

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

(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 approved medical marihuana product was filled by the dispensing facility;

(8) the metric quantity for the approved medical marihuana product;

(9) the medical marihuana product drug code number, which shall be populated by a number provided by the department, to represent the approved medical marihuana brand that was dispensed to the certified patient or designated caregiver, as applicable;

(10) the number of days supply dispensed;

(11) the registered practitioner's Drug Enforcement Administration number;

(12) the date the written certification was issued by the registered practitioner; and

(13) the payment method.

(c) When applicable, a registered organization shall file a zero report with the department, in a format acceptable to the department. For the purposes of this section, a zero report shall mean a report that no approved medical marihuana 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 an approved medical marihuana product or the submission of a prior zero report.

§80-1.18 Prohibition the use of approved medical marihuana products in certain places.

(a) Approved medical marihuana products shall not be vaporized in a public place. In no event shall approved medical marihuana products be consumed through vaporization in any location in which smoking is prohibited under section thirteen hundred ninety-nine of the public health law, including

(1) places of employment;

(2) bars;

(3) food service establishments, except as provided in subdivision six of section thirteen hundred ninety-nine-q of the public health law;

(4) enclosed indoor areas open to the public containing a swimming pool;

(5) public means of mass transportation, including subways, underground subway stations, and when occupied by passengers, buses, vans, taxicabs and limousines;

(6) ticketing, boarding and waiting areas in public transportation terminals;

(7) youth centers and facilities for detention as defined in sections five hundred twenty-seven-a and five hundred three of the executive law;

(8) any facility that provides child care services as defined in section four hundred ten-p of the social services law, provided that such services provided in a private home are excluded from this subdivision when children enrolled in such day care are not present;

(9) child day care centers as defined in section three hundred ninety of the social services law and child day care centers licensed by the city of New York;

(10) group homes for children as defined in section three hundred seventy-one of the social services law;

(11) public institutions for children as defined in section three hundred seventy-one of the social services law;

(12) residential treatment facilities for children and youth as defined in section 1.03 of the mental hygiene law;

(13) all public and private colleges, universities and other educational and vocational institutions, including dormitories, residence halls, and other group residential facilities that are owned or operated by such colleges, universities and other educational and vocational institutions;

(14) general hospitals and residential health care facilities as defined in article twenty-eight of the public health law, and other health care facilities licensed by the state in which persons reside; provided, however, that the provisions of this subdivision shall not prohibit vaporization by patients in separate enclosed rooms of hospitals, residential health care facilities, and adult care facilities established or certified under title two of article seven of the social services law, community mental health residences established under section 41.44 of the mental hygiene law, or facilities where day treatment programs are provided, which are designated as smoking rooms for patients of such facilities or programs;

(15) commercial establishments used for the purpose of carrying on or exercising any trade, profession, vocation or charitable activity;

(16) indoor arenas;

(17) zoos;

(18) bingo facilities

(b) Vaporization of approved medical marihuana products shall not be permitted and no person shall vaporize an approved medical marihuana product within one hundred feet of the entrances, exits or outdoor areas of any public or private elementary or secondary schools; however, that the provisions of this subdivision shall not apply to vaporization in a residence, or within real property boundary lines of such residential real property.

(c) Consumption of approved medical marihuana product shall not be permitted in any motor vehicle, either public or private, that is located upon public highways, private roads open to motor vehicle traffic, parking area of a shopping center or any parking lot, as defined in section 129 of the Vehicle and Traffic Law.

§80-1.19 Reporting requirements for registered practitioners, certified patients and designated caregivers.

(a) A practitioner shall report to the department, in a manner determined by the department, the death of a certified patient or change in status of a serious 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 approved medical marihuana product. 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 department by the certified patient or designated caregiver.

(c) a practitioner shall report patient adverse events to the department, in a manner determined by the department, 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 department of any change in the information provided to the department 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 department. Should a certified patient cease to have the serious condition noted on his or her certification, the certified

patient or designated caregiver shall notify the department 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 department.

(e) If a certified patient's or designated caregiver's appearance has substantially changed such that the photograph submitted to the department 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 department.

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

(g) If a certified patient or designated caregiver notifies the department 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 department 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 department, on a form and in a manner prescribed by the department, not later than ten days of becoming aware of the loss, theft or destruction. The department shall inactivate the initial registry identification card upon receiving such notice and issue a replacement registry identification card upon receiving the applicable fee provided the applicant continues to satisfy the requirements of section thirty-three hundred sixty-one of the public health law and section 80-1.3 of this subpart. Prior to issuance of the first replacement registry identification card, a certified patient or designated caregiver shall submit to the department a fee of $25, transmitted in a fashion as determined by the department. For each subsequent replacement registry identification card a certified patient or designated caregiver shall submit to the department a fee of $50, transmitted in a fashion as determined by the department.

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

(1) The department shall issue a notification, in a format determined by the department, 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 department 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 department as defined in section 80-1.4 of this subpart.

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

(1) the department shall issue a notification, in a format determined by the department, to the certified patient and the designated caregiver that the designated caregiver has terminated his or her 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 department within ten business days.

§80-1.20 Proper disposal of medical marihuana products by certified patients or designated caregivers

(a) A certified patient or designated caregiver shall dispose of all approved medical marihuana 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 marihuana.

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

(1) rendering the approved medical marihuana product non-recoverable in accordance with the department's proper disposal instructions, which are available on the department's Internet web site;

(2) disposing of the approved medical marihuana product at a department-recognized drug take-back program located in New York.

§80-1.21 General Prohibitions.

(a) No person, except for a certified patient or designated caregiver, or an approved laboratorian shall open or break the seal placed on an approved medical marihuana 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 approved medical marihuana products.

(c) No approved medical marihuana product shall be sold, dispensed or distributed via a delivery service without prior written approval to the registered organization by the department, except that a designated caregiver may deliver the approved medical marihuana product to the designated caregiver's certified patient as allowed by section 80-1.4 (b)(6) of this subpart.

(d) No employee of a registered organization shall counsel the certified patient or designated caregiver on the use, administration of, and the risks associated with approved medical marihuana products, unless the employee is a pharmacist with an active New York State license who has completed a course pursuant to section 80-1.1 of this subpart, or the employee is under the direct supervision of, and in consultation with, the pharmacist on-site in the dispensing facility.

(e) No certified patient or designated caregiver shall be in possession of approved medical marihuana products without having in his or her possession his or her registry identification card. The certified patient or designated caregiver, upon request by the department or law enforcement, shall present such card to verify that the certified patient or designated caregiver is authorized to possess approved medical marihuana products.

§80-1.22 Practitioner prohibitions

(a) A practitioner that is registered with the department shall not:

(1) directly or indirectly accept, solicit, or receive any item of value from a registered organization;

(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 approved medical marihuana product produced by a registered organization;

(3) examine a qualifying patient for purposes of diagnosing a debilitating medical condition at any location owned or operated by a registered organization, or where medical marihuana products or related products necessary for the approved forms of administration of medical marihuana are acquired, distributed, dispensed, manufactured, sold, or produced; or

(4) directly or indirectly benefit from a patient obtaining a written certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

(b) A practitioner that issues written 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 approved medical marihuana 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 himself/herself or for the practitioner's family members, employees or co-workers.

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

(e) A practitioner shall not be a designated caregiver for any patients that he or she has certified under section 80-1.2 of this subpart.

§80-1.23 Designated Caregiver Prohibitions

(a) An individual shall not serve as a designated caregiver for more than five certified patients at any given time.

(b) A designated caregiver may only obtain payment from the certified patient to be used for the cost of the approved medical marihuana 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 and delivery of medical marihuana product to the certified patient.

Paragraph 5 of section 55-2.2 is renumbered as paragraph 6, and a new paragraph 5 is added to read as follows:

Section 55-2.2 Certificates of approval.

(a) Certificates of approval shall be issued to environmental laboratories in one or more categories, including, but not limited to:

(1) examination of potable water, including, but not limited to, the analytes listed in Part 5 of the New York State Sanitary Code;

(2) examination of nonpotable water, such as wastewater and samples for water quality monitoring of lakes, streams and rivers;

(3) examination of solid waste, soil and sediment, including, but not limited to, hazardous wastes (see New York State Environmental Conservation Law article 27);

(4) examination of air;

(5) examination of medical marihuana (see New York State Public Health Law Article 33, Title 5-A); and

(6) examination of any sample, specimen or substance listed or otherwise described in section 502 of the public health law.

Certificates of approval shall limit approval to specific analytes within one or more of the above categories.

A new section 55-2.15 is added to read as follows:

55-2.15 Requirements for laboratories performing testing for medical marihuana.

(a). For purposes of this subpart, the following terms shall have the following meanings:

(1) "medical marihuana" shall mean marihuana as defined in subdivision twenty-one of section thirty-three hundred two of the public health law, intended for a certified medical use, as determined by the commissioner in his or her sole discretion.

(2) "medical marihuana product" shall mean any material produced from medical marihuana prior to its final packaging, e.g, extracts.

(3) "final medical marihuana product" shall mean the final medical marihuana product as dispensed to the patient. Any form of medical marihuana not approved by the commissioner is expressly prohibited.

(4) "registered organization" shall mean a for-profit business entity or not-for-profit corporation organized for the purpose of acquiring, processing manufacturing, selling, delivering, transporting, distributing or dispensing medical marihuana in accordance with the requirements of title 5-A of article 33 of the public health law.

(b) (1) Prior to performing testing for any medical marihuana, medical marihuana product or final medical marihuana product, a laboratory physically located within New York State shall submit a request to the department, and receive an initial or revised certificate of approval that includes the specialty of medical marihuana testing and the approved method(s) the laboratory is authorized to employ as stipulated in sections 55-2.1 and 55-2.5 of this subpart, in addition to a valid and federally-recognized Drug Enforcement Agency license. The certificate of approval shall also list the specific subcategories, analytes, and approved methods included in the approval. No laboratory shall examine a sample related to medical marihuana without certification of approval specific to this category and meeting all other provisions within this subpart; and

(2) the department may withhold or limit its approval if the department is not satisfied that: (i) the laboratory has in place adequate policies, procedures, and facility security (physical and cyber security) to ensure proper: collection; labeling; accessioning; preparation; analysis; result reporting for; and storage of medical marihuana, medical marihuana product or final medical marihuana product as defined in section 55-2.15(a) of this subpart; or (ii) the laboratory is able to meet the requirements applicable to it as set forth in title V-A of article 33 of the public health law, and section 80-1.14 of this title.

(c) In addition to application and attestation requirements found elsewhere in this subpart, a laboratory seeking approval to perform medical marihuana, medical marihuana product or final medical marihuana product testing shall submit:

(1) a standard operating procedure manual documenting laboratory policies, procedures, facilities, equipment, supplies, instrumentation and personnel for medical marihuana, medical marihuana product or final medical marihuana product testing, which are designed to ensure proper: collection; labeling; accessioning; preparation; analysis; result reporting or, storage of medical marihuana, medical marihuana product or final medical marihuana product as defined in section 55-2.15(a) of this subpart; and

(2) an attestation signed by the owner(s) and director(s) that, in addition to meeting the preceding requirements of this subpart, a laboratory engaged in medical marihuana testing, through its owner(s) and director(s), shall:

(i) confirm that the laboratory shall accept only the type(s) of samples specified on the laboratory's certificate of approval;

(ii) confirm that the laboratory owner(s) and director(s) is independent of any owner and employee of a registered organization; and

(iii) confirm that the owner(s) and director(s) will ensure that all test results are reported in a manner and form consistent with the approved method and with requirements in title V-A of article thirty-three of the public health law, including but not limited to:

(a) reporting of results, as applicable, including regulated analytes as well as any contaminants listed in section 80-1.11(h)(2) of this title to the registered organization and the department using a department approved mechanism; and

(b) reporting of any improprieties regarding the medical marihuana product testing, including but not limited to, theft and the falsification of any data, documentation, or attestation related to the medical marihuana product testing to the department within two (2) business days from the date of learning of the impropriety.

(d) The approval of mobile laboratories is prohibited for the purposes of this section.

SUMMARY OF REGULATORY IMPACT STATEMENT

Statutory Authority:

Chapter 90 of the Laws of 2014 amended Article 33 of the Public Health Law to add a new Title V-A. Title V-A of the Public Health Law sets forth the requirements for manufacturing, dispensing and making available to certified patients, medical marihuana. The Commissioner is authorized pursuant to Section 3369-a of the Public Health Law to promulgate rules and regulations necessary to effectuate the provisions of Title V-A of Article 33 of the Public Health Law.

Legislative Objectives:

In enacting Title V-A, the legislative objective was to establish a comprehensive program for the manufacture, sale and use of medical marihuana by striking a balance between potentially relieving the pain and suffering of those individuals suffering from a serious medical condition as defined in Section 3360(7) of the Public Health Law and protecting the public against risks to its health and safety.

Needs and Benefits:

The proposed regulations implement the medical marihuana program established in Title V-A of Article 33 of the Public Health Law. They promote the safe and effective use of approved medical marihuana products while safeguarding against diversion and other public safety concerns.

Compliance Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

There will be costs associated with the application for registration as a registered organization. In order to apply for registration, an applicant must submit a $10,000 non-refundable application fee along with an additional $200,000 refundable registration fee. The $10,000 non-refundable application fee will cover the cost to the department in reviewing the application. The additional $200,000 registration fee will be refunded to those applicants not selected as registered organizations. For those applicants selected as registered organizations, the $200,000 registration fee will cover all of the registered organization's manufacturing and dispensing facilities for a period of two-years.

Applicants selected as registered organizations will have ongoing costs related to reporting and response to issues regarding oversight. In addition, registered organizations will have costs associated with requirements for testing of medical marihuana products by approved independent laboratories. These costs are necessary to ensure that the approved medical marihuana product made available to certified patients is safe and reliable.

The proposed regulations set forth manufacturing and dispensing requirements for the registered organizations. There will be costs associated with the manufacture, laboratory testing, packaging, labeling and distribution of the product to dispensing facilities. Costs will also be associated with the reporting requirements of the registered organization, security of the facilities, and labor.

Certified Patients and designated caregivers will incur costs in the form of a fifty dollar fee for a registry identification card, which may be reduced or waived in the case of financial hardship, and the cost of purchasing the dispensed approved medical marihuana product.

Costs to State and Local Government:

The proposed rules do not require the state or local government to perform any additional tasks.

Costs to the Department of Health:

The review of practitioner registration, patient certification, registration identification card and registered organization applications will require the commitment of department staff resources. The Department of Health also anticipates an increased administrative cost to support the ongoing monitoring and compliance of the medical marihuana program, and for laboratory services provided by the Wadsworth Center for quality assurance testing of medical marihuana products and for any ongoing testing required to investigate serious adverse events.

Local Government Mandates:

The proposed rule does not impose any new programs, services, duties or responsibilities on local government.

Paperwork:

The paperwork associated with processing applications for entities who wish to become registered organizations in New York State will include, but are not limited to, detailed

architectural plans, standard operating procedures, and security procedures. The process to certify patients and provide registry identification cards will require minimal paperwork as the process will be automated to the fullest extent possible.

Duplication:

The proposed regulations do not duplicate any existing State or federal requirements.

Alternatives:

There are no alternatives to the adoption of regulations to be considered during the regulatory process since regulations are required by Title V-A of Article 33 of the Public Health Law.

Federal Standards:

Federal requirements do not include provisions for a medical marihuana program.

Compliance Schedule:

The proposed regulations will take effect upon publication of a Notice of Adoption in the New York State Register.

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REGULATORY IMPACT STATEMENT

Statutory Authority:

Chapter 90 of the Laws of 2014 amended Article 33 of the Public Health Law to add a new Title V-A. Title V-A of the Public Health Law sets forth the requirements for manufacturing, dispensing and making available to certified patients, medical marihuana. The Commissioner is authorized pursuant to Section 3369-a of the Public Health Law to promulgate rules and regulations necessary to effectuate the provisions of Title V-A of Article 33 of the Public Health Law.

Legislative Objectives:

In enacting Title V-A , the legislative objective was to comprehensively regulate the manufacture, sale and use of medical marihuana by striking a balance between potentially relieving the pain and suffering of those individuals with serious medical conditions as defined in Section 3360(7) of the Public Health law and protecting the public against risks to its health and safety. The proposed regulations accomplish this objective by establishing standards for practitioner registration, practitioner issuance of certifications, certified patient and designated caregiver registrations, applications for initial and renewal registration as a registered organization, requirements for manufacturing and dispensing facilities of registered organizations, general registered organization requirements, medical marihuana laboratory testing requirements, security requirements for manufacturing and dispensing facilities, pricing, medical marihuana marketing and advertising by registered organizations, reporting of dispensed

medical marihuana, prohibition of vaporization of medical marihuana in certain places, reporting requirements, and proper disposal of marihuana by patients and designated caregivers.

Needs and Benefits: These proposed regulations promote the safe and effective use of approved medical marihuana products while safeguarding against diversion and other public safety concerns. Populations that will benefit from the proposed regulations include patients who are suffering from severe debilitating or life-threatening conditions. To allow for implementation of the medical marihuana program, the Department is proposing a new subpart 80-1 to Title 10 NYCRR. The regulations will serve the following needs:

1. Practitioner registration requirements – In order to register with the department, practitioners are required to complete a four hour course approved by the Commissioner of Health and must have a license in good standing as a physician to practice medicine in New York State.
2. Practitioner issuance of certifications to patients – Registered practitioners may only issue a certification to a patient with a serious condition as defined in the proposed regulations. The patient must be under the practitioner's continuing care for the serious condition. The certification may be issued for up to one year. In the event that a patient is terminally ill, the certification shall not expire until the patient's death or the practitioner revokes the certification. If the practitioner issues a certification to a patient who is a non-resident of New York but is receiving care and treatment in New York, the certification shall be for no longer

than the applicant is reasonably anticipated to be residing in New York State for the purposes of care and treatment, up to one year.

3. Certified patient and designated caregiver registrations – Upon receipt of a certification from a registered practitioner, the patient must apply to the department for a registry identification card. The patient will be required to submit proof of New York State residency or proof that the patient is temporarily residing within New York State for the purposes of receiving medical care and treatment in New York State. A certified patient may designate up to two caregivers. The information concerning the proposed designated caregiver must be provided to the department by the certified patient. The proposed designated caregiver must be a resident of New York State. The proposed designated caregiver must then apply to the department for a registry identification card. The ability to have a designated caregiver will benefit those patients who are incapable of going to a dispensing facility to obtain the approved medical marihuana product.
4. Applications for initial and renewal registration as a registered organization – Applicants will apply to the department for registration as a registered organization. Registered organizations will be authorized to manufacture and dispense approved medical marihuana products. Applications for initial registration and renewal registration must include, amongst other requirements, detailed information concerning buildings, facilities and equipment that would be used, detailed operating plans, architectural plans, construction timetables, organization details and financial statements. In order to apply for registration, an

applicant must submit a $10,000 non-refundable application fee along with a $200,000 refundable registration fee. The $200,000 registration fee will be refunded to those applicants not selected as registered organizations.

5. Registered organization requirements for manufacturing and dispensing facilities - All manufacturing and dispensing of medical marihuana by registered organizations must take place in New York State. Dispensing of approved medical marihuana products may not be from the same facility where the product is manufactured. The proposed regulations further define the manufacturing requirements for the production of a final approved medical marihuana product. In order to implement a program that will protect the public health and safety, products will be limited to the brands, forms and routes of administration approved by the Commissioner of Health. Registered organizations will be authorized initially to produce up to five approved 'brands' of medical marihuana product, with approval of the department, with a consistent cannabinoid profile, which will be demonstrated by the registered organization through laboratory testing. Registered organizations shall only dispense approved medical marihuana products to certified patients or designated caregivers who present a valid registry identification card.
6. General registered organization requirements – Additional requirements of registered organizations are defined in the regulations, including, but not limited to documentation of all materials used in the cultivation and processing of approved medical marihuana products, record retention requirements, adverse event reporting, disposal of unusable approved medical marihuana products, and

provisions for registered organizations where a registration is to be surrendered. The ability to track adverse event reporting will serve to protect the health of certified patients in identifying issues related to the quality of different lots of an approved medical marihuana.

7. Laboratory testing requirements – Laboratory testing of the final manufactured medical marihuana product is required to be performed by an independent commercial laboratory certified by the NYS Environmental Laboratory Approval Program (ELAP) to perform testing on medical marihuana products. Until independent commercial laboratories are certified by the NYS ELAP to perform this testing, the testing will be completed by the Department's Wadsworth Center, upon its certification by the NYS ELAP. Testing of the final manufactured medical marihuana product will benefit certified patients by ensuring a product that is consistent in cannabinoid profile and free of contaminants.
8. Security requirements for manufacturing and dispensing facilities – The regulations define surveillance and security requirements for the manufacturing and dispensing facilities, as well as for the secure transport of approved medical marihuana products from the manufacturing facility to the dispensing facility. The security requirements will aid in the prevention of diversion of marihuana and all manufactured medical marihuana products.
9. Pricing requirements – The regulations establish the process for registered organizations to obtain approval from the department for the per dose price of each form of approved medical marihuana sold by the registered organization.

10. Medical marihuana marketing and advertising by registered organizations – The regulations define the requirements for advertising and marketing and require approval of the commissioner prior to advertisement of an approved medical marihuana product.
11. Reporting dispensed medical marihuana –The dispensing facilities of registered organizations will be required to submit dispensing data for approved medical marihuana products to the department within 24 hours of dispensing to the certified patient or designated caregiver. A zero report must be submitted to the department when no approved medical marihuana product was dispensed by the dispensing facility of the registered organization. A zero report must be submitted no later than fourteen days following the most recent previously reported dispensing of an approved medical marihuana product or the submission of a prior zero report.
12. Prohibition of the use of medical marihuana in certain places – The regulations prohibit vaporization of approved medical marihuana products in places where smoking is prohibited to protect individuals from unnecessary exposure of approved medical marihuana products that are administered through vaporization.
13. Reporting requirements for practitioners, patients, and designated caregivers – The regulations establish reporting requirements for practitioners, patients and designated caregivers to capture scenarios including, but not limited to, changes in a certified patient's circumstances, changes to designated caregivers, and adverse event reporting.

14. Proper disposal of marihuana by certified patients or designated caregivers - These regulations require certified patients or their designated caregivers, if applicable, to dispose of all approved medical marihuana product in their possession no later than ten calendar days after the expiration of the patient's certification, if the certification is not renewed, or sooner should the patient no longer wish to possess medical marihuana.
15. Prohibitions; general, practitioner and designated caregiver – The regulations define prohibited acts to prevent diversion and promote the health and safety of certified patients.

Costs

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity

There will be costs associated with the application for registration as a registered organization. In order to apply for registration, an applicant must submit a $10,000 non-refundable application fee along with an additional $200,000 refundable registration fee. The $10,000 non-refundable application fee will cover the cost to the department in reviewing the application. The additional $200,000 registration fee will be refunded to those applicants not selected as registered organizations. For those applicants selected as registered organizations, the $200,000 registration fee will cover all of the registered organization's manufacturing and dispensing facilities for a period of two-years.

The proposed regulations set forth manufacturing and dispensing requirements for the registered organizations. There will be costs associated with the manufacture, laboratory testing, packaging, labeling and distribution of the product to dispensing facilities. Costs will also be associated with the reporting requirements of the registered organization, security of the facilities, and labor.

The proposed regulations set forth laboratory testing requirements for the final product, which will incur a cost to the registered organization. The laboratory testing will be performed by the Department's Wadsworth Center until independent laboratories are certified for testing of marihuana in New York State. Registered organizations will need to contract with approved laboratories for testing, although there will be no cost for laboratory testing performed by Wadsworth Center until independent laboratories are approved for this testing. Independent laboratories approved by the NYS ELAP to perform testing on medical marihuana products will be required to pay an annual fee which includes a $500 fee and an additional sum based on their annual test volume [the fee calculation is described in 10NYCRR55-3.7 (a)(b)].

Costs to certified patients and designated caregivers will be related to the application fee required for obtaining a registry identification card. The fee for a registry identification card is fifty dollars, but may be reduced or waived in the case of financial hardship. Patients will also incur the costs of purchasing dispensed medical marihuana products.

Costs to State and Local Government

The proposed rule does not require the state or local government to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

Costs to the Department of Health

The Department of Health anticipates an increased administrative cost to support the ongoing monitoring and compliance for the medical marihuana program. Additional staff will be required to manage the applications for registered organizations submitted, compliance associated with dosing, laboratory testing, practitioner education, patient certification and registry identification card processes. It is anticipated that the process for registering practitioners who have completed the required course, certifying patients, and issuing registry identification cards will be automated to the fullest extent possible.

There will be costs for laboratory services provided by the NYS DOH Wadsworth Center for initial quality assurance testing of medical marihuana products and for any ongoing testing required to investigate serious adverse events. It is anticipated that a percentage of the sales taxes generated from the sale of approved medical marihuana products and added to the NYS General Fund will offset these costs.

Local Government Mandates:

The proposed rule does not impose any new programs, services, duties or responsibilities on local government.

Paperwork:

The paperwork associated with processing applications for entities who wish to become registered organizations in New York State will include detailed architectural plans, standard operating procedures, and security procedures, amongst other requirements. It is anticipated that processing applications will be ongoing as registered organizations apply and renew. The process to certify patients and provide registry identification cards will require minimal paperwork as the process will be automated to the fullest extent possible.

Paperwork will be associated with the maintenance of records for the registered organization's standard operating procedures, transportation manifests, visitor logs, as well other records required of the registered organization.

Practitioners will be required to maintain a copy of the patient's certification in the patient's medical record.

Certified patients and their designated caregivers will be required to carry their registry identification card at all times when in possession of approved medical marihuana products.

Duplication:

The proposed regulations do not duplicate any existing State or federal requirements that are applicable to a medical marihuana program.

Alternatives:

There are no alternatives to the adoption of regulations to be considered during the regulatory process since regulations are required by Title V-A of Article 33 of the Public Health Law.

Federal Standards:

Federal requirements do not include provisions for a medical marihuana program.

Compliance Schedule:

The proposed regulations will take effect upon publication of a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

This proposed rule will allow registered organizations to manufacture, distribute and sell approved medical marihuana products in New York State. Each registered organization may have up to four dispensaries, geographically dispersed. There are no costs to existing small business establishments or government entities in New York State.

Compliance Requirements:

There are no new compliance requirements imposed to existing small business establishments as a result of these amendments.

Professional Services:

No new professional services will be required of small business entities and local governments.

Compliance Costs:

Since there are no small business entities which currently provide for the manufacture, distribution and dispensing of medical marihuana, the proposed regulations do not impose an economic impact on any existing small business entity. Entities who wish to become licensed as a registered organization will incur costs associated with the building and operation of facilities to manufacture, distribute and dispense the approved medical marihuana product. Laboratory

testing of the final product, which will also incur a cost to the registered organization, will be required. The manufacture of the plant into approved dosage forms and product testing are required to minimize the risk of adverse events to patients from mislabeled products or products containing contaminants.

Economic and Technological Feasibility:

This proposal is economically and technologically feasible. Statute requires the registered organization to pay a 7% excise tax to the Commissioner of Tax and Finance. This tax will provide for a return of 22.5% to the counties in New York State where medical marihuana is manufactured, 22.5% to the counties in New York State in which the medical marihuana is dispensed, 5% to the Division of Criminal Justice Services and 5% to the Office of Alcoholism and Substance Abuse Services.

Minimizing Adverse Impact:

These regulations will allow for the manufacture, distribution and sale of medical marihuana to patients suffering from a severe debilitating or life-threatening condition. To minimize the potential for patient adverse effects associated with the use of medical marihuana, the regulations provide for a limited number of approved brands (cannabinoid profiles) and dosage forms that registered organizations may manufacture. In addition, the regulations require laboratory testing of the final manufactured product by a laboratory certified by New York State and located in New York State. These requirements do not create an adverse impact to small business and local governments.

Small Business and Local Government Participation:

The Department consulted with other state agencies, including the Department of Environmental Conservation, the Department of Agriculture and Markets, the Division of New York State Police, the Division of Criminal Justice Services, the Empire State Development Corporation, the Department of Taxation and Finance and the Office for Alcoholism and Substance Abuse Services. The Department also discussed the statute and received input from various advocacy organizations. These organizations and advocates spoke on behalf of patients and their families, physicians, addiction treatment specialists, and potential employees of registered organizations. The Department also solicited feedback from interested parties through a web form on the Medical Marihuana Program website. There will be a 45-day public comment period with the regulations that will allow for additional comments to be considered.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

Outside of major cities and metropolitan population centers, the majority of counties in New York State contain rural areas. Entities who wish to become a registered organization may have up to four dispensaries, geographically dispersed. The selection of the five registered organizations will take into account geographic distribution to ensure the needs of patients in rural areas are met. Due to the limited number of dispensing facilities that will operate in New York State, the ability for a patient to designate a caregiver was included in the regulations to increase accessibility to patients in rural areas.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

Costs:

There are no compliance costs to existing establishments in rural areas since no new compliance activities are imposed upon them. Compliance costs will be limited to the entities who become licensed as a registered organization.

Minimizing Adverse Impact:

The proposed rule will apply to practitioners who wish to complete the educational requirement in order to issue certifications to patients for medical marihuana. Practitioners in rural areas of the state may complete this course, which will be offered online to make the course easily accessible to all practitioners who wish to issue certifications to patients for approved medical marihuana products. Due to the limited number of dispensing facilities that will operate

in New York State, designated caregivers are authorized to obtain approved medical marihuana products from dispensing facilities to increase accessibility to patients in rural areas.

Rural Area Participation:

The Department consulted with other state agencies, including Department of Environmental Conservation, Department of Agriculture and Markets, Division of New York State Police, Division of Criminal Justice Services, Empire State Development Corporation, Department of Taxation and Finance, and the Office of Alcoholism and Substance Abuse Services. The Department also solicited feedback from interested parties through a web form on the Medical Marihuana Program website. There will be a 45-day public comment period with the regulations that will allow for additional comments to be considered regarding rural areas.

JOB IMPACT STATEMENT

A Job Impact Statement is not included because the Department has concluded that the proposed regulatory amendments will not have a substantial adverse effect on jobs and employment opportunities. The proposed amendments will allow for the opposite effect on jobs as new jobs will be created to support the activities of registered organizations.