Medical Use of Marihuana

Effective date: 4/15/15

SUMMARY OF EXPRESS TERMS

Pursuant to the authority vested in the Commissioner of Health by Section 3369-a of the Public Health Law (PHL), a new Chapter XIII, Part 1004 is hereby added to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, and in accordance with section 502 of the PHL, Subpart 55-2 of Title 10 is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

§**1004.1 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.

§**1004.2 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.

§**1004.3 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.

§**1004.4 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.

§**1004.5 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.

§**1004.6 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.

§1004.7 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.

§1004.8 Registrations non-transferable. Prohibits the transfer or assignment of registrations issued under this part.

§**1004.9 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.

§**1004.10 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.

§1004.11 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 marihuana 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.

§**1004.12 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.

§1004.13 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.

§1004.14 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.

§1004.15 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.

§**1004.16 Medical marihuana marketing and advertising by registered organizations.** Restricts the marketing and advertising of medical marihuana.

§**1004.17 Reporting dispensed medical marihuana products.** Details reporting requirements for dispensed medical marihuana products.

§**1004.18 Prohibition of the use of medical marihuana in certain places.** Restricts the vaporization of medical marihuana in certain places.

§**1004.19 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.

§**1004.20 Proper disposal of medical marihuana products by patients or designated caregivers.** Details the required disposal procedures for medical marihuana products.

§**1004.21 General prohibitions.** Contains general prohibitions.

§**1004.22 Practitioner prohibitions.** Lists prohibitions on practitioners.

§1004.23 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 (PHL), a new Chapter XIII, Part 1004 is hereby added to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, and in accordance with section 502 of the PHL, Subpart 55-2 of Title 10 is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Chapter XIII

MEDICAL USE OF MARIHUANA

Part 1004

MEDICAL USE OF MARIHUANA

§1004.1 Practitioner registration.

§1004.2 Practitioner issuance of certification.

§1004.3 Application for registration as a certified patient.

§1004.4 Designated caregiver registration.

§1004.5 Application for initial registration as a registered organization.

§1004.6 Consideration of registered organization applications.

§1004.7 Application for renewal of registered organization registrations.

§1004.8 Registrations non-transferable.

§1004.9 Failure to operate.

§1004.10 Registered organizations; general requirements.

§1004.11 Manufacturing requirements for approved medical marihuana product(s).

§1004.1 Practitioner registration.

(a) No practitioner shall be authorized to issue a patient certification as set forth in §1004.2 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.

§1004.2 Practitioner issuance of certification.

(a) Requirements for Patient Certification. A practitioner who is registered pursuant to 1004.1 of this part 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.

§1004.3 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 part, 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 part 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 1004.4 of this part.

(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.

§**1004. 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.

§1004.5 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 part 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 1004.11 of this part, 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 part;

(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 1004.11 of this part.

(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 incidents and document the investigated source of such incidents, 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 part 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 1004.13 of this part.

(12) a construction timetable;

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

(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.

§**1004.6 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 §1004.5, 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 part.

(3) Only applications completed in accordance with this part 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 part;

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

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

(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.

§1004.7 Applications for renewal of registration as registered organization

(a) An application to renew any registration issued under this part 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 part 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 1004.5 of this part;

(2) every known complaint, charge or investigation, pending or concluded during the period of the registration, by any governmental or administrative agency with respect to:

(i) each incident or alleged incidence involving the theft, loss, or possible diversion of medical 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.

§ **1004.8 Registrations non-transferable.**

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

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

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

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

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

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

§ **1004.9 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.

§1004.10 Registered organizations; general requirements

(a) In addition to the requirements in public health law and as otherwise set forth in this part, 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 part;

(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 part;

(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 part 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 part 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.

§**1004.11 Manufacturing requirements for approved medical marihuana product**s

(a) Definitions. Wherever used in this part, 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 (CO2, 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 1004.14 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.

§1004.12 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 part, 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 certifying practitioner's name;

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

(4) the dosing and administration instructions;

(5) the quantity and date dispensed; 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 1004.20 of this part; 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.

§ **1004.13 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.

§1004.14 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 1004.11(c)(2) of this part.

(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.

§1004.15 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.

§1004.16 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.

§1004.17 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.

§1004.18 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.

§1004.19 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 1004.3 of this part. 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 1004.4 of this part.

(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.

§1004.20 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.

§1004.21 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.

(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 1004.1 of this part, 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.

§1004.22 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 1004.2 of this part.

§1004.23 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 1004.14 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 1004.14(g) 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.

(c) 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:

There are no new reporting, recordkeeping or other compliance requirements imposed on rural areas as a result of these amendments. No new professional services will be required of rural areas. Compliance requirements will be limited to the entities who become licensed as a registered organization.

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.

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

New York State recognizes that possession and use of marijuana is illegal in the United States. However, the State also recognizes the benefit in making available medical marijuana to qualified individuals with debilitating and life threatening illnesses and conditions. To that end, the Compassionate Care Act (PHL §3360 et. seq.) (the "Act") is balanced legislation that ensures appropriate access through comprehensive regulations and safeguards.

The State subsequently developed the regulations through this very critical lens to ensure that the entire program would not be subject to enforcement action or legal challenges. Expanding the initial set of regulations would have subjected the State to unnecessary scrutiny and jeopardized the program's ability to move forward in any meaningful manner. The Compassionate Care Act and the proposed regulations strike the required balance by implementing a strong and effective medical marijuana program in New York State.

The Department of Health (the "Department") received comments from hundreds of stakeholders (many of whom were affiliated with the same entity or organization). A summary of the comments received is set forth below. The full text of the regulations and the full assessment of public comment are available on the Department's website.

The Department reviewed and assessed each comment. Some comments were not incorporated as they were inconsistent with the statutory authority underlying the rulemaking or concerned issues outside the scope of the rulemaking. Other comments appeared to warrant further consideration as to whether clarification would be helpful in guidance or for possible inclusion in

future rulemaking. Revisions were determined to be unnecessary for other comments, as the regulations are adequate to address the topic areas raised.

Several comments were received on similar topics, including the following:

- Comments were received concerning practitioner education requirements, and the exclusion of health care practitioners (other than physicians) from those authorized to issue patient certifications. The regulations require practitioners complete a four hour course, which is consistent with the Act. The course will be available online. With respect to issuance of certifications, Public Health Law (PHL) § 3360 (12) defines "practitioner" as a licensed physician, and authorizes the Commissioner of Health to consider the inclusion of nurse practitioners. The Commissioner will consider adding nurse practitioners in the future.
- Commenters recommended expanding the list of serious conditions, and including a transparent process for adding new conditions. PHL § 3360(7)(a) authorizes the Commissioner to add conditions to those already included in statute, and to consider expanding the list of conditions in the future. The Department will issue guidance concerning the process to add new conditions.
- Comments were received concerning the patient certification process as well as the financial hardship waiver of the registry identification card application fee. A single electronic system for practitioners to issue certifications, and for patients and designated caregivers to apply for registry identification cards, will be utilized to ensure a more timely process. The Department is authorized to waive application fees and will provide guidance for applying for a hardship waiver.
- Comments were received concerning whether a registered organization must perform both manufacturing and dispensing activities in order to obtain a registration, and recommended

that registered organizations be allowed to manufacture and dispense from the same location. The Act requires registered organizations to manufacture and dispense medical marijuana. With respect to authorizing such activities at the same location, however, there is a risk of theft and diversion in allowing co-location of these facilities, and it is therefore prohibited.

- Comments were received concerning the qualifications and consideration of applicants seeking to become a registered organization. PHL § 3360(17) defines a registered organization applicant as "a for-profit entity or not-for-profit corporation." Although New York State residency, or formation of the entity or corporation in New York State, is not a requirement of the statute, all manufacturing, processing, and dispensing must occur within the State. Upon receipt the Department will evaluate the application pursuant to the criteria in Section 80-1.6.
- Commenters wanted to increase the number of registered organizations, and to allow for delivery services. The Act and the regulations provide that the Commissioner shall register no more than five registered organizations, but the Commissioner may register additional registered organizations thereafter as needed. The regulations are consistent. Delivery services are prohibited unless prior written approval has been obtained from the Department.
- Commenter wanted to know how the Department would consider whether an applicant is ready to begin operations. The Department will carefully review an applicant's operating plans and other documentation to ensure that the registered organization will be able to successfully begin operations within six months of the date of issuance of the registration, and will issue guidance if necessary.
- Comments were received concerning how the registered organization will ensure availability of at least a one year supply of any offered brand. The regulations require the registered

organization to demonstrate, through their standard operating procedures, that they are able to ensure availability of the brand for a one year time period. The regulation does not require physical availability of a one year supply of product.

- Comments were received concerning the one thousand foot prohibition as it relates to the location of a dispensing facility. Section 80-1.10(7) provides that a dispensing facility may not be located 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. Accordingly, the restriction only applies if both conditions are met. Should it be determined that this limitation restricts access, the Department will consider revising its policy in subsequent rulemaking.
- Comments were received concerning a registered organization's ability to transfer or wholesale marihuana or approved products between registered organizations or from one dispensing facility to another. While the regulations allow a registered organization that intends to cease operations to transfer its supply, it must first submit a plan to DOH for doing so. With respect to transfers between dispensing facilities, the regulations limit transporting medical marihuana from a manufacturing site to a dispensing site, and to a laboratory for submission of samples for required testing.
- Comments were received concerning the use of pesticides or, in the alternative, imposing labeling requirements to show all elements in the product. The regulations allow a registered organization to use pesticides, fungicides or herbicides if approved by the NYS Department of Agriculture and Markets. With respect to labeling, the Department must approve a registered organization's package safety insert which must include a list of excipients used.

- Comments were received regarding limits on brands, forms and extraction methods. Section 80-1.11(c)(1) provides that each registered organization may initially produce up to five brands of medical marihuana, and thereafter, the Department has discretion to approve additional brands. Section 80-1.11 (g) authorizes the Commissioner to approve additional forms of medical marijuana. Similarly, with respect to extraction methods, Section 80-1.11(b) allows the use of other extraction methods than those listed in the regulations (carbon dioxide (CO2, super-critical) or alcohol for cannabinoid extraction) with the prior written approval from the Department.
- Comments were received objecting to the prohibitions on whole plant and plant based products. PHL § 3360 (8) provides that any form of medical marihuana not approved by the Commissioner is expressly prohibited. At this time, the Commissioner has not approved medical marihuana in plant form. Section 80-1.11 authorizes the Commissioner to approve additional forms.
- Comments were received concerning why a pharmacist must be on-site at dispensing facilities and over liability. Pharmacists have the training and skill-set necessary to identify drug-related issues that a patient may face. The regulations require the pharmacist complete a course approved by the Department, which is the same as that required of physicians who seek registration to certify patients. With respect to liability concerns, the statute makes clear that medical marihuana is not deemed a "drug" for purposes of Article 137 of the Education Law, in relation to the practice of pharmacy (PHL § 3368 (1)(b)). In addition, PHL § 3369 (1) provides protection from arrest, prosecution or penalty in any manner, including but not limited to disciplinary actions by a professional licensing board, to employees of registered organizations, which would include pharmacists.

- Comments were received in opposition to the prohibition on consuming food or drink, and limitation of visitors, on the premises of the dispensing facility. The regulations allow food or beverage consumption if necessary for medical reasons. With respect to visitors, the limitation is a proper security measure to ensure that only individuals authorized to obtain medical marihuana products are permitted on the premises of a dispensing facility, unless waived by the Department upon prior written request. The regulations provide that if an unforeseen circumstance requires the presence of a visitor and makes it impractical for the dispensing facility to obtain a waiver, 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.
- Comments were received concerning the Commissioner's ability to set prices for medical marijuana, and affordability and access to medical marihuana by low income patients. PHL § 3369-d requires the Commissioner to set the price per dose for each form of medical marihuana sold, and to take into account the fixed and variable costs of producing the form of marihuana in approving such price. The statute does not provide for differentiation of price based on income. Although the regulations prohibit distribution of products or samples at no cost, they allow exceptions to be authorized by the Commissioner, which could include a charity program offered by a registered organization.
- Comments were received concerns restrictions on advertising. PHL § 3364 authorizes the Commissioner to make rules and regulations restricting the advertising and marketing of medical marihuana, which must be consistent with the federal regulations governing prescription drug advertising and marketing. The advertising requirements in the regulations are consistent with federal regulations.

- Comments were received concerning the prohibition of the use of approved medical marihuana products in certain places. PHL § 3362 (2)(a) provides that possession of medical marihuana shall not be lawful if it is consumed or vaporized in a public place. No changes have been made to the regulations in response to these comments.
- Commenters indicated that the regulations fail to provide expedited access to medical marihuana, including for children who suffer from intractable epilepsy. Compassionate Care Act establishes a comprehensive system for the manufacture, dispensing, obtaining and use of medical marihuana in this State. The Department is moving forward aggressively to implement the provisions of the Act.
- Finally, technical, non-substantive clarifications have been made to the regulations as a result of comments received. The Department made a technical change in the numbering of the regulations. A new Part 1004 is added entitled "Medical Use of Marihuana". This document refers to the regulations as numbered in the published Notice of Proposed Rulemaking. In addition, the following technical, non-substantive clarifications have been made: (1) § 80-1.5(b)(4)(vi) was revised to change the word "incidence" to "incidents"; (2) § 80-1.5(b)(13) was revised to clarify that any prior bankruptcy of the applicant entity must be disclosed, as it must with its owners, managers and others listed in this section; (3) § 80-1.12(h)(2) was revised to change the word "ordering" to "certifying"; (4) § 80-1.14(f) was revised to correctly reference § 80-1.11(c)(2); (5) § 80-1.21 (c) was revised to remove an inaccurate citation and (6) § 55-2.15(c)(2)(iii)(a) was revised to reference contaminants listed in § 80-1.14(g).

ASSESSMENT OF PUBLIC COMMENT

The Department of Health ("DOH" or the "Department") received hundreds of comments from various stakeholders, including but not limited to healthcare providers, potential registered organization applicants, and legislators. The comments are summarized below with responses. Many comments were received on topics concerning accessibility, affordability, limitations on the brands offered, registered organization selection, manufacturing requirements, and prohibitions on vaporization. Some of the proposed revisions were not incorporated because they were not consistent with the statutory authority underlying the proposed rulemaking. Other comments appeared to warrant further consideration for possible guidance or inclusion of future revisions to the regulations.

The Department made a technical change in the numbering of the regulations. A new Chapter XIII consisting of Part 1004 is added entitled "Medical Use of Marihuana." For ease of reference, this document refers to the regulation as numbered in the published Notice of Proposed Rulemaking.

80-1.1 Comments: Practitioner Registration

COMMENT: Comments were received concerning the practitioner education requirements:

(a) <u>Duration of the course and online vs. classroom setting:</u>

- A commenter recommended a two-hour online course with online verification and attestation to streamline the process of registering practitioners. The commenter asked whether the four-hour course is required to be in a live classroom setting, and also recommended an online course or webinar.

- A commenter stated the proposed regulations appear to give preemptive weight to the mandatory four hour course as opposed to a two or three hour option and recommended revising practitioner education requirements to be consistent with those provided in the Compassionate Care Act.
- A commenter stated that the four hour course is not enough time to convey all the information. The commenter recommended that the practitioner course be lengthened to eight hours and accompanied by written materials.
- A commenter stated that the physicians should be required to take a refresher course every year.
- A commenter wanted to know how often the training course will be offered to meet practitioner demand.
- A commenter stated that no training course should be required.

(b) The possibility of offering continuing medical education (CME) credits:

- A commenter stated that CME credits should be offered with the required course.
- A commenter suggested a three stage educational approach should be used consisting of a 4 hour primer; 6-8 Dynamic CME credits per year, specific to medical cannabis and upon practitioner license renewal, an additional 2 CMEs should be required which highlight new science/research/dosing.

(c) Concerning how the course would be developed:

- A commenter asked what would be included in the course that is uniquely beyond the acquired knowledge from a practitioner's career, training, experience and CME.
- A commenter recommended revising this section to be consistent with the qualifications provided in the Compassionate Care Act.

- A commenter recommended that the State model its course after Massachusetts.
- A commenter suggested involving MSSNY, New York Society of Addiction Medicine, and medical groups, and physicians in developing this course.
- A commenter asked whether the State Education department would have a role in development of the course.
- A commenter stated that the marihuana industry and groups supported by it should not be involved in the development of the course.

(d) Concerning the content of course:

- A commenter stated that the course should include information on addiction and guidance that marihuana should be prescribed with the same care as other controlled substances.
- A commenter stated that the course should also include: Indications and Usage, Use in Specific Populations, Overdosage, Description, Non-clinical Toxicology, Clinical Studies, References, How Supplied/Storage and Handling, Patient Counseling Information, Federal law - the Controlled Substances Act and FDA and DEA rules recommend including indications (not just contraindications), pharmaceutics (formulations and their differences) and vulnerable populations.
- A commenter recommended the course emphasize therapeutic efficacy of forms of administration (e.g., inhalation vs. ingestion) as well as consideration of the pharmacology of the top 3-5 cannabinoids beyond THC and CBD, and also include terpenes and other potential therapeutic constituents.

- A commenter stated that specialists in the diseases being treated might recommend dosages or create research protocols for determining the proper dosage range for practitioner education.
- A commenter stated that Sativex and Marinol already have package inserts, which can serve as models for physicians and this information might be added as an appendix or resource to the required course.
- A commenter stated that the Department should issue regular updates on marihuana as medicine to all physicians who are registered and have the physicians pay a fee for those updates.

RESPONSE: No changes to the proposed regulation were made as a result of these comments. In order to certify patients for the medical marijuana program, a practitioner must be (i) a physician licensed by New York State and practicing within the state; (ii) who by training or expertise is qualified to treat a serious condition as defined in PHL § 3360(7); and (iii) has complete a two to four hour course as determined by the Commissioner of Health in regulation. Public Health Law § 3360(12). With regard to the third requirement, the Commissioner has determined that practitioners must complete a four hour course that includes the following content: 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. The length of the course is consistent with the requirements of the Compassionate Care Act as it falls within the two to four hour duration required. Comments from stakeholders regarding course content have been, and will continue to be, taken into consideration as the Department develops the course. The Department will ensure that the

course offerings meet demand. The Department will implement the practitioner course and registration process in a manner which will allow for practitioners to complete the course online at their own pace. The Department is also evaluating the ability to offer CME credit for the course.

COMMENT: A commenter suggested removing the overdose prevention from the list of required course components because there is no evidence of patients dying from marihuana overdose.

RESPONSE: No changes to the proposed regulation were made as a result of this comment. There are consequences, other than death, associated with an overdose of marihuana, such as extreme anxiety, panic attacks, or psychotic reactions. An overdose could also result in self injury due to impaired judgment, perception and coordination.

COMMENT: Comments were received regarding a practitioner's qualifications to treat a disease:

- A commenter stated that primary care physicians are treating a patient with a certain diagnosis but may not be a specialist in that particular disease and that the regulations should account for this and not limit a patient to a specialist.
- A commenter stated that the Department of Health should determine which physicians are qualified to treat the various conditions by requiring board certification or other specialized training and experience in those conditions. The commenter stated that unless the physician is specialized in his or her knowledge for that condition, the Department will be inviting abuse and negligence.

- A commenter wanted DOH to request that a physician list the diseases for which he or she will be treating in the practitioner registration application. The commenter does not want to require a physician to be a specialist in that particular disease, but stated that having the physician indicate the diseases they would be treating, as well as their qualifications, would help reduce creation of "marihuana mills" in physician practices.

RESPONSE: No revisions to the regulation are necessary to address these comments. In order to certify patients for the medical marijuana program, a practitioner must be (i) a physician licensed by New York State and practicing within the state; (ii) who by training or expertise is qualified to treat a serious condition as defined in PHL § 3360(7); and (iii) has completed a two to four hour course as determined by the Commissioner of Health in regulation. Public Health Law § 3360(12); *see also* PHL § 3361(1)(b) (a patient certification may only be issued if the practitioner, by training or experience is qualified to treat the serious condition). The proposed regulations require that the practitioner certification form include a statement to that effect. *See* § 80-1.2(1). The proposed regulations do not require a board certification for each practitioner as the practitioner's experience would suffice as long as it was clearly articulated in the certification. The Department plans to issue separate guidance for completing the practitioner certification form.

COMMENT: A commenter noted that any delay in the approval of physician courses may limit the number of physicians available to prescribe medical marihuana once registered organizations are selected.

RESPONSE: The Department will ensure there are sufficient course offerings to meet demand, and that such courses will be available in a manner consistent to meet the effective date requirements set forth in PHL § 3369-b.

COMMENT: A commenter stated that New York should implement a prescriber education program based upon the education and patient peer-to-peer program developed in Canada.
RESPONSE: The Department will take this comment under advisement as it develops and implements the course requirements. No revisions changes to the regulation are necessary to address this comment.

COMMENT: A commenter requested that that the Department create a board of physicians, health officials, addiction experts and law enforcement officials, who are unaffiliated with the marihuana industry, to create the course based on scientific evidence and upon establishment of the course, the Department should ensure that any changes to the course come only from the board who will review the course every year.
RESPONSE: These comments address issues beyond the intended scope of the regulation, and no changes were made to the proposed regulation in response to them. However, the Department will take this comment under advisement.

COMMENT: A commenter stated that, in rural areas, access to certification classes by practitioners may be limited. The commenter requests that registered organizations be allowed to operate classes or subsidize classes.

RESPONSE: No revisions to the regulation are necessary to address this comment. The Department will make the course available online for practitioners to complete at their own pace, which eliminates the need for a practitioner to complete the department-approved course in a live classroom environment and addresses access issues. Courses provided or subsidized by registered organizations raise conflict of interest concerns.

COMMENT: A commenter stated that medical providers need education around how to work with "communities" eligible for medical marihuana services.

RESPONSE: The proposed regulations address this comment. Pursuant to Section 80-1.1 of the regulations, practitioners who wish to issue certifications for their patients will be required to complete a four hour course, approved by the Commissioner, which will include, but not be limited to the pharmacology of marihuana, contraindications, side effects, adverse reactions, overdose prevention, drug interactions, dosing, routes of administration, risks and benefits, warnings and precautions, and abuse and dependence.

COMMENT: Several comments were received regarding who is qualified to be a practitioner, including:

- A commenter requested that Medical Doctors (MD), Doctors of Osteopathic Medicine (DO), Nurse Practitioners and Physician Assistants be included in the definition of "practitioner."
- A commenter stated that any health care practitioner qualified to issue a prescription or dispense a controlled substance should also meet the minimum qualifications for

recommending medical marihuana to patients, which would include nurse practitioners and physician assistants.

- A commenter stated restricting the definition of "practitioner" to physicians would limit the availability of qualified medical professionals to serve patients in need of medical marihuana.
- A commenter stated that statute provides authority to the Commissioner to include nurse practitioners as "practitioners" under the law; therefore, the regulations should reflect that Nurse Practitioners may issue patient certifications and should be required to receive the same training materials as practitioners with a medical degree. The commenter stated the Nurse Practitioner Modernization Act allows nurse practitioners to practice independently, and there is a physician shortage that would make access to a physician difficult in certain areas. A commenter stated that nurse practitioners are more directly integrated into the day to day care of patients and will need additional training in the management of patients under the influence of marihuana, similar to any other prescription treatment.
- Commenter stated that, if nurse practitioners were not authorized to issue patient certifications at this time, the regulations should be revised to reflect that nurse practitioners may be deemed practitioners in the future.

RESPONSE: Pursuant to Public Health Law § 3360(12), the type of "practitioner" authorized to certify patients is limited solely to a physician licensed by and practicing in New York State. However, the Commissioner is authorized to consider the inclusion of nurse practitioners as "practitioners" based upon considerations including access and availability after the program has been implemented. The statute does not authorize other health care practitioners, such as

physician assistants, to issue certifications. The Department will review accessibility and availability issues after implementation of the program and consider the inclusion of nurse practitioners as "practitioners" authorized to issue patient certifications. Any such change will be addressed in subsequent rulemaking. No revisions to the regulation are necessary.

80-1.2 Comments: Practitioner Issuance of Certification

COMMENT: A number of comments dealt with the number and scope of serious conditions as defined in PHL § 3360(7) and §§ 80.1.2(8)-(9) that would allow a practitioner to issue a certification to a registered patient. Those comments include:

- Eliminating all of the conditions in favor of a single standard that would allow the practitioner to determine whether the patient is eligible for medical marijuana.
- Replacing the statement that "such other conditions, symptoms or complications as added by the commissioner" should be removed and replaced with "or any condition for which treatment with medical marihuana would be beneficial as determined by the patient's physician.
- Not requiring the pain required to be associated with the severe debilitating or life-threatening illness to be "substantially limiting in function" for the applicant to be eligible for treatment.
- The list of conditions should be amended to include one or more of the following conditions: Alzheimer's disease and dementia, anorexia, ankylosing spondylitis, anxiety disorders, appetite stimulation, asthma, autism, autoimmune illnesses, bipolar disorder, cerebral palsy, chronic pain, Crohn's disease, depression, diabetes, dystonia, eating disorders, fibromyalgia, glaucoma, head trauma or stroke, hemochromatosis, hepatitis C,

intractable seizure conditions, Irritable Bowel Syndrome, Lupus, Lyme disease, mental health disorders, migraines, motion sickness, musculoskeletal disease, muscular dystrophies, nausea, neuromuscular disease, neuromuscular dystrophies, neuropathies (including diabetic neuropathy and chemotherapy-induced neuropathy), osteoarthritis, pain, psychological conditions, relaxation, rheumatoid arthritis, spinal problems, traumatic brain injury. Several commenters also recommended that post-traumatic stress disorder be added in support of veterans who served this country.

- Allowing September 11th first responders in the World Trade Center health and treatment program to receive a certification for medical marijuana.
- Allowing patients transferring from opiates, pain killers and alcohol should able to use medical marijuana regardless of whether they suffer from a serious condition;

RESPONSE: Public Health Law § 3360(7)(a) defines "serious condition" and lists the severe debilitating or life-threating conditions, and the conditions clinically associated with, or a complication of, one of the listed severe debilitating or life-threatening conditions, that are covered under the program. The statute also provides the Commissioner with authority to add additional serious conditions, associated conditions, symptoms or complications. The Commissioner is willing to consider expanding the list of conditions in the future and will take these comments under advisement as part of that analysis. At this time, however, the Commissioner believes the current list is reasonable and supported by scientific-based evidence. As the proposed regulation mirrors the statute, no revisions to the regulations are necessary. Moreover, the Public Health Law § 3360(7)(b) already requires the Commissioner to make a determination whether to add Alzheimer's, muscular dystrophy, dystonia, post-traumatic stress disorder and rheumatoid arthritis as serious conditions within eighteen months from the date the

Compassionate Care Act was signed into law. The Commissioner will make such a determination based upon a review of literature and current scientific evidence.

COMMENT: A commenter suggested clarifying and expanding the definition of "epilepsy" in the regulations by specifying Intractable Seizures caused by conditions traditionally or not traditionally considered epilepsy, and including chromosomal abnormalities/ genetic mutations, brain injuries, brain tumors, cancer, undiagnosed refractory seizures, Lennox-Gastaut Syndrome, Doose Syndrome, Angelman Syndrome, Aicardi Syndrome and Dravet Syndrome, as well as others that are legally allowed recommendations. Another commenter stated that intractable seizure conditions should be added since a patient with an acute brain injury or condition other than Epilepsy would not qualify.

RESPONSE: "Epilepsy" is already included in the list of severe debilitating or life-threatening conditions identified in PHL § 3360(7) and the proposed regulations. Syndromes (including, but not limited to, Lennox-Gastaut Syndrome, Doose Syndrome, and Dravet Syndrome) which are a specific form of epilepsy or syndromes which contain epilepsy as a complicating factor of the syndrome (including, but not limited to, Aicardi Syndrome and Angelman Syndrome) would fall under "epilepsy" listed in 80-1.2(a)(8). Cancer is also listed as a severe debilitating or life-threatening condition under 80-1.2(a)(8)(i). The Commissioner has the authority to add additional serious conditions, associated conditions, symptoms or complications, and will make such a determination based upon a complete review of literature and current scientific evidence.

COMMENT: Some commenters recommended that in the absence of reliable, scientific evidence, no new serious conditions should be added until further research can be done. One

commenter suggested that additional conditions, if added, should be done by the rule making process.

RESPONSE: The Department will take these comments under advisement. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Some commenters suggested that additional illnesses should be added so that practitioners could certify those patients to use medical marijuana as opposed to prescription medications that could arguably be more addictive. A commenter stated that this may provide a non-opioid alternative in the midst of a nationwide opioid epidemic.

RESPONSE: These comments address issues beyond the intended scope of the regulation, and no changes were made to the proposed regulation in response to them. However, the Department will take these comments under advisement.

COMMENT: Several comments were submitted regarding the process for adding new conditions to PHL § 3360(7). Those comments include:

- The Department should identify a clear and transparent, regularly occurring process for how new conditions are added, based on science with criteria for determining conditions to be added, and involve expert advisors and advocates in suggesting best practices that are proven effective.
- The regulations do not provide any legal standard by which the Commissioner will evaluate whether to add or modify the list of conditions for which cannabis products may be dispensed. The Department should publicly release the criteria used when determining inclusion of other illnesses.

- The Department should convene a working group or an advisory board should be formed with the inclusion of industry experts, medical professionals and advocates.
- The Department should consult with experts and patients and review scientific literature in an open forum to determine what conditions should be covered.

RESPONSE: The statute and proposed regulations authorize the Commissioner to add to the list of conditions for which a practitioner may certify a patient for medical marijuana use. The Department will issue guidance on this issue. No changes to the proposed regulation are necessary to address these comments. The Department will consider making a clarifying change to the regulation in a subsequent rulemaking as needed, and will consider these comments in doing so.

COMMENT: A commenter recommended adding language requiring that a diagnosis must be accompanied by a seriously debilitating symptom which has not adequately responded to conventional treatment since many diagnoses that are listed are not inherently serious, especially in early phases.

RESPONSE: Public Health Law § 3361(1) requires that a patient certification only be issued if, 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. The proposed regulations at 80-1.2 requires this statement in the patient certification. No changes to the proposed regulation are necessary.

COMMENT: Several comments were submitted regarding the nexus between the severe debilitating or life-threating conditions listed in the statute, and the conditions clinically

associated with, or a complication of, one of those severe debilitating or life-threatening conditions:

- One commenter stated that the regulations were unclear as to whether a patient qualifies if he or she has a condition without one of the symptoms listed. The commenter suggests to make clear that having the condition, even absent any symptoms would qualify a person.
- A commenter stated that regulations should make clear that the symptom must be a result of that condition or the doctor will be in violation of the law and provided the following example: if a person has cancer pain and receives radiation treatment so that the pain goes away, the person cannot be continued on the marihuana for some other non-cancer related pain.
- One commenter stated that the regulations should not require that the condition result in substantial limitation of function, a requirement not in statute itself.

RESPONSE: Public Health Law § 3360(7)(a) defines "serious condition" as having one of the severe debilitating or life-threatening conditions listed therein, and also having a condition that is clinically associated with, or a complication of, the severe debilitating or life-threatening condition. The proposed regulations mirror the statute as the patient must have at least one of the severe debilitating or life-threatening conditions listed in § 80-1.2(a)(8) and one of the conditions or symptoms listed in § 80-1.2(a)(9) that is clinically associated with, or is a complication of the severe debilitating or life-threatening condition. Only requiring a patient to have a severe debilitating or life-threatening condition without an accompanying condition or symptom would violate the statute. The regulations state that a condition or associated symptom of the severe debilitating or life-threatening condition could include severe or chronic pain, and clarifies that

this condition or symptom must result in substantial limitation of function. No changes to the proposed regulation are necessary.

COMMENT: Several commenters sought additional clarification regarding how the Department will define the scope of certain conditions. Those comments include:

- One commenter stated that the term "neuropathies" needs to be clearly defined otherwise they can be used to permit too broad a use of marihuana. Another commented that the Department should consider requiring proof of neuropathies by an EMG or nerve biopsy test.
- A commenter stated that a physical exam should be performed to diagnose the condition, and test and/or exam results should be documented in the patient's record.
- A commenter stated that to prevent abuse, the terms "severe or chronic pain" and "substantial limitation of function" need better definitions.
- A commenter suggested changing language to include long-term or expected long-term presence of symptoms, not dependent upon the diagnosis.

RESPONSE: Public Health Law § 3361 requires a practitioner, who has completed a course approved by the Department and has been registered with the Department, to attest in the patient certification that the patient has a serious condition (as defined in the statute). A patient certification may be issued if, 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 use of marihuana for the serious condition. The proposed regulations are consistent with the statute. The determination as to whether a patient meets one of the conditions listed, and any supporting medical examination or procedures the practitioner

feels necessary to verify the condition, is within the scope of practice of the practitioner. No changes to the proposed regulation were made as result of these comments.

COMMENT: A commenter suggested that documentation in the patient's medical record should be required to support a determination that the symptoms are severe or life threatening.

RESPONSE: Public Health Law § 3361(1) states that a patient certification may only be issued if the patient has a serious condition (as defined in the statute) which shall be specified in the patient's health care record. The practitioner must, in his or her professional opinion, determine whether the patient meets the requirements for certification. In addition to the requirements of the Compassionate Care Act and the proposed regulations, the practitioner must follow all applicable rules and regulations or standards pertaining to the practice of medicine, which includes any record-keeping requirements. Failing to maintain proper records could be found to be professional misconduct under Education Law § 6530. No changes to the proposed regulation are necessary.

COMMENT: A commenter stated that a patient should be referred for addiction treatment if he or she cannot stop taking their prescribed marihuana due to addiction.

RESPONSE: In addition to the requirements of the Compassionate Care Act and the proposed regulations, the practitioner must follow all applicable rules and regulations or standards pertaining to the practice of medicine. A determination of whether a patient should be referred for addiction treatment is within the scope of practice of the practitioner. No changes to the proposed regulation are necessary.

COMMENT: A commenter stated that any scientific studies considered by the Department in approving marihuana for any condition should include: independent verification where the study is not financed by industry who has a financial gain to be had on the study's outcome, and double-blind controls where the study is done on a significant patient population peer reviewed and published in a respectable journal dedicated to medicine or the particular illness. A comment was received that a controlled comparison of medical marihuana to existing medications for the particular illness could also be performed. A commenter noted that the anecdotal reports regarding "medical" marihuana are not reliable as scientific evidence because the claimed benefits are not independently verified and do not reflect double-blind controls.

RESPONSE: The Commissioner has the authority pursuant to Public Health Law § 3360(7) to add additional serious conditions, associated conditions, symptoms or complications, and will make such a determination based upon a complete review of literature and current scientific evidence. The Department will take these comments under advisement in making such a determination. No changes to the proposed regulation are necessary.

COMMENT: Several comments were submitted regarding record-keeping requirements, location and storage of records, and electronic record retention by practitioners, including:

- A commenter suggested that document retention should include retention of signed original copies by scanning the original and retaining it in a practitioner's Electronic Health Record ("EHR"), in addition to physical file formats.
- A commenter stated that requiring retention of a hard copy of the patient certification, in addition to its retention in the patient's medical record, will create redundancy and discrepancy with patients' records.

- A commenter recommended cross referencing regulatory standards for retention of records related to controlled substances.
- A commenter also stated that documentation requirements would discourage practitioners from participating in the program.

RESPONSE: Public Health Law § 3361(2) requires that the patient certification include the handwritten signature of the certifying practitioner. The proposed regulations are consistent with Public Health Law § 3361(5), which requires that the practitioner give the certification to the patient and place a copy in the patient's health care record. No changes to the regulation are necessary to address these comments.

COMMENT: A commenter stated that a patient taking medication could be arrested for not having their card immediately available for the purpose of proving that possession of the medical marihuana was lawful.

RESPONSE: Public Health Law § 3362 requires that a person possessing medical marihuana possess his or her registry identification card at all times when in immediate possession of medical marihuana. The proposed regulations are in accord with these requirements. No changes to the proposed regulation is necessary.

COMMENT: Comments were received supporting use of the prescription monitoring program (PMP) or I-STOP, within the Health Commerce System, as follows:

- Require physicians to check a patient in the I-STOP registry before recommending marihuana.
- Require physicians to enter patient certification data in I-STOP.

- Require dispensaries to check each time marihuana is dispensed to a patient or caregiver.
- Require the pharmacist employed by the dispensary to enter data into I-STOP as they do now for actual prescriptions.

RESPONSE: Requirements that practitioners and registered organizations use the PMP are expressly included in the statute and proposed regulations. Pursuant to Public Health Law § 3361(4), every practitioner shall consult the PMP registry prior to making or issuing a certification. Pursuant to Public Health Law § 3364(5)(b), all dispensaries must consult the PMP prior to dispensing medical marihuana to a certified patient. The proposed regulations further require dispensing facilities to submit dispensing data to I-STOP within 24 hours. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A commenter voiced support for allowing a physician to certify a patient for a shorter time period and allowing physicians to terminate the certification if in his/her medical judgment the use of marihuana is not working for the patient.

RESPONSE: The proposed regulations are consistent with Public Health Law § 3361(8)(a), which allows a practitioner to state in the certification that, in the practitioner's professional opinion, the patient would benefit from medical marihuana only until a specified earlier date, and in those circumstances, the certification will expire on that date. Section 80-1.1(b)(1) provides that the patient's certification shall state the date upon which it expires, which shall not be longer than one year (except if a patient is terminally ill).

COMMENT: A commenter suggested revising the regulations to clarify that practitioners can purchase medical marihuana or vaporizers for otherwise lawful use (such as their own use or for patient demonstrations).

RESPONSE: A practitioner may only obtain medical marihuana for his or her own use if the practitioner meets the definition of "certified patient" in Public Health Law § 3360(3) and has been issued a patient registry identification card. Section 80-1.22 of the proposed regulation prohibits a practitioner from issuing him or herself a patient certification in order to apply for a patient registry identification card. With respect to purchasing vaporizers for patient demonstrations, a pharmacist is required to be on-site at the dispensing facility to assist certified patients or their designated caregivers, including on proper use of vaporizers. No change to the proposed regulation has been made as a result of this comment.

COMMENT: Commenters asked how the Commissioner would provide information or guidelines for dosing when there is inadequate dosing information in the literature, and little or no scientific evidence available. A commenter further noted that given the variety of cannabis based products and formulations, the physician may not have sufficient information and training necessary to provide required prescription information for brand, form, administration method and dosage (even with the four hour training requirement).

RESPONSE: Pursuant to § 80-1.1, the required education course will include information on dosing and routes of administration. Information concerning specific dosing recommendations are beyond the intended scope of the regulation, and no changes were made to the proposed regulation in response to these comments. However, the Department will take these comments under advisement.

COMMENT: A commenter requested clarification as to what constitutes terminally ill or terminal illness in the context of the period of time within which a certification is valid. A comment also suggested that the Department define "normal course" as used in the statutory definition of terminally ill.

RESPONSE: PHL § 3360(13) defines "terminally ill" as an individual who has a medical prognosis that the individual's life expectancy is approximately one year or less if the illness runs its normal course. Determining whether a patient meets the terminally ill standard is subject to his or practitioner's judgment, and beyond the intended scope of the regulations. No changes to the regulation were made as a result of this comment.

COMMENT: A commenter stated that the proposed regulations describe the Department's ability to "decertify" patients, even though the Compassionate Care Act grants this responsibility to the patient's practitioner as a decision related to the care and treatment of the patient. The commenter also noted that Public Health Law § 3361 does not grant such authority to the Department.

RESPONSE: The proposed regulations do not contain provisions that allow the Department to "decertify" patients. Certification of a patient who meets the requirements of the Compassionate Care Act is instead left to the registered practitioner's discretion. However, Public Health Law § 3363(15) authorizes the Department to suspend or a revoke registry identification card if a certified patient or designated caregiver willfully violates any provision of Title V-A as determined by the Department.

COMMENT: A commenter sought a definition of "qualifying patient" as used in § 80-1.2(a).

RESPONSE: A "qualifying patient" refers to a patient who has one of the serious conditions listed in § 80-1.2(a)(8) and a condition or symptom listed in § 80-1.2(a)(9) that is clinically associated with, or a complication of the serious condition.

COMMENT: A commenter suggested removing the requirement that a practitioner state a patient's diagnosis and personal information on the certification, as it violates patient confidentiality and privacy laws.

RESPONSE: Identification of a patient's diagnosis is necessary to ensure that only patients who meet the qualifications set forth in statute and regulations are authorized to obtain medical marihuana. Section 80-1.2(b)(15) of the proposed regulations requires that the practitioner include in the certification a statement that the patient, or the patient's parent or legal guardian, if applicable, has provided informed consent. Accordingly, practitioners are required to obtain consent from patients prior to providing any information concerning the patient on the patient certification form.

COMMENT: A comment was received suggesting that provisions requiring practitioners to advise patients or their guardians of risks of medical marihuana are unnecessary given other laws governing medical practice. Another commenter recommended that rather than requiring a practitioner to explain the potential risks and benefits of the use of medical marihuana to the qualifying patient and documenting such in the patient's medical record, it could be done in the safety insert as with an FDA package insert on prescription medications.

RESPONSE: The proposed regulations seek to ensure that patients and their guardians are advised by the practitioner of the potential risks and benefits of the use of medical marihuana.

The Department believes this provision is necessary to protect the patient's health and safety. Further, an FDA package insert is not specific to a patient and does not substitute for a practitioner's evaluation of the patient to determine the individual patient's risk versus benefit. No changes to the proposed regulation were made as a result of this comment.

COMMENT: A commenter requested that the words "Presenting Certification" before the words "Medical Retention" be added to § 80-1.3(d) for clarity.

RESPONSE: The Department believes the commenter was referring to § 80-1.2(d), entitled "Medical Record Retention." This section makes clear that the practitioner is required to maintain a copy of the signed certification in the patient's medical record. No changes to the proposed regulation were made as a result of this comment.

COMMENT: A commenter noted that it may be difficult for a physician to include the authorized brand on the patient certification since the brands will be specific to the registered organizations. The commenter also noted that it will be especially difficult for physicians to recommend an authorized brand before growing and manufacturing has been completed.

RESPONSE: The Department will take these comments under advisement and determine whether clarification is needed through guidance or future rulemaking.

COMMENT: A commenter recommended that all patients receiving marihuana receive a base line drug screen to determine whether any drugs are in the patient's system before a doctor is allowed to certify a patient for medical marijuana. The commenter also suggested that all registered physicians provide their certified patients with monthly drug screens. Another

commenter suggested that marihuana should be used as a last resort for patients who have tried traditional medications unsuccessfully and that the patient's medical record should document the medications tried, the length of time used, and the absence of improvement.

RESPONSE: Public Health Law § 3361(1) states that a certification may only be issued if, 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 use of marihuana for the serious condition. It is within the practitioner's scope of practice to determine whether and to what extent laboratory procedures are necessary to properly monitor his or her patients. No revisions to the regulation are necessary to address these comments.

COMMENT: A commenter stated that if the Department is responsible for building and maintaining a secure website for electronic transmission, it could be very costly and may spend fees that should be used for enforcement.

RESPONSE: This comment addresses issues that are beyond the intended scope of the regulation, and no changes were made to the proposed regulation in response to them.

COMMENT: A commenter stated that practitioners often find it necessary to adjust a dose or make other changes in a patient's medication regimen. The commenter noted that the proposed regulations should include the flexibility to allow such adjustments without the need to issue a new certification (with a new registry ID card and new fees), or to wait until the certification expires. The commenter also noted that this could cause practitioners to avoid the inclusion of any limitations in a certification.

RESPONSE: The Department will implement the technology necessary to support the certification process and will do so in a manner which will allow practitioners to make changes to dosing recommendations within the timeframe of the certification. No revisions to the regulation are necessary to address this comment.

COMMENT: A commenter stated that several subsections contained in § 80-1.2 require physicians to perform tasks that go beyond what federal courts have said physicians may do with respect to state medical marihuana programs. The commenter specifically referenced the *Conant* decision, which limits the type of information a physician may include with a medical marihuana recommendation. The commenter noted that physicians may be unwilling to participate in the program with the requirements this section imposes and suggested striking Section 80-1.2(a)(12).

RESPONSE: It is the Department's opinion that the information required for patient certification is in line with the decision in *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002). Public Health Law § 3361(3) provides that that practitioner shall state in the certification any "recommendation or limitation the practitioner makes, in his or her professional opinion, concerning the appropriate form or forms of medical marijuana and dosage." The regulations include this language and require the recommendation of the practitioner concerning forms and dosage. A patient may not obtain medical marihuana from a registered organization utilizing a patient certification. Instead, a patient must apply for and obtain from the Department a registry identification card in order to access medical marihuana. A certification is only one of the documents required for a patient to obtain a registry identification card.

COMMENT: A commenter suggested that the regulations make clear that those with criminal records who are eligible for services should have the ability to access services.

RESPONSE: A certification may be issued to a patient who has one of the severe debilitating or life-threatening conditions defined in § 80-1.2(a)(8) and clinically associated condition or complication listed in § 80-1.2 (a)(9), so long as the patient's practitioner is registered with the Department and determines in his or her clinical discretion that a certification for medical marijuana is appropriate for the patient, and all other requirements of certification are met as defined in § 80-1.2(a). A patient's criminal history is not a factor considered for issuance of a patient certification. No revisions to the regulation are necessary to address these comments.

COMMENT: A commenter stated that requiring a practitioner's DEA number as well as the statement that "the practitioner is licensed and in good standing in NYS and possesses an active registration with the DEA" should be deleted from the regulations. The commenter noted that practitioners will not be writing prescriptions regulated by the DEA but rather recommendations, and this requirement may limit the number of practitioners willing to register and issue certifications.

RESPONSE: Marijuana is classified as a controlled substance under New York State Public Health Law, including the Compassionate Care Act. These regulations support the requirement that the certification of medical use of marijuana is appropriate by requiring that practitioners be appropriately licensed or registered for both the practice of medicine as well as authorizing the use of controlled substances. As such, the regulations require that a practitioner be licensed within the State, be in good standing, and possess an active registration with the Drug

Enforcement Agency (DEA). No changes to the proposed regulation were made as a result of this comment.

COMMENT: A commenter suggested removing the word “if” in “if required by law” for the requirement that the practitioner document in the patient's medical record a statement that the patient, or the patient's parent or legal guardian if applicable, has provided informed consent, if required by law.

RESPONSE: The Department will take this comment under advisement in future changes to the regulations. No changes to the proposed regulation were made as a result of this comment.

COMMENT: Several commenters recommended that the Department explicitly indicate that a physician’s certification alone is not enough to allow a person to lawfully use or possess marihuana.

RESPONSE: Public Health Law § 3362 provides that the use of medical marihuana by a certified patient or designated caregiver is lawful only when possessing a valid registry identification card, and the certified patient must possess his or her registry identification card at all times when in immediate possession of medical marihuana. A registered organization may lawfully sell medical marihuana to a certified patient or designated caregiver upon presentation of a valid registry identification card. Public Health Law § 3364. The patient certification is just one of the items needed to apply for the registry identification card.

COMMENT: A commenter stated that mandating a visit to a physician to refill a prescription every 30 days will place an undue burden on already overburdened providers.

RESPONSE: The proposed regulations do not require a certified patient to visit a practitioner every 30 days in order to refill his or her prescription. Practitioners will not be issuing prescriptions under the proposed regulations but will be certifying patients for the medical use of marihuana. Patient certifications may be issued for up to one year, unless the patient is terminally ill in which case the certification shall not expire until the patient's death or the certifying practitioner revokes the certification.

COMMENT: A commenter stated that the regulations seem to prohibit a physician from certifying patients if the physician is employed by a health system that obtains a registration as a registered organization. Another commenter suggested that certain payments and business practices should not be treated as an offense, such as when there is a bona fide employment relationship between the practitioner and registered organization.

RESPONSE: The regulations contain provisions prohibiting conflicts of interest necessary to ensure the proper care and administration of the registered organization's activities. No changes have been made to the proposed regulation as a result of these comments.

80-1.3 Comments: Application for Registration as a Certified Patient

COMMENT: Several comments focused on the Department's ability to develop and implement timely and expeditious registration process for registry identification cards. Commenters suggested:

- Developing a unified patient registration application.
- Making sure the regulations provide clear, specific and non-conflicting parameters for the approval process for qualified practitioners and patients.

- Notifying applicants of incomplete applications immediately
- The Department's decision to reject an application should not delay or interfere with patient care even though the certification has been issued.
- That the patient and caregiver registration process does not need to be electronic.
- **RESPONSE**: Section 80-1.3 of the proposed regulations requires the Department to issue registry identification cards as soon as reasonably practicable after Department approval of the application. The Department is developing and implementing a single electronic process for practitioners to issue certifications, and for patients and designated caregivers to apply for registry identification cards. This will ensure a more timely, efficient and expeditious process that is fully compliant with the statute and regulations. The Department will consider the comments concerning the approval process for qualified practitioners and patients and determine whether clarification is needed through guidance or future revisions to the regulations. With respect to the comment stating that patient care should not be delayed or interfered with even though a certification has been issued, Public Health Law § 3364 (4) provides that a registered organization may lawfully dispense medical marihuana product to a certified patient when presented with a registry identification card. A registered organization may not dispense medical marihuana products to a certified patient who does not hold a valid registry identification card. Applications for registry identification cards will be reviewed in a timely manner. The proposed regulations at 80-1.3(g) require the Department to approve, deny or determine incomplete or inaccurate a registry identification card application within thirty days of receipt of the application. No changes have been made to the proposed regulation as a result of the comments.

COMMENT: A commenter noted it was unclear whether the Department will review applications within 30 days or "as soon as reasonably practicable," as the proposed regulations reference both. The commenter noted that if the intent is to add an additional 30 day period to the "reasonably practicable" timeframe, this may not comport with legislative intent and could unnecessarily delay the issuance of registry ID cards.

RESPONSE: The proposed regulations require the Department to approve, deny or determine incomplete or inaccurate an application within 30 days of receipt of the application. The additional 30 day time period is provided in the event that an application is incomplete or factually inaccurate, to provide the applicant an opportunity to submit materials that would complete or substantiate information in the application. The Department will provide guidance concerning the certification and registration process. No revisions to the regulation are necessary to address these comments.

COMMENT: A commenter requested clarity as to the specific technical specifications of the physical registry identification cards that will be issued by the Department, stating that registered organizations will need to build the proper technical infrastructure to read and communicate with the data included in the cards.

RESPONSE: This comment addresses matters beyond the intended scope of the regulations. The Department will issue guidance to registered organizations regarding the specific technical specifications of the registry identification cards to ensure that potential applicants have sufficient information to develop their technical infrastructure.

COMMENT: Several commenters requested that patients be able to begin registering prior to the opening of dispensing facilities.

RESPONSE: Implementation timelines are beyond the intended scope of the regulation. However, in order to ensure expeditious access to medical marijuana, the Department will ensure that patients, who have been issued a certification by a practitioner registered with the Department, have the ability to apply for a registry identification card prior to the opening of dispensing facilities.

COMMENT: Several comments addressed the $50 application fee required to register as a certified patient.

- Many commenters noted there is no defined standard of "hardship" for waiving the fee and requested explicit standards for financial hardship.
- Many commenters suggested using SNAP, Medicaid, SSI, and temporary assistance for needy families as examples of standards for determining financial hardship.
- Several commenters noted that the non-refundable application fee is cost prohibitive to low-income individuals.
- Many commenters requested a reduction of the application fee.
- A commenter questioned why there was a $50 fee for a registry identification card when New York State will be imposing an excise tax on the product.
- A commenter stated that there are other items provided by the State to people without charge, as is the case with handicapped tags.

RESPONSE: Public Health Law § 3363(2)(f) requires the Department to charge a $50 fee for registry identification card applications. However, the Department is also expressly authorized

to reduce or waive the fee in cases of financial hardship. The proposed regulations mirror Public Health Law § 3363(2)(f). The Department will provide guidance concerning the criteria for financial hardship, and will take the comments received under advisement when doing so. No revisions to the regulation are necessary to address these comments.

COMMENT: Commenters asked whether or not it is permissible, once registration is obtained, for a certified patient under the age of eighteen to purchase medical marihuana from a dispensing facility.

RESPONSE: No. Public Health Law § 3363(3)(b) requires a certified patient under the age of eighteen to designate a caregiver, who shall be (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. Section 80-1.3(e)(1) states that the applicant for a minor is required to acknowledge that a parent, legal guardian or other appropriate person, as applicable, will control the acquisition and possession of the medical marihuana and any device for its administration. Therefore, the minor patient's designated caregiver(s) will be in charge of acquiring any medical marihuana and the minor patient will not be allowed to purchase medical marihuana from a dispensing facility.

COMMENT: A commenter suggested narrowing the provision that allows the Department to ask for "other identifying information," because it could be an unwarranted invasion of privacy.

RESPONSE: The Department will consider this comment as it develops the registry identification card application and renewal application.

COMMENT: Several comments were received concerning the ability of non-New York State residents to participate in the medical marijuana program. Those comments include:

- A commenter indicated that the statute does not provide for non-New York State residents and that the Department should not encourage people from other states to come to New York to use marihuana.
- A commenter suggested the Department remove the temporary residency requirement from the proposed regulations, stating that individuals living in New York for only part of the year may be excluded.
- A commenter noted that requiring proof of residency for both resident and non-resident patients is burdensome and not required by statute.
- A commenter suggested the regulations provide reciprocity to patients who are non-New York State residents but who are certified patients in another state that permits medicinal marihuana.

RESPONSE: Public Health Law § 3360(3) defines "certified patient" as a patient who is a resident of New York, and specifically limits the ability of non-New York State residents to participate in the medical marijuana program solely to those patients who are in New York for purposes of receiving care and treatment as determined by the Commissioner in regulation. The proposed regulations are in accord with the statute, and provide specific guidance regarding the types of documentation necessary to satisfy this standard. Federal law and policy prohibits New York State from providing reciprocity to patients who are certified to use medical marijuana in another state.

COMMENT: A commenter suggested adding language to the accepted forms of documentation for proof of temporary residency, to include instances where patients live with relatives or friends.

RESPONSE: Section 80-1.3(c)(1) requires an applicant who is a non-New York State resident to submit proof of temporary residence in New York State, including but not limited to a lease, utility bill, hospital bill, or such other documentation as approved by the Department. The Department will provide guidance concerning acceptable documentation, and will take this comment under advisement. No changes to the proposed regulation were made as a result of this comment.

COMMENT: A commenter noted that patients should be allowed to take medical marihuana out of the state as this would not constitute "diversion" under the Department of Justice memo.

RESPONSE: This is incorrect and would violate federal law and policy. Section 80-1.3(c)(2) provides that nothing in the regulations shall be construed to grant to an applicant authorization to transport approved medical marijuana products outside of New York State. This position is in line with the requirements for a "strong and effective regulatory and enforcement system" referenced in the memo from James M. Cole, Deputy Attorney General, US Department of Justice to United States Attorneys, dated August 29 2013, which states the following when considering marijuana-related enforcement priorities: in jurisdictions that have enacted laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale and possession of marijuana, conduct in compliance with those laws and regulations is less likely to threaten the federal enforcement priorities set forth in said memo.

COMMENT: A commenter suggested making registry identification cards valid from the date of issuance rather than the date the patient is certified. The commenter noted that patients may not receive an identification card for up to 30 days after submitting their application to the Department and that patients should not be short-changed any time for their period of safe and legal access.

RESPONSE: Public Health Law § 3361(7) provides that a registry identification card shall expire one year after the date the patient certification is signed by the practitioner. Therefore the registry identification card cannot have an expiration date that is tied to anything other than the date the patient certification is signed by the practitioner. The proposed regulations are in line with this statutory requirement. No revisions to the regulation are necessary to address this comment.

COMMENT: A commenter noted that it would be unnecessarily burdensome to require two separate applications with accompanying fees, where a parent or guardian will be a designated caregiver (for both the patient and the designated caregiver). The commenter recommended a single streamlined application for parents or guardians of minors or adults who cannot consent to medical treatment, allowing both applications to be submitted at the same time, with a single set of documentation and waiving the second $50 fee.

RESPONSE: Public Health Law § 3363(2) sets forth the process for issuing registry identification cards to certified patients and designated caregivers, and establishes a $50 fee for each application. Public Health Law § 3363(8) further requires the Department to issue separate registry identification cards to certified patients and designated caregivers. The proposed

regulations are in line with this statutory requirement. No changes to the proposed regulation were made as a result of this comment.

80-1.4 Comments: Designated Caregiver Registration

COMMENT: Several comments were received concerning the number of patients a designated caregiver may have. The comments include:

- Several commenters noted that limiting designated caregivers to five patients does not contemplate the administration of medical marihuana to patients in hospitals or long term residential treatment facilities such as nursing homes.
- A commenter suggested that health systems should be allowed to be designated caregivers to more than five patients because there may be circumstances where a custodial care organization (hospice or long term care facility) may reasonably exceed this number.
- A commenter recommended adding the words "more than" before the word "five" to 80-1.4(b)(9), because it makes it seem as though a caregiver can only have four certified patients.

RESPONSE: A designated caregiver is defined in Public Health Law § 3360(5) as "the individual designated by a certified patient in a registry application." A designated caregiver must be an individual and may not be an entity, such as a business or health care facility. Public Health Law § 3363(5) further provides that a person may be a designated caregiver for no more than five certified patients at one time. The proposed regulations are consistent with the statute. The information on the designated caregiver registration will be used to determine whether the Department's acceptance of such registration would cause the potential caregiver to exceed the

five patient limitation. Employees of health care facilities are not prohibited from serving as designated caregivers for up to five patients. The Department will consider whether clarification is needed in future revisions to the regulations.

COMMENT: Comments were received concerning who can serve as a designated caregiver. Those comments include:

- A commenter stated that a "business of caregiving" will develop which could potentially exploit patients with limited access to a dispensary. The commenter suggested that any caregiver with more than one patient and who is not a health care professional be required to register for a special "for profit caregiver" license and be held to higher standards.
- A commenter sought clarification as to whether home health workers, palliative care operators or other similar providers could be designated caregivers or if they are excluded because they are the patients' provider.
- A commenter wrote that any organization that provides palliative care and is authorized by the Department should be allowed to be designated as one of the caregivers, and any employee of the organization is therefore included as a registered caregiver.

RESPONSE: A designated caregiver is defined in Public Health Law § 3360(5) as "the individual designated by a certified patient in a registry application." A designated caregiver must be an individual and not an entity, including a business or health care facility. The proposed regulations are consistent with statute and require an individual to be a designated caregiver. With respect to practitioners serving as designated caregivers, the statute only prohibits registered practitioners from serving as designated caregivers for their own patients.

There is no prohibition on registered practitioners serving as designated caregivers for other registered patients. Furthermore, "practitioner" in Public Health Law § 3360 is defined to mean a physician, and therefore, there is no prohibition on other health care professionals acting as a designated caregiver for a certified patient. The Department will consider these comments and determine whether clarification is needed through guidance or future revisions to the regulations.

COMMENT: A commenter asked whether caregivers are required to be New York State residents, and noted that if they are, access could be limited to non-New York State residents who qualify as a non-resident receiving care and treatment in New York.

RESPONSE: A non-New York State resident who meets the requirements of statute and regulations and is issued a patient certification, must designate a caregiver that is a New York State resident and receives a registry identification card from the Department if the non-New York State patient wishes to utilize a designated caregiver.

COMMENT: A commenter suggested that as a mechanism to provide emergency access, caregivers be allowed to purchase, transport or cultivate marihuana in limited quantities if their certified patients reside a set distance away from a registered organization and the caregiver is registered with the State.

RESPONSE: Public Health Law § 3362 only allows designated caregivers to possess, acquire, delivery, transfer, transport, or administer medical marihuana produced in accordance with the State's medical marijuana program. It does not allow designated caregivers to cultivate or manufacture marihuana. The proposed regulations are in line with this statutory construct. No changes to the proposed regulation were made as a result of this comment.

COMMENT: Several comments were received regarding review of a designated caregiver's background and criminal record. Commenters suggested:

- That if a person has a felony drug conviction he or she should not qualify as a designated caregiver.
- That if a designated caregiver violates the Controlled Substance Act or any terms of the Compassionate Care Act, he or she should have an obligation to report such violation and should lose caregiver status.
- The Department should require prospective caregivers to include evidence of good moral character in their application, including willingness to sign a statement that they will conduct their caregiver activities in an ethical manner.

RESPONSE: The Compassionate Care Act does not authorize criminal background checks on a designated caregiver through the NYS Division of Criminal Justice Services. Nevertheless, numerous provisions in the statute and the proposed regulations place important checks on designated caregiver activity. Public Health Law § 3364 (15) provides the Department with authority to suspend or revoke a registry identification card of a designated caregiver who willfully violates law. Section 80-1.4 of the regulation requires designated caregiver applicants to include a statement that they will secure and properly handle medical marihuana products and acknowledge that a false statement in the application is punishable under Penal Law § 210.45. In addition, § 80-1.23 sets forth designated caregiver prohibitions. Willful violations of law or regulation are also subject to Public Health Law § 12-b that authorizes imprisonment, not to exceed one year, or by a fine not exceeding $2,000 dollars, or both. Furthermore, Article 179 of the Penal Law was amended to define criminal diversion of medical marihuana in the second

degree, a class B misdemeanor, and criminal retention of medical marihuana, a class A misdemeanor.

COMMENT: A commenter stated that designated caregivers should not have to swear they will properly handle medical marihuana product as they are bound by law already to do so.

RESPONSE: The regulations seek to ensure that designated caregivers are aware of the requirements concerning securing and properly handling medical marihuana. No revisions have been made with respect to this requirement.

COMMENT: A commenter stated that there should be a process for notice if a certified patient terminates a designated caregiver.

RESPONSE: Section 80-1.19(i) sets forth a process in the event a certified patient wishes to change or terminate his or her designated caregiver. No revisions to the regulation are necessary to address this comment.

COMMENT: A commenter stated that the amount of marihuana for each patient should be indicated somewhere on the designated caregiver's registry identification card.

RESPONSE: Information concerning the information to be included on the designated caregiver's registry identification card is beyond the intended scope of the regulation, and no changes were made to the proposed regulation in response to these comments. The Department will consider this comment when designing the registry identification cards.

80-1.5 comments: Application for Initial Registration as a Registered Organization

COMMENT: Comments were received regarding agricultural requirements for registered organizations:

- A commenter asked whether the production facility must be located on property that is in an agricultural district.
- A commenter stated that New York State growers are well suited to produce marihuana as they have the agricultural experience and land necessary.
- A commenter asked whether the New York State Department of Agriculture and Markets would oversee the production of marihuana, as they do with other agricultural commodities.
- A commenter asked whether members of a registered organization have to be an Agriculture and Markets registered grower or business.
- A commenter noted that someone with experience in agricultural commodities in New York State should be part of a registered organization's senior staff.

RESPONSE: Public Health Law § 3364 (8) & (9) require that manufacturing and dispensing of medical marihuana shall only be done in an indoor, enclosed, secure facility located in New York State, which may include a greenhouse. Section 80-1.5 requires an applicant for registration as a registered organization to include a standard operating procedure manual which must embrace the use of good agricultural practices and conform to all applicable laws and rules of New York State. In addition, registered organization applicants must submit a staffing plan that includes a senior staff member with a minimum of one (1) year experience in good agricultural practices (GAP) as referenced in § 80-1.5. Section 80-1.11 further requires registered organizations to use GAPs and conform to all applicable laws and rules of New York State. Registered organizations are also required to maintain records of soil, soil amendments,

nutrients, hydroponic materials, fertilizers, growth promoters, pesticides, fungicides, herbicides and any other materials used. The Department will consult with the Department of Agriculture and Markets and the Department of Environmental Conservation concerning the use of pesticides, fungicides and herbicides as well as any additional guidance necessary to effectuate these provisions of the regulations. It is at the discretion of the applicant to determine whether their business and staffing plans should include resources such as those suggested by the commenters. No revisions to the regulation are necessary to address these comments.

COMMENT: A commenter sought clarification on how large a grow site should be and how much room will be needed, indicating that Denver has close to 4.5 million square feet of marihuana cultivation.

RESPONSE: There are no restrictions on the size of a registered organization's grow site. Applicants will need to determine the size of a grow site based upon the applicant's proposed business plan. As set forth in Section 80-1.5 of the regulations, the Department will consider this information when evaluating a registered organization's application. No changes to the regulation are necessary to address this comment.

COMMENT: Several commenters suggested the Department provide greater detail for the numerous operating plans, policies and procedures referenced throughout the proposed regulations, by giving a more exact description of what each plan, policy or procedure should include. Specific comments included:

- How to investigate a product complaint; what is entailed in a recall plan; what are specific process controls to capture data for a batch record; and what are minimum sanitation practices for a cultivation operation.
- Approved methodologies for destruction of the product and raw materials. The commenter recommended disposal through mixing the product with bleach or dirt.
- Whether a registered organization applicant needs to be a NYS Department of Environmental Conservation (DEC) licensed commercial pesticide applicator.

RESPONSE: The Department cannot specify a single operating plan that will fit the needs of each registered organization due to differences in organizational structure, manufacturing, and other variances between organizations. A person who is applying pesticides must meet the NYS Department of Environmental Conservation license requirements and must use a pesticide approved by the Department of Agriculture and Markets. The Department will issue guidance concerning adverse event reporting, disposal methods, and recalls outside of the regulations and will consider whether clarification is needed in future revisions to the regulations.

COMMENT: A commenter recommended the Department select registered organizations which are New York owned and operated agricultural/pharmaceutical companies with client-centered, environmentally-friendly and affordable medical marihuana market team visions.

RESPONSE: The statute and regulations do not limit applicants to organizations formed in New York State. However, the manufacturing and dispensing facilities of the registered organization must be located in New York State.

COMMENT: A commenter asked whether a registered organization's manufacturing and dispensing facilities will be required to register with the DEA for a DEA Number.

RESPONSE: A registered organization's manufacturing and dispensing facilities will not be required to register with the DEA for a DEA number.

COMMENT: Several comments were received concerning the manufacturing practices of registered organizations. Those comments include:

- A commenter recommended the use of greenhouses.
- A commenter suggested that registered organizations be certified in the use of good agricultural practice (GAP).
- A commenter suggested a co-generation setup for heat/electricity/CO2; or a 4-5 acre solar farm to go along side of the production facility.
- A commenter noted that the proposed regulations conflicts with cGMP approach, used by the FDA, and interferes with US drug manufacturing standards and processes. The commenter recommended revising § 80-2 to follow the concepts and structure of the cGMP model and make accepted industry standards the benchmark for implementation of the act.

RESPONSE: Public Health Law §§ 3364(8)-(9) require that manufacturing and dispensing of medical marihuana shall only be done in an indoor, enclosed, secure facility located in New York State, which may include a greenhouse. Section 80-1.5 requires an application for registration as a registered organization include a standard operating procedure manual which must embrace the use of GAP and § 80-1.11 further requires registered organizations to use GAPs. In addition, applicants must submit a staffing plan that includes a senior staff member

with a minimum of one (1) year experience in GAP. It is at the discretion of applicants to determine whether their standard operating procedure manual and business plan will include a co-generation setup or solar panels. Section 80-1.5 (b)(4) requires applicants to include a detailed description of the registered organization's manufacturing processes. The regulations do not prohibit a manufacturer from incorporating manufacturing methods from the cGMP approach, but this information must be included in their submitted operating plan. No changes to the proposed regulation are necessary to address these comments.

COMMENT: Several comments were received regarding a registered organizations' manufacturing facilities. Those comments include:

- Commenters asked if there will be any limitation on the distance between the manufacturing location and one or more of the permitted dispensing facilities.
- A commenter recommended allowing a registered organization to grow and manufacture product in more than one location.
- A commenter recommended changing "or" to "and" in §§ 80-1.10(b)(1)-(2), unless the Department's intent was to allow growing and manufacturing at different sites.
- Commenter stated that a registered organization should be able to make use of an available cGMP facility already built and approved by regulatory agencies, including through a contract arrangement, where the extracted product can be transported and produced in a finished form.
- Comment was received asking if the manufacturing of final medical marihuana product be completed in an existing, nearby, OSHA/FDA approved pharmaceutical production

facility if all transportation of extracted medical marihuana products and onsite security meets all standards proposed by Registered Organization.

RESPONSE: The statute and regulations do not provide for a specific distance limitation between the manufacturing and dispensing facility. The definition of "manufacturing" in 80-1.11 includes cultivation, harvesting, extraction (or other processing), packaging and labeling. Growing of medical marihuana must occur at the manufacturing facility. A registered organization may have more than one manufacturing facility for all of its manufacturing activities, provided that all real property, buildings and facilities used in the manufacturing process were properly identified in the registered organization's application in accordance with § 80-1.5(b)(2) and specified in the registration. The regulations do not prohibit an applicant from utilizing an available cGMP facility or OSHA/FDA approved pharmaceutical production facility provided that the employees of these facilities are employees of the registered organization, not contractors. No revisions to the regulation are necessary to address these comments.

COMMENT: A commenter stated that the use of greenhouses should be eliminated or registered organizations who use greenhouses should be required to have designs that provide additional security and obscure side views (including rigid walls and reinforced structures) and are sealed to prevent odor and product from leaking out of the facility/and to keep pests and impurities from entering the facility.

RESPONSE: Public Health Law §§ 3364 (8)-(9) require that manufacturing and dispensing of medical marihuana by a registered organization shall only occur in an indoor, enclosed, secure facility located in New York State, which may include a greenhouse. The proposed regulations

are in line with this statutory requirement. Section 80-1.5(b)(10) of the proposed regulations require an applicant to submit architectural design and sketches of the proposed manufacturing and dispensing facilities. Registered organizations must be able to comply with the security requirements defined in 80-1.13. With respect to the concern regarding pests and impurities entering the facility, the regulations require the use of good agricultural practices and the laboratory testing requirements in 80-1.14 also require testing of the final medical marihuana product for contaminants. No changes to the proposed regulation were made as a result of this comment.

COMMENT: A commenter noted the proposed regulations do not require a registered organization applicant to disclose any prior bankruptcy filings. The commenter stated that fiscal responsibility is an important issue and that a period of no less than 10 years since the filing of a bankruptcy should be a fair time period for disclosure as it pertains to potential applicants.

RESPONSE: Section 80-1.5(b)(13) of the proposed regulations requires 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. The intent of this provision was to ensure the fiscal responsibility of the applicant, its owners and officers and directors. The Department agrees with the commenter and will make this clarification to the proposed regulations as it pertains to specifically naming the applicant. With respect to the time period to be considered since the filing of a bankruptcy as recommended by the commenter, the proposed regulations do not

specify a time period or limitation to this reporting requirement. No revisions to the regulation with respect to the time period have been made.

COMMENT: Comments were received regarding the $2,000,000 bond which can be furnished by applicants in lieu of furnishing copies of all deeds and leases for properties to be used for the growing and/or dispensing of medical marihuana. Those comments include:

- A commenter asked what coverage would be afforded by the bond, as well as what obligations the bond would be securing.
- A commenter noted that furnishing a bond to secure an activity that is legal under state law, but may be illegal under federal law, places the surety into an unusual dynamic.
- A commenter stated that an applicant with limited net worth and capital may have difficulty securing a $2,000,000 bond.
- A commenter recommended that a letter of intent from the facility owner should be sufficient.
- A commenter also requested that the bond requirement be changed to not less than $10,000,000.

RESPONSE: Consistent with Public Health Law § 3365(1)(a)(ii)(B), the proposed regulations require a registered organization applicant to show the possession or right to use of land, buildings, and equipment to carry on the registered organization's activities, or in the alternative to post a bond of not less than $2,000,000. The regulations state that if an applicant posts a bond in lieu of providing documentation of sufficient land, buildings and equipment, and the applicant is selected to be granted a registration, the applicant will be required to submit applicable executed deeds, leases and rental agreements prior to issuance of the registration to the

applicant. The bond will be used to guarantee that the applicant chosen for registration will obtain possession or right to use land, buildings, and equipment sufficient to carry on the registered organization's activities prior to the registration being awarded. The bond is subject to forfeiture if the applicant selected for registration fails to obtain possession or right to use the land, buildings, and equipment as described in the application approved by the Department. The bond is not intended to secure the ongoing operations of the registered organization. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A commenter recommended that registered organization applicants be limited to New York state residents only.

RESPONSE: Public Health Law § 3360(17) defines a registered organization applicant as "a for-profit entity or not-for-profit corporation." The statute does not limit applicants to New York State residents. Nevertheless, applicants selected by the Department to be registered organizations must locate their manufacturing and dispensing facilities in New York State. No changes to the proposed regulation were made as a result of this comment.

COMMENT: A commenter noted that the regulations do not contain provisions concerning whether a municipality may share in the ownership of a registered organization applicant. A commenter suggested that the regulations be amended to explicitly forbid a municipality from being an ownership partner in a registered organization.

RESPONSE: Public Health Law § 3360(17) defines a registered organization applicant as "a for-profit entity or not-for-profit corporation and includes: board members, officers, managers, owners, partners, principal stakeholders and members who submit an application to become a

registered organization." The Department will take these comments under advisement. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Several comments were received regarding the requirement of a labor peace agreement with a bona-fide labor organization. Those comments include:

- A commenter opined that the decision to have a union should be left to the management of the registered organization and not dictated by New York.
- A commenter stated that labor unions have the potential to prevent good employees from upward mobility within a company.
- A commenter recommended requiring that the labor peace agreement be in place after a registered organization is approved and that the Department provide waivers where appropriate.
- A commenter stated that it will not be clear at the time of application which, if any, labor organizations will be attempting to represent employees.
- A commenter asked which union should be used as there is no particular union suited to the industry.
- A commenter noted that collection of union dues would be a violation of federal law and a New York labor organization having an affiliation with a national labor organization could lose their status.
- A commenter asked whether guidance will be provided on how to satisfy the labor peace agreement requirement.
- A commenter suggested that the definition of labor peace agreement be included or cross referenced to the definition in Title V-A of Article 33.

- A commenter stated that the unions should sign an acknowledgment of violation of federal law and should not be misled.

RESPONSE: Public Health Law § 3365(1)(a)(iii) requires, as a condition of application, evidence that the applicant has entered into a labor peace agreement with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees. This section makes clear that the maintenance of such a labor peace agreement shall be an ongoing material condition of certification. The proposed regulations are in accord with this requirement. The applicant for registration will need to identify appropriate labor organizations to negotiate with in order to meet the requirements of statute and regulation. Applicants for registration as a registered organization should consult with their legal counsel to determine appropriate requirements that need to be followed. Whether an acknowledgement of potential violation of federal law is signed is at the discretion of labor unions, registered organizations, and their respective legal counsels. No revisions to the regulation are necessary to address these comments.

COMMENT: Several comments were received regarding employees of registered organizations. Comments included:

- A commenter asked whether each individual staff member must be identified in the staffing plan, or whether the plan can indicate a proposed date for hiring staff in the future.
- A commenter recommended that the regulations be revised to require that the senior staff member have 10 years of experience in GAP, as opposed to the current 1 year requirement.

- A commenter stated that it may be difficult to find a senior staff member with 1 year of experience in GAP, as there are limited GAP-certified hydroponic operations on the east coast. The commenter stated that it would be more feasible to hire someone with a commercial agricultural background from any non-hydroponic GAP farm.
- A commenter asked whether all employees must be covered under the labor union.

RESPONSE: Applicants are required to submit a staffing plan for staff involved in activities related to the cultivation, manufacturing and dispensing of medical marihuana and staff with oversight responsibilities of such activities. Employees involved in these activities are required to be covered under the labor union. Managers who may come into contact with or handle marihuana must be identified on the application as they will be subject to a fingerprinting process as part of a criminal history background check. The staffing plan must identify a senior staff member with a minimum of 1 year experience in good agricultural practices (GAP), and a quality assurance officer who has documented training and experience in quality assurance and quality control procedures. All staff must be twenty-one (21) years of age or older and all staff involved in manufacturing must be trained in and conform to general sanitary practices. The staffing plan must have policies and procedures to ensure that the proposed registered organization does not employ anyone who will come in contact with or handle medical marihuana who has been convicted of any felony for sale or possession of drugs, narcotics, or controlled substances in accordance with the requirements Public Health Law § 3364. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Multiple comments were received seeking clarifications to employment eligibility for working at a manufacturing or dispensing facility. Those comments include:

- Age limitation to staff being 21 years of age or older, which applies to all activities. A commenter stated that employees that are between the ages 18 to 20 are permitted to work in a pharmacy setting and patients have access to medical marihuana at age 18 to 20.
- Clarification is sought as to whether the requirement that employees have no conviction of felony of sale or possession of drugs or controlled substances includes cannabis or marihuana convictions. A commenter recommended expanding the provision that excludes employment of anyone who has been convicted of a felony to all staff and owners.
- A commenter noted that the Department should specify when, and to whom notification of drug felonies should be sent.

RESPONSE: The age restriction of 21 years of age or older is modeled after the employment requirements in regulation for manufacturers and distributors of controlled substances in New York State. *See* § 80.11(b)(3)). A felony of sale or possession of drugs or controlled substances includes cannabis or marihuana related felony convictions. Additional information concerning the application process will be provided outside of regulation. The Department will consider these comments and determine whether clarification is needed through guidance or future revisions to the regulations.

COMMENT: Commenters inquired about the inclusion of contractors and ancillary businesses in an applicant's proposed business plan. A commenter gave an example of using an ancillary company for distribution of products rather than purchasing trucks and contracting for the provision of security guard services at the facilities. A commenter also asked whether transportation personnel must be direct employees of the registered organization or if registered organizations may subcontract transportation services.

RESPONSE: Public Health Law § 3364 defines a registered organization as a for-profit business entity or not-for-profit corporation organized for the purpose of acquiring, possessing, manufacturing, selling, delivering, transporting, distributing, or dispensing marihuana for certified medical use. Employeesmust be used for the provision of services directly related to these activities. The registered organization may not contract out for these services, including with contractors or ancillary businesses.

COMMENT: A commenter stated that the regulations seem to permit a parent corporation of a registered organization applicant to be a foreign corporation and also permit stock or equity rights in such corporations to be held by institutions and non-natural persons. The commenter noted that § 80-1.5 and § 80-1.6 do not refer to stockholders with reference to owners, members or partners and would specifically suggest that stockholders be included.

RESPONSE: Public Health Law § 3360(17) defines a registered organization applicant as "a for-profit entity or not-for-profit corporation and includes: board members, officers, managers, owners, partners, principal stakeholders and members who submit an application to become a registered organization." The statute does not restrict applicants to only entities formed in New York State. No revisions to the regulation are necessary to address these comments.

COMMENT: A commenter asked whether an applicant for registration as a registered organization must be able to perform all activities, from manufacturing to dispensing, in order to obtain a registration, and stated this requirement will limit sites to highly populated urban areas. Another commenter recommended allowing organizations to apply for licenses in three separate

categories: Manufacturing, Processing, and Retail. A commenter also suggested that applicants be allowed to apply for joint manufacturing operations with specific regulations of their own.

RESPONSE: Public Health Law § 3365(9) provides that the Commissioner shall register no more than five registered organizations that manufacture medical marihuana with no more than four dispensing sites wholly owned and operated by such registered organizations. Requiring registered organizations to provide both manufacturing and dispensing services is consistent with this provision of the statute. The Department will take into consideration the geographic distribution of the registered organizations. No revisions to the regulation are necessary to address these comments.

COMMENT: Commenters raised concerns about the high cost of producing oil-based medical marihuana products and the large-scale indoor grow operations that will be required to produce oil extracts. A commenter stated that marihuana oil products produced through the extraction process reduce the bulk harvest of marihuana leaves and flowers by a factor of 10-15 times. Another commenter stated that a 20,000 sq. ft. indoor grow facility can only provide enough oil products to supply the needs of less than 1,000 patients, and will require significant capital investments that only large scale enterprises can fund.

RESPONSE: Pursuant to Public Health Law § 3360(8), the Commissioner is authorized to approve the forms of marihuana certified for medical use. Section 80-1.11(g) sets forth the forms approved of medical marihuana. This section also authorizes the Commissioner to approve additional forms of medical marihuana in the future. The Department will take these comments under advisement. It should be noted that, pursuant to 80-1.6, in determining whether to grant a registration, the Department will take into consideration whether the applicant will be

able to produce sufficient quantities of medical marihuana to meet the needs of certified patients. The Department will consider these comments when determining if an applicant will be able to produce sufficient quantities of medical marihuana. No revisions to the regulation are necessary to address these comments.

COMMENT: A commenter stated that the Regulatory Impact Statement does not quantify the additional costs to registered organizations for regulatory compliance apart from the application and registration fees, and estimates the cost of regulatory compliance to be $7.56 million just for produced and stored inventory over the two year period of initial registration. The commenter stated the following:

- Applicants for registration as registered organizations will have to expend substantial sums of money for land, construction and infrastructure before they are even approved in order to assure that they will be operation within the time limit set.
- The requirements that a registered organization maintain a sample for at least two years and that the registered organization maintain a one year supply of their product will result in the need for expensive cold chain pharmaceutical storage.
- The regulations require extensive security that will amount to constant lock measures and will increase costs to the registered organizations.
- The estimated cost of regulatory compliance is $7.56 million just for produced and stored inventory over the two year period of initial registration.
- The regulatory impact statement should be expanded to provide a forthright estimate of the costs of regulatory compliance and cite that production and inventory costs will not

contribute to the tax revenues from the law for NY and municipalities since the required inventories will not be sold.

- Overburdening the registered organization with requirements that do not actually add to the quality, safety, or security of the product will impose unnecessary costs on certified patients.

RESPONSE: The Regulatory Impact Statement stated that costs will be incurred by the registered organization 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." Exact costs cannot be quantified as each organization will incur distinct costs depending on the size and location of their facilities, as well as their specific operating plans. Costs will also be factored into the approved price a registered organization may charge for its medical marihuana products. Pursuant to Public Health Law § 3369-d requires a consideration of fixed and variable costs in setting the price per dose of each form of medical marihuana.

With respect to commenter's statement that a registered organization would have to expend large sums of money for land, construction and infrastructure as part of the application process before it is approved, the statute and the proposed regulations allow the applicant to post of bond in lieu of submitting copies of leases, deeds, rental agreements or contracts on real property and buildings proposed to be utilized for registered organization activities. Also, some applicants may already own certain assets and, therefore, will not be required to expend funds to obtain them.

In addition, the commenter's estimates presume that the proposed regulations require the registered organization to physically maintain a one year supply of medical marihuana product. This is incorrect. The requirement that registered organizations ensure availability of at least a one year supply for each brand offered requires the registered organization to demonstrate, through their standard operating procedures, that they are able to ensure availability of the brand for a one year time period. The proposed regulation does not require physical availability of a one year supply of product. The proposed regulation also authorizes the Department to modify this requirement, and the Department will take these comments under advisement.

With respect to the requirement that registered organizations maintain samples, the availability of samples of each lot of medical marihuana product offered to certified patients is important for further evaluation in the event that a serious adverse event or side effect is reported. Such adverse events or side effects may not be immediately apparent. The registered organization, in its application for registration, must describe in its operating plan, its method of sampling each lot of medical marihuana product.

Finally, with respect to the security requirements, marihuana is a Schedule I controlled substance according to both the federal Controlled Substance Act and Article 33 of New York's Public Health Law. Strong and effective controls must be in place to ensure that medical marijuana is secured. No changes to the proposed regulation were made as a result of these comments. However, the Department will take these comments under advisement in determining whether future amendments to the regulations are necessary.

COMMENT: A commenter stated that any capital raised through the sale of equities should be exempt from the investor/owner affidavit requirements, except if the investor is also a manger of the registered organization, because such information falls within the disclosure requirements of the Securities and Exchange Commission.

RESPONSE: Public Health Law § 3365(1)(a)(v) requires applicants for registration as a registered organization to include the name, residence address and title of each of the officers and directors, as well as the name and residence address of any person or entity that is a member of the applicant. The statute further requires that each such person submit an affidavit setting forth 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 the state, manufacturing or distributing drugs. The statute does not make an exception for sale of equities regulated by the SEC. The proposed regulations are consistent with the statute. No revisions to the regulation are necessary to address this comment.

COMMENT: Comments were received concerning the real property requirements in the application for registration as a registered organization, including:

- A commenter stated that requiring identification of specific dispensing facility sites on the application is too onerous and imposes significant costs and financial commitments on applicants.
- A commenter stated that leases should not be required as a condition of approval.
- A commenter recommended a rollout process whereby a registered organization could roll out additional dispensing facilities over a period of 4 years, at the discretion of the registered organization based upon patient enrollments.

- A commenter suggested allowing applicants to submit a single prototype dispensing facility location and provide the Department with subsequent disclosure as other locations are identified and leases are obtained.
- A commenter stated that § 80-1.5(b)(17) indicates that this requirement is optional and questions how much weight will be given to this factor.

RESPONSE: Public Health Law § 3365(1)(a)(ii)(B) requires applicants to show the possession or right to use land, buildings, and equipment to carry on the registered organization's activities, which would include the land, buildings and equipment related to dispensing facility activities; or in the alternative, to post a bond of not less than $2,000,000. The regulations are consistent with statute and clarify that if an applicant posts a bond in lieu of providing documentation of sufficient land, buildings and equipment, the applicant will be required to submit applicable executed deeds, leases and rental agreements prior to being issued a registration by the Department. Section 80-1.5(b)(17) only requires information on the source of funds anticipated by the applicant to complete the construction, lease, rental or purchase of the manufacturing and dispensing facilities. If the manufacturing and dispensing facilities have already been constructed, leased, rented or purchased when the application is submitted, then the applicant does not need to indicate the source of funds used.

COMMENT: A commenter asked if all four dispensing facilities need to be operational at the same time.

RESPONSE: Section 80-1.5(b)(9) requires the applicant to provide 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 the registration is sought; or in the alternative, to post a bond of at least $2,000,000. This requirement encompasses both manufacturing and dispensing facilities. All four dispensing facilities of a registered organization selected do not have to be operational at the same time.

COMMENT: A commenter suggested that given the diverse client base that will be relying on wheelchairs and mobility devices, a full outline of architectural accessibility requirements, including what is necessary for wheelchair entry and passageway, should be included in the proposed regulations.

RESPONSE: The Department will complete a full architectural review of registered organization applications, and all registered organization buildings must comply with state and local building codes. No revisions to the regulation are necessary to address this comment.

COMMENT: Commenters inquired as to what constitutes "good moral character" of applicants. A commenter stated that this will be a larger burden on large organizations. A commenter indicated that the practical method for determining "the moral character" of these individuals needs to be explained. A commenter suggested that applicants should be required to fill out a character and competence review and that criminal background checks similar to those required by OASAS for substance abuse treatment providers should be used.

RESPONSE: Public Health Law § 3360(17) defines a registered organization applicant as "a for-profit entity or not-for-profit corporation and includes: board members, officers, managers,

owners, partners, principal stakeholders and members who submit an application to become a registered organization." Public Health Law § 3365\(1) sets forth the requirements of the application for initial registration and requires information that the applicant is of good moral character. Therefore, the Department must consider this factor when determining whether to grant a registration. The regulations are consistent with the requirements of the statute. Some of the factors the Department will consider in the registered organization application process related to "good moral character" include prior bankruptcy, criminal background, and any license suspensions. Criminal background checks will be conducted on certain managers of the registered organizations in accordance with § 80-1.5(b)(6) and Public Health Law § 3364(7). No changes to the proposed regulation were made as a result of these comments.

COMMENT: A commenter noted that the regulations require applicants to detail all business transactions connected with the submission of the application and suggested that the identification of lawyers and the payment of legal fees be exempted due to the confidential nature of the attorney-client relationship.

RESPONSE: The retention of counsel and legal fees paid is ordinarily not confidential or privileged. Disclosure of such business transactions are appropriate, including for the purpose of providing the Department with notice as to who it is authorized to interact with on behalf of the applicant. No revisions to the regulation are necessary to address this comment.

COMMENT: Comments were received concerning financial statements and funds related to the application for registration, including:

- The regulations should require the applicant to submit financial statements that also include a sub ledger of payments by vendor.
- Section 80-1.5(b)(17) should be amended to include the phrase "if funds will come from external sources, a listing of those investors/lenders and a timeline for receipt of cash must be documented and submitted to the department."
- The requirement for a description of all business transactions with the application seems very broad and should be more defined.
- Applicants should provide letters from two financial institutions demonstrating active banking relationships for at least six months and confirming the banks' awareness of the applicant's involvement in this industry and willingness to serve as a counterparty and depositary institution.
- Applicants should provide proof of property, casualty, general liability and professional liability insurance in adequate limits covering all dispensary and cultivation locations.
- Applicants should provide a cash management plan for review by the Department with an emphasis on limiting the number of cash transactions in favor of electronic transactions, to demonstrate expertise and capability.
- Applicants should provide proof of experience managing compliance in businesses that have 50% or greater cash transactions, due to the unique risks of managing a business that has the potential for an atypical volume/utilization rate for cash.

RESPONSE: Section 80-1.5 requires applicants to submit adequate information and documentation to allow the Department to determine fiscal viability. No changes to the proposed regulation were made as a result of these comments. However, the Department will

consider these comments in determining whether clarification is needed, either through Department issued guidance or future revisions to regulation.

COMMENT: Several comments were received concerning the qualifications of applicants. Those comments include:

- Applicants should have a demonstrated competency in the production of pharmaceutical grade medical marihuana. A commenter similarly stated that the regulations should consider whether the applicant has previously produced medical marihuana in a jurisdiction in which production is well regulated.
- Whether there will be preference awarded to New York state applicants.
- Whether additional points will be awarded to a company that has experience in growing alternative crops, working with hydroponics, or working in a medical background who has not faced serious compliance issues with other state regulators.
- Requiring each applicant to describe each state or jurisdiction in which its relevant industry experience was obtained, including such information as to whether or not an applicant has been awarded a license to operate by a state regulatory authority (including the District of Columbia), and that applicants disclose any loss or suspension of a marihuana license in any jurisdiction.
- That applicants provide experience with tracking each plant from seed to sale (including waste disposal and chain of custody experience) for each harvest and demonstrate knowledge and experience of manufacturing and selling concentrates using New York approved extraction techniques.

- That applicants should provide evidence of experience with or participation in research with an Institutional Review Board ("IRB") approved clinical trial focused on the use of medical marihuana to assess each applicant's commitment to research and furthering the medical mission of New York's program.
- Requiring applicants describe the involvement of any owners, directors or key employees in the cultivation or dispensing of marihuana in any jurisdiction that permits recreational/adult use without a physician's certification.
- Requiring applicants provide evidence of support and approval from the local officials and/or community leaders, including any necessary zoning approvals, to ensure each community and their leaders have a voice in the selection process.
- That licenses should not be awarded to big corporations to grow and produce medical marihuana but rather licenses should be awarded to New York State farmer collectives and producers that are non-profits.
- Requiring applicants prove residence in New York for 5 years prior to application and have a clean criminal record, raising concerns over what the commenter saw as an opportunity for organized crime from within and outside of NY to be a part of the business due to the cash only nature of the business
- Requiring proof of product in all states that they claim to operate in, and that all teams be properly vetted to show that the members have maintained compliance during their time in this industry.
- Requiring applicants provide evidence of experience operating facilities with security considerations detailed in the regulations for both dispensing and cultivating facility types using similar equipment.

- Requiring applicants provide evidence of experience in handling Schedule I substances in a controlled and secure manner and indicate whether such experience is within a medical marihuana state-regulated jurisdiction or a jurisdiction that allows for adult/recreational use.

RESPONSE: Public Health Law § 3360(17) defines a registered organization applicant as "a for-profit entity or not-for-profit corporation." New York State residency, or formation of the entity or corporation in New York State is not a requirement of the statute. The Department will review applications based upon an overall evaluation of all the considerations provided for in § 80-1.6. The fact that an applicant does not have demonstrated experience producing medical marihuana in another state does not prohibit the applicant from applying for registration in New York State. The Department will provide additional information concerning the application process and consideration of applications outside of regulation. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A commenter sought clarification as to whether an applicant for registration as a registered organizations needs to seek prior approval or guidance from the Department with regard to the applicant's operating plan and architectural/engineering design of proposed facilities.

RESPONSE: The Department will not review, comment, or provide approval, of any component of an application until the complete application is submitted to the Department.

COMMENT: A commenter stated that allowing applicants to develop protocols and policies to satisfy the regulatory requirements will create variation amongst registered organizations, both in

format and in specific operational functions. A commenter stated that this variation will make uniform enforcement and inspections very difficult for the Department. For example, commenters stated that more detail and structure was needed concerning the requirement that an applicant be able to maintain effective control against diversion of marihuana and medical marihuana products, and that the Department needs to explain that diversion of marihuana, even to the slightest amount, is a violation of this provision.

RESPONSE: The Department will consider these comments in subsequent rulemaking as needed. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A commenter suggested that, in relation to the operating plan submitted as part of the application process, the words "quality control" in § 80-1.5(b)(4)(iii) be inserted as follows: a standard operating procedure manual for all methods used from cultivation of the medical marihuana quality control through packaging, sealing and labeling of each lot of medical marihuana product.

RESPONSE: The Department will consider these comments in subsequent rulemaking as needed.

COMMENT: A commenter suggested that the word "incidents" be used rather than "incidence" in 80-1.5(b)(4)(vi) to read as follows: a quality assurance program to track contamination incidents and document the investigated source of such incidents and the appropriate corrective action(s) taken.

RESPONSE: The Department has made this clarifying change. .

COMMENT: A commenter stated that the Department should specify that all of such tracking hardware and associated software be in full working order prior to any retail sales.

RESPONSE: The Department will consider this comment in subsequent rulemaking, as needed.

COMMENT: Several comments were received regarding the interaction between the proposed regulations and federal law, including that:

- Guidance should be provided relative to any laws or regulations that might conflict with federal statute or regulations concerning the requirement that registered organizations comply with all applicable state and local laws, including the federal Controlled Substances Act.
- The Department provide landlords with the same guidance as to federal statute and regulations.
- Everyone, including employees and landlords, should sign a statement acknowledging violation of federal law and explaining the potential penalties for doing so.

RESPONSE: Under Public Health Law § 3369(1), certified patients, designated caregivers, practitioners, registered organizations and the employees of registered organizations shall not be subject to State arrest, prosecution, or penalty in any manner or denied any right or privilege, including but not limited to a penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for the certified medical use or manufacture of marihuana, or for any other action or conduct in accordance with Title V-A of Article 33 of the Public Health Law. Registered organizations, labor unions, and landlords should seek advice of legal counsel as to whether or not they wish to require the written statements suggested by the commenters.

COMMENT: comments were received concerning Freedom of Information Law (FOIL) requests for information on the medical marijuana program and potential registered organization applicants:

- All applications and written submissions to the Department by registered organizations should be open to public inspection.
- The Department should shield the intellectual property and trade secrets of the applicants by ensuring confidentiality of these materials and not making them available for public distribution, download or access in keeping with applicable FOIL provisions.
- The Department must ensure that there are regulations in place pursuant to Public Officers Law § 87(4)(a) for the handling of such information prior to the call for applications.

RESPONSE: The Department strictly complies with New York State law governing the disclosure of records under FOIL, as well as any applicable exemptions. The Department's compliance will extend to a thorough review of any request for documents relating to the medical marijuana program. For example, under Public Officers Law § 87(2)(d) the Department may deny access to any records that are trade secrets or are submitted to an agency by a commercial enterprise or derived from information obtained from a commercial enterprise and which if disclosed would cause substantial injury to the competitive position of the subject enterprise. Public Officers Law § 89(5)(a)(1) contains further protections for trade secrets and authorizes a commercial enterprise to request an exemption from disclosure based on the trade secret exception. Applicants should consider requesting an exemption in accordance with Public Officers Law § 89(5)(a)(1) for any document or information it considers a trade secret. *See also,* 10 NYCRR § 50-1.8.

80-1.6 Comments: Consideration of Registered Organization Applications

COMMENT: A number of comments were received concerning the application and registration fee required for registration as a registered organization and renewal of registrations for registered organizations.

- Several commenters stated that the $200,000 registration fee was either too excessive or too low.
- A commenter stated that high fees should not be assessed due to the state's recoupment of administrative costs from the excise tax, and that the registration fee should be reduced in order to increase the availability and application of more experienced yet less established medical professionals in the field. The commenter stated that the high entry costs and limitation to primarily oil based products will make it doubtful that for-profit enterprises would step into this market.
- A commenter stated that the Department should not be expected to pay for all of the staff time it will take to review applications and possible appeals.
- Commenters suggested making the $200,000 registration fee refundable.
- A number of commenters recommended using the fees for community-based prevention efforts or to help offset costs for the indigent population of NY.
- A commenter requested the Department allow a $2 million dollar bond in lieu of the $200,000 fee.

- A commenter requested clarification as to whether the fees are returned if the applicant is not selected. The commenter stated that the terms under which the registration fee will be released should an applicant not be issued a registration should be delineated.
- A commenter stated that the Department should consider lowering the fee for registered organizations when they seek to re-register given the costs associated with the program.
- One commenter suggested a plan to dedicate some of the fees to insure proper enforcement, indicating that there should be annual fees for all registered organizations in order to pay for enforcement and monitoring.
- A commenter stated that the application process is unfairly biased towards those with extraordinary financial resources and that local New York based groups will have a difficult time qualifying.

RESPONSE: The application and registration fees were determined after evaluating the medical marihuana program application review process and requirements for monitoring regulatory compliance and enforcement. The $10,000 application fee is non-refundable to the applicant. The $200,000 registration fee is refundable if the applicant is not selected for registration as a registered organization; however, if a registration is surrendered due to the registered organization's failure to begin operations in a timely manner, the $200,000 fee will not be refunded. No revisions to the regulation are necessary to address these comments.

COMMENT: A number of comments were received concerning criminal history, fingerprinting and background checks for registered organization applicants. Those comments include:

- Commenters stated that fingerprinting and background checks of registered organization managers is not provided for in statute.
- Commenters stated that the Department should require background checks on any parties who submit an application for registration as a registered organization.
- A commenter stated that those with felony convictions must be able to work in the industry and that discrimination against this group has to end as they have paid their debt to society and need jobs.
- A commenter indicated that the regulations omit a section of the statute that prohibits anyone with a felony drug conviction from working in a registered organization facility in a position where they will be handling marihuana directly, unless the conviction is more than 10 years old for which the person received a certificate of good conduct.
- A commenter suggested having applicants undergo extensive background investigations to ensure that any and all of their principles will meet or exceed the standards set forth by the State and recommended a number of searches that may be conducted with each registered organization application.

RESPONSE: Public Health law § 3364(7) states that registered organizations shall not be managed by, or employ, anyone who has been convicted of any felony for sale or possession of drugs, narcotics, or controlled substances. This prohibition only applies to managers or employees who come into contact with or handle medical marihuana, and only if they have a conviction less than ten years prior to being employed for which they have not received a certificate of relief from disabilities or a certificate of good conduct. Public Health law § 3364(7). This section provides the Department with authority to conduct criminal history background checks on those managers or employees who will come into contact with or handle

medical marihuana. Section 80-1.5 of the regulations requires the applicant for registration as a registered organization to identify its managers. Any manager who may come in contact with or handle medical marihuana is subject to a fingerprinting process for a criminal history background check in accordance with statute. If a criminal history background check reveals a felony conviction of sale or possession of drugs, narcotics, or controlled substances, a registered organization is prohibited from employing the proposed manager, if said conviction is less than ten years old and the proposed manager has not received a certificate of relief from disabilities or certificate of good conduct. Registered organizations will be expected to follow the same process for employees who meet the criteria in Public Health Law § 3364(7). The Department will consider whether clarification on this issue is needed in guidance or in future revisions to the regulations.

COMMENT: Commenters sought clarification on why any controlling person of the applicant must disclose that he or she that maintains a ten percent interest or greater in any firm, association, foundation, trust, partnership, corporation, or other entity that manufacturers or distributes drugs.

RESPONSE: Public Health Law § 3365(1)(a)(v)(A) requires applicants to disclose 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 this State, that manufactures or distributes drugs. The proposed regulations are consistent with the statutory requirement.

COMMENT: A commenter suggested that, when applicable to demonstrate whether an applicant's prior operating history is consistent with New York's requirements, the applicant

should provide photos of existing facilities in other markets along with any educational materials currently provided to patients.

RESPONSE: Section 80-1.5 of the proposed regulations does not prohibit an applicant from submitting photos of its existing operations to visually demonstrate specific requirements, nor does it prohibit submission of educational materials currently being provided by an applicant. No changes to the proposed regulation were made as a result of this comment.

COMMENT: A few commenters suggested changing the length of registration for registered organizations. One commenter stated that the first issuance of a registration should be for four years due to the significant capital investment from private investors who might view the two year period as too risky. Another commenter suggested a registration period of seven years, to match the Compassionate Care Act's sunset provision.

RESPONSE: Public Health Law § 3365(4) provides that a registration shall be valid for a period of two years from the date of issue. The proposed regulations are consistent with the statutory requirement.

COMMENT: A number of comments were received concerning the number of registered organizations to be issued registrations, and the number of dispensing facilities:

- Many commenters stated that five organizations with four dispensing facilities will not be sufficient to meet the needs of patients considering the square mileage of New York State.
- Commenters stated that the number of registered organizations or dispensing facilities should be expanded to include more dispensing facilities.
- Commenters asked how the Department will ensure geographic coverage throughout the state.

- Commenters noted issues with time that caregivers would spend away from patients due to travel to a dispensing facility, long waits, shortage of supply and transportation issues.
- A commenter sought clarification as to whether the Commissioner can, in his discretion, authorize more than five registered organizations.
- A commenter stated that if more registered organizations were to be approved, there would be a larger user set to draw data from since the current limited scope provides no idea what other types and sizes of operations may be more effective.
- Several commenters stated that there should be no less than one dispensing facility per county for registered organizations; others suggested there be a dispensary every 50 miles.
- A commenter stated that it is unclear what the distinction is, and what the number limits are, for registered organizations' cultivation and production facilities versus dispensing facilities.
- A commenter recommended the Department consider asking each applicant to describe how a specific number of its planned dispensing facilities combined with a secure courier service will reach all patients, however remote a patient may be.
- Commenters stated that the proposed regulations should allow the Department to register more than four dispensing facilities and secure courier services as appropriate.
- Commenters stated that the Department should conduct an analysis of patient need and license a sufficient number of registered organizations across the state to meet patient need, and provide information to the public on how it will determine regional need and the location of the ROs.
- Some commenters supported authorizing 20 dispensing facilities and making adjustments going forward.

- One commenter supported the limitation on the dispensing facilities and cautioned that interested parties would seek to allow for dozens, if not hundreds more, of these locations, which, the commenter stated, occurred in Denver, Colorado.
- A commenter stated that the density that will trigger another application being accepted needs to be defined.

RESPONSE: Public Health Law § 3365(9) states that the Commissioner shall register no more than five registered organizations to manufacture medical marihuana, with no more than four dispensing sites wholly owned and operated by each such registered organization. The statute authorizes the Commissioner to consider registering additional registered organizations and dispensing facilities. The regulations are consistent with statute. In considering an application for registration, the Commissioner will take into consideration whether the number of registered organizations in an area will be adequate or excessive to reasonably serve an area, including whether there is sufficient geographic distribution across the state. *See*, § 80-1.6. With respect to the comment regarding use of a courier service, section 80-1.21 prohibits the use of a delivery service unless prior written approval has been obtained from the Department. The Department will carefully monitor patient needs following implementation of the program. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A number of comments were received concerning geographic location and selection of manufacturing and dispensing facilities, as follows:

- A commenter stated that the regulations do not specify regions or allocations.

- A commenter noted that the regulations do not indicate whether each registered organization will have an exclusive presence in its geographic region, with one license per region, or if another registered organization can be registered in the same area.
- Commenters sought clarification as to whether the Commissioner or the State is going to choose the geographic region or establish where the dispensing sites are to be located.
- Commenters also sought clarification as to whether it is a prerequisite for a registered organization to have a minimum ability to serve the entire state or if a registered organization can target a particularly highly populated market.
- A few commenters supported the creation of different regions to operate in a manner that suits the needs of a particular region.
- A commenter stated that the regulations do not adequately define "area" in the requirement that the Department will "consider whether the number of registered organizations in an area will be adequate to serve the area, and whether there is sufficient geographic distribution."
- Some commenters stated that geographic coverage should be assured regardless of population density and geographic area.

RESPONSE: Public Health Law § 3365(9) requires the Commissioner to ensure that registered organizations and dispensing sites are geographically distributed across the state. Section 80-1.6 sets forth the considerations for approval of registered organization applications. One such consideration is whether 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. An applicant should ensure that its dispensing facilities are geographically distributed across the state, rather than focused on a particular region. The

Department will provide additional information concerning the application process. No revisions to the regulation are necessary to address these comments.

COMMENT: Several comments were received recommending that the regulations be revised to authorize delivery or courier services. Commenters stated that delivery service will be necessary for patients who may be homebound, have mobility or transportation issues and due to the limited number of dispensing facilities to serve the state. A few commenters stated that the regulations should be revised to allow registered organizations to conduct deliveries if they can describe a safe and secure means of doing so as part of their application, including through third party bonded and insured courier services.

RESPONSE: Section 80-1.21(c) prohibits the use of delivery service unless prior written approval has been provided by the Department to the registered organization. In deciding whether to grant an applicant for registration as a registered organization, the Department will consider whether the number of registered organization in an area will be adequate or excessive to reasonable serve the area, including whether these is sufficient geographic distribution across the state. *See* § 80-1.6(b)(8). The regulations also allow certified patients to have up to two designated caregivers. These individuals will be able to assist certified patients in obtaining medical marihuana in the event that a delivery service is not authorized. The Department will monitor this issue and determine whether approval of delivery services should be granted in the future to registered organizations who seek to offer such services. No revisions to the regulation are necessary to address these comments.

COMMENT: Several comments were received asking the Department to grant registrations in a way that supports diversity in the medical marihuana industry and includes minority and women-owned businesses, small businesses, disabled veterans, and New York businesses. A few commenters recommended that applicants be required to explain how their business already, or will, include and employ local people, low-income people, women, and people of color. Commenters also suggested the Department take into consideration applicants that include a community benefits package, detailing benefits to the community, including but not limited to, employing veterans and providing subsidy programs for families with certified patients under the age of 18 who demonstrate financial hardship.

RESPONSE: The Department supports diversity in the medical marihuana industry and encourages applicants for registration to consider how it may include minority and women-owned businesses, small businesses, disabled veterans, and New York businesses in its operations while maintaining consistency with the requirements of the Compassionate Care Act.

COMMENT: Several comment were received concerning how the Department will consider whether an applicant can produce sufficient quantities of medical marihuana to meet demands and what parameters will be used. Commenters specifically sought information concerning potential demand, including the number of anticipated certified patients and manufacturing expectations needed to meet such demand. A few commenters recommended that applicants specifically address how they will ensure that safe, high quality plants will be produced in sufficient quantities to meet the demands of certified patients.

RESPONSE: The demand for medical marihuana products will ultimately depend upon the number of patients who meet the requirements for certification outlined in Public Health Law §

3360(7), as well as in the proposed regulations. The registered organization must address how it will ensure sufficient supply to meet demand in its submission of its application.

80-1.7 Comments: Applications for renewal of registration as registered organization

COMMENT: Several comments were received regarding the renewal of registration process for a registered organization:

- A commenter stated that the Department should be required to provide notice to a registered organization when renewal is required.
- A commenter recommended that the regulations be revised to include a process describing how renewal determinations are made, including timeframes for such determinations, and if the renewal application is denied a designated closing process so that patients and physicians will not be impacted.
- A commenter stated that clarification is needed as to whether the registered organization can operate while the renewal application is under consideration by the Department.
- A commenter stated that the Department may wish to consider removing the word "possible" before "diversion" from the incident notification requirement during renewal stated in § 80-1.7(c)(2)(i). The commenter stated that requiring a written account of potential diversion events that could possibly have occurred but did not, could be overly burdensome for businesses and regulators.

RESPONSE: Public Health Law § 3365 (5) requires that an application for renewal of any registration be filed with the Department not more than six months nor less than four months prior to the expiration thereof. The Department plans to issue separate guidance concerning the

renewal process, and will take these comments under advisement. The registered organization may continue to operate while undergoing the renewal process provided that the initial registration has not reached its expiration. No changes to the proposed regulation are necessary to address these comments.

80-1.8 Comments: Registrations non-transferrable

COMMENT: A commenter recommended that the regulations be revised to include the words "or sale" in the provision of the regulation which states that if a registered organization's application for renewal of registration is denied, the registered organization shall submit a proposed plan for closure. The commenter recommends that the plan could include a sale of the registered organization.

RESPONSE: PHL § 3365 (d) states that registrations shall be effective only for the registered organization that received a license. Accordingly, registrations are non-transferrable. No changes to the proposed regulations are necessary.

80-1.9 Comments: Failure to Operate

COMMENT: Several comments were received regarding the failure to operate provisions in the proposed regulations, including:

- A commenter sought clarification on the meaning of the terms "begin operations" and "to the satisfaction of the Department"
- A commenter requested that the word "substantial" to be inserted between begin and operations.
- A commenter stated that it will be difficult for any registered organization to begin operations within six months of the date of issuance of the registration because the

Department itself has many tasks to complete before the program is operational. The commenter recommends removing the time limit, or that it should be minimally connected to completion of necessary actions by the Department to implement the Act.

- A commenter stated that there should be prior notice and opportunity for corrective action before the Department determines that the organization has failed to commence operations.
- A commenter sought clarification as to whether the regulations required that the manufacturer have medical marihuana products ready for sale at the end of six months.
- Other commenters supported this provision as it provides an incentive for operators to not subject patients to needless delays.
- A commenter recommended that, if a registration was surrendered as a result of a failure to begin operations, the regulations should provide the following: "if there are fewer than 5 licenses in good standing, the Department shall open the application process until 5 valid registered organization licenses are issued."
- A commenter stated that 6 months will not provide sufficient time to build the facility, grow, process and manufacture an inventory of products necessary to launch the registered organization's operations.
- A commenter stated that the regulation would benefit by the addition of a "good faith" standard.
- A commenter recommended that the Department consider extending the timeframe or defining "begin operations to the satisfaction of the Department" as having made sufficient progress toward commencing operations during the 6-month window.

RESPONSE: As detailed in the proposed regulations, the Department will carefully review an applicant's operating plans, and proposed manufacturing and dispensing facilities plans, including suitability of the location and architectural and engineering design of the proposed facilities, to ensure that each selected registered organization will be able to successfully begin operations within six months of the date of issuance of the registration. The Department plans to closely monitor the progress of a registered organization's operations upon issuance of a registration. The Department intends to issue separate guidance on this provision, and take the comments on terminology and good faith standards of review under advisement. The Department further notes that if a registration is surrendered due to a failure to operate, the Department will seek applications for initial registration of another registered organization. No changes are necessary to the proposed regulation.

80-1.10 Registered Organization: General Requirements

COMMENT: A commenter recommended that the Department allow registered organizations to cease operation with less than 120 day notice for good cause.

RESPONSE: The Department is willing to consider this comment in future proposed rulemaking but currently believes this timeline is necessary to ensure that certified patients have sufficient notice.

COMMENT: A commenter asked whether § 80-1.10(c), requiring notification of all certified patients and designated caregivers of an impending closure of the registered organization, includes all active patients and caregivers or all of those who have ever purchased from the registered organization.

RESPONSE: Section 80-1.10(c)(2)(i) states that the registered organization shall notify affected certified patients and designated caregivers of the closure. Patients who no longer have an active certification and their designated caregivers would not require notification. No changes to the proposed regulation were made as a result of this comment.

COMMENT: A commenter suggested the $2,000 fee associated with a registered organization that elects to cease operation of all permitted activities as set forth in § 80-1.10 is insufficient as a registered organization would likely choose paying a small fine rather than deal with compliance. The Commenter stated that penalties for failing to comply with a provision in § 80-1.10 should begin at $5,000 and be correlated to severity.

RESPONSE: Public Health Law § 12 imposes a $2,000 fee for violations of law or regulation. The proposed regulation mirrors the fee set forth in statute.

COMMENT: A Commenter sought clarification of the phrase "substantial alteration" in § 80-1.10(b)(4), regarding the requirement that a registered organizations may not make substantial alterations to the structure or architectural design of a manufacturing or dispensing facility or change the composition of the entity without Department approval. The commenter recommended that the Department create a protocol for submission of written requests for such modifications as well as a reasonable timeline for departmental consideration of submissions.

RESPONSE: The Department will issue separate guidance concerning what constitutes a "substantial alteration" requiring Department approval and the process by which a registered organization may request approval to make substantial alterations to the structure or architectural

design of a facility or change the composition of the entity. No changes to the proposed regulation are necessary.

COMMENT: Numerous comments were received seeking clarification or changes to § 80-1.10(7) prohibiting a registered organization from locating "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": including

- A number of commenters supported the restriction. Other commenters requested that childcare facilities, after school programs, and anything involving children be included.
- Several commenters suggested that zoning restrictions should be eliminated, or at least reduced to the same distances used for liquor stores, which is 200ft to 500ft.
- Several commenters assert this restriction is overly burdensome since the dispensing facilities will have discreet and limited signage, and there is a prohibition on the use of products in the facility and vaporization in public places. One commentator noted that the same restrictions do not apply to pharmacies, or to entities that sell tobacco or alcohol products.
- Several commenters stated this restriction will make it impossible to locate a dispensing facility in certain densely populated areas, such as Manhattan or New York City. A number of comments suggested that the restrictions should be loosened for more urban locations, perhaps identified above a certain threshold of population density (per sq. mile). For example, a comment was received stating that this setback requirement should be revised to require a distance of 1000 feet, door to door radius, with the exception of

metropolitan areas with populations of over 200,000 at 750 feet and metropolitan areas with over 1 million people having a recommended 400 foot radius, door to door.

- A commenter stated that a waiver should be granted if the institution in question confirms, in writing, that it does not object to the dispensing facility's location.
- A commenter stated that dispensing facilities should be in relatively close proximity to hospitals or health care facilities.
- A commenter stated that the Federal statute does not include places of worship.
- One commenter recommended striking the word "exclusively" from the following prohibition on a registered organization: "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". A commenter stated that the setback requirements should define 'school' as primary or secondary school, so as to not apply the requirement out of context to research institutions and other organizations of higher education.

RESPONSE: Section § 80-1.10(7) provides that a dispensing facility may not be located 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. Accordingly, the restriction only applies if both conditions are met. This will allow dispensing facilities to be located in both urban and rural areas. Should it be determined that this limitation restricts access, the Department will consider revising its policy in subsequent rulemaking.

COMMENT: A commenter stated that in relation to patient and product record-keeping, the regulations should specify minimum standards for the keeping of certain data (data retention, disaster recovery, security breach reporting, medical records, etc.).

RESPONSE: Section 80-1.5(b)(4)(vii) requires an applicant to submit a detailed description of plans, procedures and systems adopted and maintained by the proposed registered organization for tracking, record keeping, record retention and surveillance systems, relating to all medical marihuana at every stage including cultivating, processing of marihuana, manufacturing, delivery, transport, distribution, sale and dispensing. No changes to the proposed regulation were made as a result of this comment.

COMMENT: Comments were received regarding whether records can be centralized within a registered organization to one location, and recommending that the Department consider allowing registered organizations to maintain electronic books and records or centralized records at a single corporate office known to the Department.

RESPONSE: Any records maintained must be readily retrievable at the dispensing facility and manufacturing facility. No revisions to the regulation are necessary to address these comments.

COMMENT: A commenter suggested the regulations require training for growers and noted that it is important that all aspects of the process are known and growers understand the medical systems they are producing. The commenter also stated that New York should require growers to know and understand the potential for impurities and strain irregularities and how to mitigate them before the product is sold.

RESPONSE: An applicant for registration as a registered organization must include a staffing plan that includes a senior staff member with a minimum of one (1) year experience in good agricultural practices (GAP). *See* § 80-1.5. A registered organization must have a standard operating procedure manual, which must include the use of GAP and must conform to all applicable laws and rules of New York State. Records of materials, including soil, soil amendment, nutrients, hydroponic materials, fertilizers, growth promoters, pesticides, fungicides, herbicides and any other materials must be maintained. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A commenter asked how research, development and education play into the registered organization and if the registered organizations will provide some of these things versus the state. The commenter stated that a production site in the Albany area would be a great location to do some of these things with its close proximity to the Department of Health, Department of Agriculture and Markets, and other governing bodies.

RESPONSE: Research and evaluation methods will be explored outside of the proposed regulations. No revisions to the regulation are necessary to address these comments.

COMMENT: A number of comments were received concerning the requirement that registered organizations not dispense approved medical marihuana products from the same location where the marihuana is grown or manufactured. Many commenters recommended the regulations be revised to allow manufacturing and dispensing to occur in the same facility. Commenters noted that this would capture business efficiencies and reduce risk, allow for medical marihuana products to be more easily secured, reduce the need for transport to dispensing facilities, and

decrease the costs associated with production. Commenters also felt that this may result in large amounts of marihuana traveling around the state, risking theft, diversion, and other problems. Commenters felt that this requirement will require more ground to be covered and inspected by the Department and law enforcement. Commenters stated that they would like to see vertical integration between the growing/manufacturing facilities and the point-of-sale.

RESPONSE: There is a risk of theft and diversion in allowing manufacturing operations to be co-located with dispensing facilities. No revisions have been made to this section.

COMMENT: A comment was received that data collected under the five-year record retention period will rapidly become voluminous and provisions should be made to allow registered organizations to eventually engage state certified secure data storage organizations of the kind that maintain medical and other sensitive information. The commenter stated that electronic media or digital record keeping should be utilized to satisfy this requirement to the greatest extent possible.

RESPONSE: The regulations do not prohibit registered organizations from maintaining electronic records, so long as the records are readily retrievable. The Department will take these comments under advisement and determine whether clarification is needed through guidance or future rulemaking.

COMMENT: A commenter stated that tracking returned product is a critical control measure to detect a trend of poor quality or contaminated product and noted that this data will also assist with inventory reconciliation.

RESPONSE: Section 80-1.10 requires registered organizations to implement policies and procedures to document and investigate complaints and adverse events and report these events to the Department within 24 hours of their occurrence. Specifically, § 80-1.10(a)(4) requires a registered organization to submit approved medical marihuana product samples to the Department upon request, including for quality assurance testing. The Department believes the proposed regulations adequately address quality control measures and no changes to the proposed regulation were made.

COMMENT: A number of comments recommended that registered organizations should be able to transfer or wholesale marihuana (including the plant) or approved medical marihuana product between registered organizations in the event of closure of a registered organization, to address shortages, or to manage unexpected demand. In order to do so, the commenters suggested the following:

- Security requirements should be expanded to allow a registered organization to transport approved medical marihuana products to other registered organizations.
- Transport of medical marihuana products should be authorized from one dispensing facility owned by the registered organization to another dispensing facility owned by the same registered organization.

RESPONSE: Allowing a registered organization to transfer or wholesale its medical marijuana product, in any form, to another registered organization raises significant safety and logistical concerns. While the proposed regulations allow a registered organization that intends to cease operations to transfer its supply of medical marijuana and medical marijuana products, it must first submit a plan for doing so, and that plan is subject to Department review and approval. [§

80-1.10(c)(2)(ii)] With respect to wholesaling medical marijuana products, this comment is beyond the scope of the proposed regulations but may be considered by the Department in future rulemaking. With respect to transfers between dispensing facilities, the proposed regulations restrict transportation of medical marihuana from a manufacturing site to a dispensing site, and necessarily to a laboratory for submission of samples for required testing. No changes to the proposed regulations are necessary to address these comments.

COMMENT: A comment was received seeking clarification as to whether, if transfers were permitted, would the commissioner regulate the transfer or sale price and would it be subject to taxation.

RESPONSE: A transfer may be authorized when a registered organization intends to cease operations and submits a plan for closure that includes properly transferring its supply. [§ 80-1.10(c)(2)(ii)] The plan for closure should include any proposed transfer of its supply to another registered organization, including the terms of such transfer. The Department will review the plan for closure and proposed transfers carefully. With respect to taxation, Article 20-B of the Tax Law states that the excise tax is on the gross receipts from the sale of medical marihuana to a certified patient or designated caregiver.

COMMENT: A comment was received recommending that the regulations require that all registered organizations conduct a physical inventory of finished products daily at opening and closing, and keep a running inventory of finished product on hand.

RESPONSE: The Department will take these comments under advisement. However, nothing in the proposed regulations prohibit a registered organization from conducting a physical

inventory of finished products and including this task in their plan of operation. No changes to the proposed regulation were made as a result of this comment.

COMMENT: Several comments were received seeking clarification on titration of dose and compounding. One commenter in particular sought clarification as to whether a registered organization, in consultation with a certified patient's doctor, was authorized to titrate the exact dosing and ratios for each individual patient. Another commenter recommended that registered organizations should be allowed to compound their own brands into hybrid solutions and suggested that each brand be subject to an additional yearly fee of $250.00.

RESPONSE: Public Health Law § 3361 (3) requires that a practitioner state, in the patient's certification, any recommendation or limitation the practitioner makes, in his or her professional opinion, concerning the appropriate form or forms of medical marihuana and dosage. Pursuant to Public Health Law § 3364 (5)(c), medical marihuana dispensed to a certified patient or designated caregiver by a registered organization shall conform to any recommendation or limitation by the practitioner as to form or forms of medical marihuana or dosage for the certified patient. The proposed regulations are in accord with the requirements of statute. The proposed regulations do not include provisions for compounding or creating hybrid solutions from approved brands. The proposed regulations seek to ensure products have a consistent cannabinoid profile as labeled and are free of contaminants. After a registered organization initially produces up to five brands of medical marihuana product, additional brands may be approved by the department. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A comment was received recommending that the word "unannounced" be added before the words "on-site inspection" in 80-1.10(a) which requires that a registered organization make its facilities available to the department for monitoring and inspection.

RESPONSE: The Department will take this comment under advisement. The proposed regulations do not restrict the Department's ability to perform an unannounced inspection. No changes to the proposed regulation were made as a result of this comment.

80-1.11 Comments: Manufacturing Requirements for Approved Medical Marihuana Products

COMMENT: A commenter asked whether "growing" when used in the regulations encompasses "manufacturing".

RESPONSE: Yes. "Manufacturing" is defined in Section 80-1.11 and includes growing.

COMMENT: Several comments dealt with the forms of medical marihuana allowed in 80-1.11(g). Those comments include:

- Restricting medical marihuana to only pill and oil forms would be costly for patients. Commenters noted access to the whole plant would be more cost effective for low income individuals and would cut down on manufacturing costs.
- Augmentation of analgesic effects does not occur with oil or pill form.
- Support of the regulation to exclude raw marihuana from the medical marihuana program.

RESPONSE: Public Health Law § 3360 states that any form of medical marihuana not approved by the Commissioner is expressly prohibited. The proposed regulations currently

allow the following acceptable forms of medical marijuana: liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube, metered liquid or oil preparations for vaporization, and capsules for oral administration. While smoking is expressly prohibited, the Commissioner is authorized to approve additional forms in the future, and the Department will issue guidance on the process for interested stakeholders to submit information on this issue. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A number of comments were received concerning the use of pesticides and agricultural products in manufacturing medical marihuana. Those comments include:

- In the absence of certifying particular agricultural products, the regulations should reflect what types or classes of agricultural products can be used.
- That the Department provide a list of approved pesticides.
- That the Department provide a list of pesticides, fungicides, and herbicides that are prohibited rather than a list of those that are approved.
- Limiting use of pesticides to those that are organic in nature.

RESPONSE: Section 80-1.11(e)(3) of the proposed regulations require that registered organization use only pesticides, fungicides, and herbicides that are approved by the New York State Department of Agriculture and Markets. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Several comment were received concerning § 80-1.11(c)(1) which initially limits registered organization to producing five brands of medical marihuana. Some commenters recommended a phase-in, where additional brands would be authorized in the future. Others

recommended no limits, while another commenter recommended that the number of brands be limited to 15. Comments include:

- Flexibility is needed as it pertains to extraction, dosage and delivery of the product.
- Limiting brands essentially forces a patient to decide which symptoms or conditions he or she will seek to ameliorate with the medical marihuana product.
- Clarification is needed as to the legal standard for reviewing and approving proposed new brands.
- Allowing a registered organization to instead produce a limited number of approved medical marihuana forms and allow a greater number of brand formulations for each of those limited forms.

RESPONSE: Section 80-1.11(c)(1) provides that each registered organization may initially produce up to five brands of medical marihuana. Thereafter, the Department may approve additional brands. The Department is authorized to consider approving additional brands in the future, and will take these comments under advisement as part of that analysis. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Some comments were received concerning the impact of brand limitations to the cultivation business. Limiting a registered organization to only five brands will result in different lighting, different strains, and different procedures, which will change the nature of the cultivation business. Another comment received indicated that restricting the amount of brands will unintentionally require the disposal or destruction of one brand to make room for the next batch of product and given the market price controls, this could potentially harm producers who have to destroy an entire crop. It was stated that Nevada's batch model system is based on best practices that do not create needless oversight.

RESPONSE: Section 80-1.11(c)(1) provides that each registered organization may initially produce up to five brands of medical marihuana. Thereafter, the Department may approve additional brands. The Department is willing to consider approving additional brands in the future, and will take these comments under advisement as part of that analysis. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Other comments were received stating that in form and function, the cannabinoid medicines that the registered organizations will produce more closely resemble pharmaceuticals than the products found on the medical Cannabis markets today. The commenter further stated that the Department, registered organizations, and other stakeholders will be challenged to create a new, reformed medical Cannabis industry operating much further up the drug development curve than the status quo.

RESPONSE: The comment is noted. No changes to the proposed regulation were made as a result of this comment.

COMMENT: A commenter stated that the restriction that patients can only obtain medicine from two lots should be removed.

RESPONSE: Section 80-1.12 (j) provides that 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. The regulations seek to ensure the Department's ability to track back to a specific lot or batch in the event of a product recall or adverse event. No changes to the proposed regulation were made as a result of this comment.

COMMENT: Several comments were submitted concerning the requirement in § 80-1.11(c)(3) that 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 a brand. Those comments include:

- The requirement will pose a challenge due to the 3-month lifecycle of the marihuana plants and each of the staged grows may have varying levels of THC and CBD.
- Recommending striking the requirement and rely instead upon high quality testing and labeling.
- Vaporizable cartridges require a ratio of 75% product, containing not less than 95% or more than 105% of total THC or CBD, and the remaining 25% is for fruit or other flavored extracts.
- Achieving ± 5% tolerances will require full fractionation and isolation of extracts into monocannabinoids to be reformulated by blending into each of the five permitted brands, which cannot be achieved through breeding of the plant strains or blending the inputs.

RESPONSE: As stated in § 80-1.5, an application for a registered organization must include a standard operating procedure manual for all methods used from cultivation through packaging, sealing and labeling each lot of medical marihuana product. The standard operating procedures must 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. Each registered organization must have appropriate validation methods, which may include pre-testing of extracts prior to packaging. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A commenter noted that there are over 400 different types of cannabinoids found in marihuana and the Department should require disclosure of all of them and their potency.

RESPONSE: Section 80-1.11 requires that any other cannabinoid component at > 0.1% must be reported for the product. Cannabinoid components that do not meet this threshold do not have to be reported. The Department will take these comments under advisement. No changes to the proposed regulation were made as a result of this comment.

COMMENT: Several comments were received recommending the proposed regulations be revised to allow other strains of medical marihuana. It appears commenters were using the word "strain" in place of "brand." Those comments include:

- Authorizing the following additional strains should be allowed: THCA; a high CBD oil referred to as "Charlotte's Web"; and a THCV oil.
- Authorizing a pure indica for pain and appetite stimulation; a pure sativa for an alert patient fighting cancer or Parkinsons; a hybrid sativa/indica; and indica/sativa mixes.

RESPONSE: Although the proposed regulations limit the number of brands to five initially, 80-1.11 authorizes the Department to approve additional brands. The Department will take these comments under advisement when it considers approving additional brands of medical marihuana. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Comments were received concerning the requirement in § 80-1.11(c)(4) and (5), stating that it was unnecessary that registered organizations make available at least one brand

that has a low THC and high CBD content, and at least one brand that has approximately equal amount of THC and CBD.

RESPONSE: Therapeutic benefit for all serious conditions cannot be covered by a single brand. However, the Department will take these comments under advisement. No changes were made to the proposed regulation in response to these comments.

COMMENT: A comment was received seeking clarification as to whether a registered organization would be authorized to develop five brands of medical marihuana with multiple delivery methods for each brand, or if a registered organization is limited to producing a total of five products.

RESPONSE: Pursuant to Public Health Law § 3360 (8) any form of medical marihuana not approved by the Commissioner is expressly prohibited. The five brands of medical marihuana produced may be offered in multiple approved forms or approved delivery methods. No changes to the proposed regulation are necessary.

COMMENT: Comment was received seeking clarification that a "brand" is defined by its ratio of THC to CBD.

RESPONSE: A brand is defined by its ratio of THC to CBD.

COMMENT: A commenter recommended that registered organizations be provided the flexibility to establish dose size and ratios with appropriate brands based upon patient needs, after consultation with the treating physician.

RESPONSE: Public Health Law § 3361 (3) provides that, in making the certification, the practitioner shall consider the form of medical marihuana the patient should consume, including the method of consumption and any particular strain, variety, and quantity or percentage of marihuana or particular active ingredient, and appropriate dosage. Medical marihuana dispensed shall conform to any recommendations or limitation by the practitioner as to the form of medical marihuana and dosage to the patient. Public Health Law § 3364 (5)(c). The registered organization is not authorized to dispense product that does not conform to the recommendations or limitations set forth on the patient registry identification card. The Department will implement the technology necessary to support the certification process and will do so in a manner which will allow practitioners to make changes to dosing recommendations within the timeframe of the certification. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Comments were received suggesting that the proposed regulations make clear that "preparations" should be defined to include liquid and oil suspensions, and that cannabis must be fully soluble in liquid.

RESPONSE: The proposed regulations include liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube. A "liquid" preparation can include homogeneous solutions, emulsions or suspensions. Each entity that applies to become a registered organization must include an operating plan that has a detailed description of the applicant's manufacturing process, which must include the process for manufacturing brands in different authorized forms. Solubility requirements are not addressed in regulation. No changes to the proposed regulations are necessary.

COMMENT: Numerous commenters objected to provisions in the proposed regulations which prohibits access to the whole plant and plant based products, stating that beneficial compounds may not be present in oils and extracts. One commenter stated that even if terpenoids are reintroduced after the extraction process, there is an intangible molecular loss that prevents the interaction of various compounds known as the "entourage effect."

RESPONSE: Smoking is expressly prohibited by the Compassionate Care Act. The definition of "certified medical use" in Public Health Law § 3360 (1) specifically states that a certified medical use does not include smoking. Although plant material can be vaporized, the Department must consider a balance between ensuring the availability of quality products for those certified patients who can appropriately utilize medical marihuana and protecting the public against risks to its health and safety. The Department will take these comments under advisement. No changes to the proposed regulations have been made as a result of these comments.

COMMENT: Several comments were received concerning the approved forms and routes of administration set forth in § 80-1.11(g). Those comments include:

- Recommending that the Department approve additional forms of marihuana, including: baths, creams, edibles, lotions, lozenges, massage oils, patches for transdermal administration, salves, suppositories, tinctures, and topicals.
- Recommending that all methods of delivery should be allowed.

- Noting that ointment, balms, and sprays should have minimal THC (0.02%) and are comparable to many over the counter products found at local pharmacies and retail outlets.

RESPONSE: Public Health Law § 3360 (8) provides that any form of medical marihuana not approved by the Commissioner is expressly prohibited. At this time, the Commissioner has determined not to approve medical marihuana in the forms noted in the comments. The proposed regulations at § 80-1.11 authorizes the Commissioner to approve additional forms. The Commissioner is authorized to consider approving additional forms in the future and will take these comments under advisement as part of that analysis. No changes have been made to the proposed regulation as a result of these comments.

COMMENT: Several commenters recommend that edible food products be an approved form of medical marihuana. Those comments include:

- Clarity was needed on the approval process for edible food products.
- Statute does not prohibit edibles and therefore the proposed regulations are beyond the statute's mandate.
- Proper labeling, dosage, and THC limitation would address any concerns raised with approving edible food products.
- Regulations are needed for edible food products since production of such products will inevitably include food preparation equipment and other regulatory considerations which will be the responsibility of the Department to approve.

- Any approval of an edible food product as a form of medical marihuana will be problematic as a THC infused food product would not be subject to oversight by the U.S. Food and Drug Administration.

RESPONSE: Public Health Law § 3360 (8) provides that any form of medical marihuana not approved by the Commissioner is expressly prohibited. At this time, the Commissioner has not approved medical marihuana in edible form. Edible products present challenges in homogeneity of the edible product produced as well as safety concerns. The proposed regulations at § 80-1.11 authorizes the Commissioner to approve additional forms. The Commissioner is authorized to consider approving additional forms in the future and will take these comments under advisement as part of that analysis. No changes have been made to the proposed regulation as a result of these comments.

COMMENT: A commenter sought clarification on the definition of "lot." The commenter asked whether "lot" as used in the proposed regulations encompasses a mixture of multiple extraction products to achieve a uniform cannabinoid concentration.

RESPONSE: A lot may encompass a mixture of multiple extraction products if the multiple extraction products were mixed as a part of an approved and stable processing protocol specific to the approved brand and form during the same cycle of manufacture.

COMMENT: Several commenters supported revisions to the proposed regulations to authorize smoking of marihuana, some stating that new scientific evidence (since passage of the Compassionate Care Act) found that marihuana is not harmful on the lungs. Conversely, a

comment was received in support of the Department's prohibition on smoking medical marihuana. The commenter stated that if smoking is added, it must be supported by science.

RESPONSE: Smoking is expressly prohibited by the Compassionate Care Act. The definition of "certified medical use" in Public Health Law § 3360 (1) specifically states that a certified medical use does not include smoking. As such, the Commissioner is not authorized to allow smoking as a delivery method through regulation. No changes to the proposed regulation has been made as a result of this comment.

COMMENT: A comment was submitted concerning the availability of technology that allows users to combust marihuana in plant form in a vaporizer, and cautioned that an argument could be made that patients were not technically 'smoking" the product. A comment was also received stating that the State should allow the distribution of marihuana in unprocessed flower form with a clear restriction that it must be administered via vaporization and not smoking.

RESPONSE: The statute provides that a certified medical use does not include smoking. Public Health Law § 3360 (1). Although it is possible to vaporize plant based products, the proposed regulations only allow for vaporization of approved metered liquids or oil preparations. These proposed regulations seek to ensure quality and consistency through the manufacturing process. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Some commenters indicated that the proposed regulations would limit patients to extracts of medical marihuana, which will come at an increased cost due to the additional manufacturing process and the need to purchase equipment for vaporization. A commenter

stated that terpenoids and other therapeutic compounds can be lost during the extraction processes, which could interfere with medically beneficial effects.

RESPONSE: The regulations allow for liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube; metered liquid or oil preparations for vaporization, and capsules for oral administration. The proposed regulations at § 80-1.11 authorizes the Commissioner to approve additional forms and will take these comments under advisement as part of that analysis. No changes have been made to the proposed regulation as a result of these comments.

COMMENT: A commenter recommended that there be strict quality control on production of medical marihuana in order to ensure a quality product.

RESPONSE: The Department agrees that quality control is a necessary component of a strong system. Several provisions in the proposed regulations seek to ensure a consistent quality product, free of contaminants which may be harmful to patients. In particular, the application process for a registered organization set forth in § 80-1.5 requires a registered organization to employ a quality assurance officer who is responsible for oversight of the organization's practices and procedures, and submission by the applicant of a standard operating procedure manual for all methods used from cultivation through packaging, sealing and labeling of each lot of medical marihuana product. The procedures must use good agricultural practices, be validated to demonstrate the ability to produce and dispense a consistent medical marihuana product such that, for each form of each brand produced, there is homogeneity, reproducibility and the absence of contamination. Finally, the proposed regulations at § 80-1.14 impose

laboratory testing requirements to ensure adherence with these requirements. No changes have been made to the proposed regulations as a result of the comment.

COMMENT: A commenter stated that the proposed regulations do not contain a provision for the transportation of the plant, or commercial products to the registered laboratories.

RESPONSE: Pursuant to Public Health Law § 3364 (3) each registered organization shall contract with an independent laboratory to test the medical marihuana produced by the registered organization. The proposed regulations at § 80-1.11 (l) requires a registered organization to submit a predetermined number of final medical marihuana products to an independent laboratory approved by the Department. This necessarily requires transporting the product from the registered organization's facilities to the laboratory. No changes have been made to the proposed regulations as a result of the comment.

COMMENT: A comment was received stating that the Department should require that the label sets forth the doses per package.

RESPONSE: The proposed regulations require that the product label affixed on the medical marihuana product at the manufacturing facility include the single dose THC and CBD content for the product set forth in milligrams, and the quantity included in the package. [§ 80-1.11 (k) (3) and (5)]. The proposed regulations further requires that the product label affixed at the dispensing facility include the quantity and date dispensed. [§ 80-1.12 (h) (5)]. No changes to the proposed regulations are necessary as a result of this comment.

COMMENT: Several comments were received concerning product naming requirements set forth in the proposed regulations. Those comments include:

- Providers will not be able to market or prove a well-known strain, such as Charlotte's Web, as equivalent to their product.
- A commenter questioned the need to create unique identifiers for cannabis products.
- Recommending that medical marihuana product naming should utilize the genus name, cannabis, rather than “marihuana”.
- A commenter stated that the restriction to letters and numbers in the naming of the product makes it difficult to develop names that are easier and more convenient for the patients and practitioners.
- Recommending that registered organizations be authorized to use a brand name on its product.
- Allowing a prefix for each registered organization to be incorporated in the product name.
- Requiring that the brand names be sufficiently distinct from other brand names in the market place.

RESPONSE: Section 80-1.11(c)(6) requires that, for each brand offered, the registered organization shall only utilize a distinct name which has been approved by the Department. Department approval of the product name seeks to avoid confusion between products, avoid selection of names similar to existing retail products, and avoid street or slang names. The product name can include letters and numbers, which can be combined in different formats to help identify the product as well as the registered organization that produced the product. No changes are being made to the proposed regulations as a result of these comments.

COMMENT: Several comments were submitted concerning the use of chemicals in growing medical marihuana, and requesting that the product's label indicate any chemicals used in growing the product. Those comments include:

- Recommending that marihuana be grown organically to ensure toxic chemicals or fertilizers are not used, which is especially important to breast cancer patients who require additive-free medical marihuana.
- Prohibiting the use of pesticides since the EPA indicates that several pesticides are probable or possible carcinogens.
- Indicating that, at a minimum, products must be labeled to show if growth additives are used, as well as all other elements (e.g., cannabinoids, terpenes, excipients) found in the product and all non-organic pesticides, herbicides, fungicides and chemicals used through cultivation and the production lifecycle.

RESPONSE: The proposed regulations at § 80-1.11 sets forth manufacturing requirements for medical marihuana products. This section allows a registered organization to use pesticides, fungicides or herbicides if approved by the NYS Department of Agriculture and Markets, but does not require the use of these chemicals. In addition, the section requires that, for each lot of medical marihuana product produced, the registered organization shall submit a sample to an independent laboratory for testing. The independent laboratory must certify the medical marihuana product lot as passing all contaminant testing prior to the medical marihuana product being released from the manufacturer to any dispensing facility. The Department must approve a registered organization's package safety insert which must include a list of excipients used. [§ 80-1.12(k)(2)] The Department will take these comments under advisement. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Several comments were submitted concerning the limitation in § 80-1.11 that prohibits a registered organization from adding 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, and that excipients must be pharmaceutical grade and approved by the Department. Those comments include:

- An objection to the requirement that registered organizations obtain prior written approval from the Department, stating that nearly every form of marihuana concentrate includes the addition of materials or ingredients and would require pre-approval.
- Recommending that ingredients or materials with a "Generally Recognized as Safe" designation from the Food and Drug Administration, be allowed without prior written approval from the Department.
- Recommending that the Department issue a list of pre-approved ingredients or materials that could be used to alter the taste or otherwise aid in oral administration.
- Seeking clarification on the meaning of "additives or preservatives" as vaporizing pens and generic food products have a preservative, such as propylene glycol.
- Recommending that the Department consider limiting excipients to being "food-grade" or "organic" in nature.
- That in some cases, excipients must be used for proper dosing and release within the blood stream and the Department should clarify whether there is an allowable percentage of excipients as it relates to active ingredients.

RESPONSE: Section 80-1.11 (d) provides that 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. The "Generally Recognized as Safe" designation from the Federal Food, Drug and Cosmetic Act is specific to food additives. Each registered organization could have different manufacturing processes outlined in their operating plans. A single Department approved list may not be appropriate for each registered organization. The Department will work with each registered organization to create a list of ingredients approved for use by the registered organization in its manufacturing process. A registered organization need only obtain prior approval of an additive one time prior to approval of the brand. No changes to the proposed regulations are necessary as a result of these comments.

COMMENT: Several commenters objected to the requirement in § 80-1.11 that the registered organization ensure availability of at least a one year supply of any offered brand unless otherwise authorized by the Department. Those comments included:

- Recommending a grace period for the first 24 months of registration.
- Patient demand will not be known until the program has been operational, including for as much as three or four years, and even when demand is known, there will be insufficient capacity for a one year supply.
- The requirement imposes additional costs on an organization to maintain such inventory.
- Requiring that a registered organization have a one year supply in stock raises product stability concerns, and health risks associated with this, in addition to concerns of mold growth.

- Seeking clarification as to whether the one year requirement is for plants to supply or only for finished product.
- Recommending that the requirement should be generalized to require reserves sufficient to meet demands in case of increase of patient population and to ensure steady supply even in case of emergency/disaster/other unforeseen events.
- Stating that the one year supply requirement created a theft risk and diversion.

RESPONSE: Registered organization must develop a standard operating procedure manual for all methods used from cultivation through packaging, sealing and labeling each lot of medical marihuana product (§ 80-1.5). The standard operating procedures must be able to be validated to demonstrate that the applicant will be able to produce and dispense consistent and reproducible medical marihuana product. The requirement that registered organizations ensure availability of at least a one year supply for each brand offered requires the registered organization to demonstrate, through their standard operating procedures, that they are able to ensure availability of the brand for a one year time period. The proposed regulation does not require physical availability of a one year supply of product. The proposed regulation also authorizes the Department to modify this requirement, and will take these comments under advisement should it receive a request for approval to vary from the regulatory requirement. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: A comment was received stating that producers must address how they will ensure that safe, high quality plants are being produced in sufficient quantities to meet the demands of the total population of patients who may be certified for the medical use of marihuana.

RESPONSE: In granting registrations to registered organizations, one of the criteria that will be considered is whether the applicant will produce sufficient quantities of medical marihuana product to meet the needs of certified patients. [§ 80-1.6(b)(2)]. The Department will evaluate all criteria carefully when making its determination. No changes to the proposed regulation are necessary as a result of this comment.

COMMENT: A commenter sought clarification on the meaning of a "stable" processing protocol.

RESPONSE: A "stable" processing protocol would be a validated protocol demonstrated to provide consistent results for a brand from lot to lot and over time.

COMMENT: A commenter suggested that the word "extraction" be removed from the definition of "lot" because "medical marihuana extraction product" is not a defined term.**RESPONSE:** Any manufactured lot would be the result of an extraction. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A comment was received stating that the Department should allow multiple extraction groups to be pooled together to allow the proper ratios to be achieved for testing (regarding the requirement that the registered organization identify each lot of medical marihuana with a unique lot identifier).

RESPONSE: The Department will take this comment under advisement. No changes to the proposed regulations have been made as a result of this comment.

COMMENT: A comment was received stating that it would be impractical for a manufacturing site to individually package medical marihuana for each patient, and recommended instead that the dispensing facility should be allowed to dispense the appropriate amount and dosage from larger containers, as done in pharmacies.

RESPONSE: The regulations require a label to be affixed when packaging the product at the manufacturing site. The label affixed at the manufacturing site is not patient-specific. Pursuant to § 80-1.12, patient specific labeling is a requirement upon dispensing the product at the dispensing facility. The Department will take this comment under advisement. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A commenter stated that in order to ensure product purity, the Department should require that registered organizations produce pharmaceutical-grade product at appropriate pharmaceutical levels (3%).

RESPONSE: The manufacturing requirements in § 80-1.11 and the laboratory requirements in § 80-1.14 ensure that registered organizations are able to demonstrate stability, consistency and purity of the product. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A comment was received requesting the words “or at the direction of” be added after the words “by” to § 80-1.11(h) to allow for frail patients to direct others to break the seal for them.

RESPONSE: The Department will take this comment under advisement. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A comment was received stating that "brand" is used inconsistently throughout the proposed regulations and should be clarified. Commenter stated that it is unclear whether it is the Department's intent to use "brand" as "strain" (see § 80.1.11(2)) or whether reference to "brand" in the proposed regulations was meant to mean finished, usable patient ready product.

RESPONSE: The reference to "brand" in the proposed regulation means the product. "Brand" is defined in § 80-1.11 (a)(2) of the proposed regulation. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A comment was received recommending that registered organizations should be required to use recycled water as it pertains to the requirement in § 80-1.11 that a registered organization 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.

RESPONSE: An applicant for registration as a registered organization must describe in its standard operating procedure manual the methods it will use from cultivation of the medical marihuana through packaging, sealing and labeling of each lot of medical marihuana product. This includes determining the source of water needed for its activities. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A commenter stated that the Department needs more robust requirements for mold mitigation.

RESPONSE: The proposed regulations require visual inspection of the harvested plant material

to ensure there is no mold, mildew, pests, rot or gray or black plant material. [§ 80-1.11(e)(5)]. The proposed regulations also require testing of the final medical marihuana product for contaminants. [§ 80-1.14] The Department will take this comment under advisement. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: Comment was received requesting the following words be inserted into § 80-1.11:

- Add the word “discreet” to (a) (4) to reflect that “Lot” means a discreet quantity.
- Add the word “method” to (a)(6) to indicate that “Manufacturing” shall include, but not be limited to cultivation, harvesting, extraction (or other processing method), packaging and labeling.
- Add the word “Fluid Extraction” to (6) (b) to reflect that a registered organization shall use either carbon dioxide (CO2, Supercritical Fluid Extraction) or alcohol for cannabinoid extraction and shall only perform extraction of the leaves and flowers of female marihuana plants.
- Add the words “an” and “leaf” to (c)(1) to reflect that in no case shall marihuana in an unprocessed whole flower or leaf form be made available to certified patients.
- Add the word “products” to (f) to reflect that poisonous or toxic materials, including but not limited to insecticides, rodenticides, detergents, sanitizers, caustics, acids and related cleaning products 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. .

RESPONSE: The Department will take these comments under advisement. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Several comments were received concerning the maximum THC per dose allowed under the proposed regulations. Those comments include:

- Placing a dosing limit on THC may not adequately cover a patient's needs. For example, chronic pain or terminal cancer may require more than 10 mg THC/dose.
- Recommending increasing the THC per dose maximum to 100 mg.
- Recommending that the THC dosing limits should be revised consistent with requirements implemented in other states.
- A commenter stated that the 10mg single dose limit may be problematic for medical marihuana to be vaporized, as the industry currently does not offer single dose vaporizers. Vaporizers designed for extracted oils use multiple dose cartridges that are used repeatedly. These multiple dose cartridges can hold approximately 250 mg of concentrate.
- Recommending that the Department approve at least one higher dosage form (e.g. 25 mg), with a protocol requiring that treatment begin with 10 mg doses and move to the higher dosage only if and when tolerance begins to rise.
- A commenter suggested that physicians should be allowed to prescribe the medication as appropriate for their patients' symptoms and if a limit is needed, to increase the limit to 200mg.
- A comment was received in support of the limitation on maximum dose.

RESPONSE: "Individual Dose" is defined in Public Health Law § 3360 to state, "[f]or ingestible or sublingual medical marihuana products, no individual dose may contain more than ten milligrams of tetrahydrocannabinol". Public Health Law § 3360 (8) provides that any form of medical marihuana not approved by the Commissioner is expressly prohibited. Public Health Law § 3360(16) defines "form of medical marihuana" as characteristics of the medical marihuana including the method of consumption and quantity or percentage of marihuana or particular active ingredient. Section 80-1.11(c)(3) of the regulations states that each brand shall have no more than 10 mg THC per dose. No changes have been made to the proposed regulation as a result of these comments.

COMMENT: A comment was received concerning the definition of "individual dose" in Public Health Law § 3360(15). The definition states that for ingestible or sub-lingual medical marihuana products, no individual dose may contain more than ten milligrams of tetrahydrocannabinol. The commenter stated that this language implies that vaporized marihuana can have more than 10 mg of tetrahydrocannabinol.

RESPONSE: Public Health Law § 3360 (8) provides that any form of medical marihuana not approved by the Commissioner is expressly prohibited. Public Health Law § 3360(16) defines "form of medical marihuana" as characteristics of the medical marihuana including the method of consumption and quantity or percentage of marihuana or particular active ingredient. Section 80-1.11(c)(3) of the proposed regulations states that each brand shall have no more than 10 mg THC per dose. No changes have been made to the proposed regulation as a result of this comment.

COMMENT: Comments were received concerning the appropriate packaging of medical marihuana products as it pertains to dosage. Those comments included:

- Clarification as to whether the registered organization will be able to package multiple doses in a single container if that container is calibrated or designed to release only single doses at a time.
- Clarification asking whether, in the case of liquid intended to be used through vaporization, each dose could be placed in a simple food safe package or, in the alternative, was the registered organization required to place each dose in separate labeled container.

RESPONSE: Section 80-1.11 (i) requires the packaging to be child-resistant, tamper-proof/ tamper-evident, light-resistant, and in a resealable package that minimizes oxygen exposure. Section (k)(3) of the regulations requires each package to be labeled with the single dose THC and CBD content for the product set forth in milligrams and the quantity included in the package. The final approved medical marihuana product must be packaged at the manufacturing site. In order for a food safe package, it must meet all of the requirements described above. Multiple doses can be packaged in a single container provided that all of the requirements described above are met.

COMMENT: A commenter sought clarification on the term "synthetic marihuana additives" in § 80-1.11(n). The commenter asked if this applies to all synthetic chemicals that may be added to a marihuana product during its manufacturing or only chemicals that are synthetically produced and intended to mimic the effects of natural cannabinoids.

RESPONSE: "Synthetic marihuana additives" refers to chemicals that are synthetically produced and intended to mimic the effect of cannabinoids.

COMMENT: A commenter sought clarification as to whether the proposed regulations restricts the growing of male plants.

RESPONSE: The proposed regulations do not prohibit the growing of male plants. However, § 80-1.11(b) restricts extraction to the leaves and flowers of female plants.

COMMENT: Comments were received concerning the limitation to processing of leaves and flowers for extraction as follows:

- A commenter is seeking the use of whole plant extraction due to its higher medicinal value, or extraction.
- A commenter stated that whole plant could be extracted from within other parts of the marihuana plant.
- A commenter stated that the registered organizations should be able to extract from the stalks of the plant which have certain medicinal terpenes and waxes not found in the flowers or leaves.
- A commenter would like to see the limitation of the extraction to the leaves and flowers of female marihuana plants removed as this limitation could lead to an over accumulation and subsequent waste of male plants. The commenter recommended that measures be taken to ensure that any unused yet usable male plants are fully utilized in the recycling and disposal process to the maximum extent possible.

- A commenter recommended that plant byproducts, such as 'trim', should be allowed to be processed and turned into refined products to avoid excess waste and reduce costs associated with the use of chemically active properties.

RESPONSE: Public Health Law § 3360 (8) provides that any form of medical marihuana not approved by the Commissioner is expressly prohibited. At this time, the Commissioner has determined not to approve medical marihuana in plant form. The proposed regulations at § 80-1.11 authorizes the Commissioner to approve additional forms. The manufacturing requirements set forth in § 80-1.11 allow for the leaves and flowers of the female plant to be processed. The Department will take these comments under advisement. No changes have been made to the proposed regulations as a result of these comments

COMMENT: Several comments were submitted recommending that the Department allow additional extraction methods other than those specified in § 80-1.11(b). Those comments included:

- Excluding H20 extractions discourages a safe and healthy method of cannabinoid extraction. The commenter recommends that the proposed regulations include H20 extraction without first requiring Department approval.
- Recommending water extraction as a viable organic, vegan solvent-free method for extracting resin from the cannabis plant.
- Recommending that, in the case of children, an organic non-GMO botanical oil extraction method ("Botanical Oil Extraction") should be permitted as a more cost effective extraction method. The closed-loop BHO (Butane Honey Oil) should be allowed as an extraction method to the extent there are solvent standards (solvent below 50 PPM), and

that a closed-loop system is required since this method has been found to have no increased risk.

- Recommending that the Department allow for the use of other extraction methods, if approved in writing.

RESPONSE: Section 80-1.11(b) provides that a registered organization shall use either carbon dioxide (CO2, super-critical) or alcohol for cannabinoid extraction. However, § 80-1.11(b) also allows the use of other extraction methods with the prior written approval from the Department. The Department will take this comment under advisement if a request is made to use an extraction method other than those listed in the proposed regulations. No changes have been made to the proposed regulations as a result of these comment.

COMMENT: Several comments were received concerning the requirement in § 80-1.11 that a registered organization use food grade CO2 or alcohol for extraction. Those comments include:

- CO2 lacks the purity needed for extraction. with the remaining 0.5% gas in food grade CO2 presenting in the form of pentane or isomers of pentane, which can cause irritation to the respiratory system, skin and eyes. The commenter recommended that SFE CO2 be utilized as an extraction method instead of CO2 since SFE CO2 can exceed 99.999 purity.
- CO2 extraction isolates and fractionalizes the extract separating the terpenes from the cannabinoids and will not result in a "whole plant" extraction product that will provide full palliative benefit.
- Alcohol evaporates at a higher temperature, which means that many of the beneficial terpenoids would be lost during the purging process.

RESPONSE: Registered organizations will be required to develop an extraction method that results in no significant residual solvent or other contaminants in the medical marihuana products. Each lot of all final medical marihuana products will be tested for residual solvents. The Department believes that CO2 is an appropriate extraction method that may be used in manufacturing medical marihuana product. However, § 80-1.11(b) also allows the use of other extraction methods with the prior written approval from the Department. The Department will take these comments under advisement if a request is made to use an alternate extraction method. No changes have been made to the proposed regulations as a result of these comments.

80-1.12 Comments: Requirements for Dispensing Facilities

COMMENT: Several commenters were opposed to the requirement in § 80-1.12 that a pharmacist be on-site at dispensing facilities and recommended that this provision be removed. Those comments included:

- The requirement creates an undue burden to the registered organization that could increase the price of the medical marihuana products and likely increase costs to patients.
- Pharmacists do not have specialized training or experience, or any specialized knowledge in this area to support this requirement. A commenter stated that dispensing facility employees are far more knowledgeable in this area.
- Using a medical model, known as Direct Observation Therapy, is the standard and requiring a pharmacist onsite is inconsistent and unnecessarily limiting.
- A comment was submitted stating that any health care provider that normally administers prescription drugs should have sufficient expertise to qualify as the authority on premises, rather than limiting this to a pharmacist.

- A commenter stated that the requirement that a pharmacist be on-site at a dispensing facility was not contained in the Compassionate Care Act.

RESPONSE: Certified patients, having one or more serious conditions and an associated condition or symptom may be on several additional medications. Pharmacists have the training and skill-set necessary to identify drug-related issues that a patient may face, not only with the use of an approved medical marihuana product, but also to other medications he or she is taking. The proposed regulations require the pharmacist to complete a course approved by the Department, which includes as components: 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. The statute provides sufficient authority to promulgate regulations to support this requirement. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Several comments were received concerning the requirement in the proposed regulations that a dispensing facility shall not be open or in operation unless a licensed pharmacist is on-site. Those comments include:

- Concern over the potential limited availability of pharmacists in rural areas.
- Requirement creates potential problems when the pharmacist is out on vacations, sick days, routine absences (e.g. lunch) or in the event of sudden resignation, termination, disability or death. The commenter stated that creating redundant staffing to cover these eventualities would be very expensive.

- Recommending removal of the requirement and require instead that registered organizations develop comprehensive communication and education processes with certified patients, detailed as part of the application for registration, that allows for a pharmacist to be available for counseling via phone.

RESPONSE: Patients with serious conditions may be on multiple medications and a pharmacist has the education and skill-set to identify any drug related problems, such as drug-to-drug interactions, therapeutic duplications, and identifying potential adverse events. The Department will take these comments under advisement. No changes to the proposed regulations were made in response to them.

COMMENT: Several commenters stated that pharmacists face potential risk in participating in the activities authorized under the proposed regulations, and sought clarification on how the activities correlate to the scope of practice of pharmacists. Those comments include:

- Authorizing an employee, who is under the direct supervision of, and in consultation with a pharmacist, to counsel a patient appears to be in violation of NYS Education Department regulations which make counseling a non-delegable duty.
- Seeking clarification as to whether revisions are required in NYS Education Law and its regulations to authorize pharmacists to perform the functions set forth in the proposed regulations.
- Recommending that the proposed regulations be revised to adequately address potential criminal, civil liability and licensure risks to pharmacists.

RESPONSE: The Compassionate Care Act contains protections applicable to pharmacists in dispensing facilities. The statute makes clear that medical marihuana is not deemed a “drug” for

purposes of article one hundred thirty-seven of the Education Law, in relation to the practice of pharmacy [Public Health Law § 3368 (1)(b)]. In addition, Public Health Law § 3369 (1) provides protection from arrest, prosecution or penalty in any manner, including but not limited to disciplinary actions by a professional licensing board, to employees of registered organizations, which would include pharmacists, solely for the certified medical use or manufacture of marihuana or for any other action or conduct in accordance with Title V-A of Article 33 of the Public Health Law. No changes were made to the proposed regulations in response to these comments.

COMMENT: Commenters suggested that marihuana should be rescheduled from a category I to a category II on both the federal and state schedules of controlled substances.

RESPONSE: These comments request action that is beyond the scope of these regulations. Controlled Substance Schedules in New York are amended only through legislation. The Compassionate Care Act did not move marihuana from Schedule 1. Similarly, the State does not have authority to amend federal schedules of controlled substances. No changes were made to the proposed regulation in response to these comments.

COMMENT: A comment was received seeking clarification on how Public Health Law and standards related to emergency oral prescriptions, refills and reporting to the PMP registry will apply to medical marihuana. A comment was also received asking how dispensing facilities will complete the required reporting of marihuana transactions to the statewide registry.

RESPONSE: These regulations do not address or allow emergency oral prescriptions or refills. Under the Public Health law, marihuana for a medical use is not prescribed. Rather, it may only

be dispensed to a certified patient or designated caregiver with a valid registry identification card. Dispensing of medical marihuana and corresponding reporting requirements are set forth in the statute. A registered organization is not permitted to dispense an amount greater than a thirty day supply to a certified patient or designated caregiver until the certified patient has exhausted all but a seven day supply provided to a previously issued patient certification. [Public Health Law § 3364 (5)(b)] The statute also requires a registered organization to file with the Department receipts for medical marihuana dispensed on a real time basis. The Department will provide guidance on this issue. No changes to the proposed regulations have been made as a result of these comments.

COMMENT: A comment was submitted indicating that the proposed regulations require registered organizations to pay a 7% tax on medical marihuana products dispensed, while prescription medication, including controlled substances, are exempt from tax. The commenter stated that if marihuana is medical, it should likewise be exempt from taxation.
RESPONSE: The excise tax on gross receipts from the sale of medical marihuana by a registered organization is established in Article 20-B of the Tax Law. The comment is beyond the scope of the proposed regulations and no changes were made in response to it.

COMMENT: Comments were received concerning the education and experience requirements of pharmacists who will be employed by a registered organization to supervise the activity of a dispensing facility. The comments include:

- A request for clarification as to whether pharmacists would be required to obtain additional certifications or education to oversee the activities of the dispensing facility.

- Recommending that the proposed regulations require the pharmacist to have 3 years of specific experience managing an inventory of controlled substances; knowledge of the pharmaceutical dosage forms and delivery systems; and specific training in the clinical use of cannabinoids.
- Recommending that the proposed regulations require the pharmacist to have a certification for medication therapy managements.

RESPONSE: Section 80-1.21(d) of the proposed regulations require the pharmacist to complete a course approved by the Department. This course is the same as that required of practitioners who wish to register in order to issue certifications to patients. The Department will take these comments under advisement. No changes were made to the proposed regulations in response to them.

COMMENT: Comments were received in support of the requirement to have a pharmacist on-site at the dispensing facility to supervise the activities therein. Those comments include:

- Pharmacists are trained healthcare professionals with experience in controlled substance inventory management, medication therapy management and compounding.
- The requirement to have a pharmacist on-site will greatly help to prevent medication errors, as well as guarantee that the patient leaves the dispensing facility with the most up-to-date information about the product and how it is used.
- Recommending that the proposed regulations also require that registered organizations make available at the dispensing facility certified pharmacy technicians as they are skilled in medications, packaging and other duties.

RESPONSE: The comments are noted. No changes to the proposed regulation are necessary.

COMMENT: Several comments were received recommending additional activities that a pharmacist should perform at the dispensing facility. Those comments include:

- Recommending that all patients be counseled by a licensed and qualified pharmacist and in accordance with NYS Department of Education regulations at 8 NYCRR 63.6(b)(8)(i).
- Pharmacist should provide education, in addition to counseling, as is done with prescription medications.
- Authorizing pharmacists to demonstrate administration techniques with the devices that the patient will be using, when necessary.

RESPONSE: The Department will take these comments under advisement. No changes to the proposed regulations have been made in response to the comments.

COMMENT: Comments were received recommending pharmacist involvement in the manufacturing of the medical marihuana product. A commenter noted that compounding is within the scope of practice of pharmacists and, therefore, pharmacists should be involved in the product preparation process as well.

RESPONSE: The Department will take these comments under advisement. No changes to the proposed regulations have been made in response to the comments.

COMMENT: A comment was received stating that registered organizations should also be required to maintain a complete profile of medications for prospective review by a qualified pharmacist to ensure there are no contraindications or drug interactions in the patient's regimen as this is a standard of care in every jurisdiction in the United States.

RESPONSE: The Department will take these comments under advisement. No changes to the proposed regulations have been made in response to the comments.

COMMENT: A comment was submitted seeking clarification on whether a dispensing facility may remain open to offer products or services other than medical marihuana and paraphernalia, without the presence of a pharmacist.

RESPONSE: The proposed regulations at § 80-1.12 provide that a dispensing facility shall not be open or in operation unless the pharmacist 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. A dispensing facility would not be permitted to remain open without the presence of a pharmacist to offer products or services other than medical marihuana and paraphernalia.

COMMENT: Several comments were submitted recommending that the proposed regulations be revised to eliminate, as too restrictive, the prohibition of visitors at the dispensing facility as set forth in § 80-1.12(g). Those comments include:

- The requirement will create a hardship for the most severely disabled who may need assistance in traveling to or obtaining the medical marihuana from the dispensing facility.
- Prior authorization for all visitors may create an unnecessary oversight obligation for the Department.

RESPONSE: The limitation set forth in § 80-1.12 is a proper security measure to ensure that only those that are authorized to obtain medical marihuana products are permitted on the premises of a dispensing facility, unless waived by the Department upon prior written request. The Department recognizes that in some cases, prior authorization is not feasible. The proposed

regulations provide that if an unforeseen circumstance requires the presence of a visitor and makes it impractical for the dispensing facility to obtain a waiver, 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. In addition, if a certified patient requires the assistance of individuals to secure medical marihuana, statute and regulations authorize a certified patient to designate up to two designated caregivers. Designated caregivers who have been issued a registry identification card are permitted in dispensing facilities under the proposed regulations. No changes were made to the proposed regulation in response to these comments

COMMENT: A commenter sought clarification as to whether a dispensing facility could make available public areas, such as a patient waiting area or similar unrestricted area that is not required to meet security measures set forth in the proposed regulations.

RESPONSE: The proposed regulations do not contain provisions for a patient waiting area. The Department will take this comment under advisement. There is nothing to preclude an individual, otherwise properly present inside a dispensing facility, from being in a waiting area. No changes were made to the proposed regulation in response to this comment.

COMMENT: A comment was received seeking clarification concerning the dispensing facility's obligations in terms of removing individuals who are not authorized to enter the dispensing facility.

RESPONSE: The dispensing facility is responsible for complying with the requirements of the proposed regulations and should determine appropriate action to take if an individual, who is not

permitted in the dispensing facility, refuses to leave the premises when directed. No changes were made to the proposed regulation in response to this comment.

COMMENT: Further comments were received concerning the restriction of visitors in dispensing facilities. Those comments include:

- Recommending the proposed regulations be revised to allow a labor union representing union employees to submit a list of names of the union representatives for preapproval by the Department.
- Recommending the proposed regulations be revised to create an exception for waste disposal, suppliers, plumbers, electricians, cleaning staff, etc.
- Recommending the proposed regulations be revised to permit contractors and consultants of the registered organization in dispensing facility.

RESPONSE: The Department will take these comments under advisement. The regulations allow for access to non-patients or non-caregivers upon prior written approval. It is anticipated that registered organizations will make requests for access for specific individuals who have legitimate business within a dispensary facility. No changes were made to the proposed regulations in response to these comments.

COMMENT: Several comments were received objecting to the prohibition on consuming medical marihuana products, as well as food and drink, on the premises of dispensing facilities. Those comments include:

- Recommended revising the proposed regulation to remove the prohibition.

- Dispensing facility staff should be able to educate patients, including those who may be using medical marihuana for the first time, by assisting them in using the medical marihuana products at the dispensing facility.
- The Department should allow the use of a placebo or inactive material (saline, water) in vaporizers or sprays, sublingual or inhalers, etc. to allow dispensing facilities to provide direct demonstration and training to patients without using active ingredients or product.
- Recommending revising the proposed regulations to prohibit only those foods that may be similar to medical marihuana product offered at the dispensing facility and have a likelihood to cause confusion with the medical marihuana product.

RESPONSE: The proposed regulations at § 80-1.12 allow for food or beverage consumption if necessary for medical reasons. The proposed regulations do not prohibit the use of a placebo, using an excipient approved by the department, to demonstrate the use of a vaporizer to a patient. The Department will take these comments under advisement. No changes were made to the proposed regulation as a result of these comments.

COMMENT: A commenter stated that the proposed regulations should allow registered organizations to counsel patients and facilitate patient services to better educate patients, offer advice and determine the appropriate product for the patient's individualized needs.

RESPONSE: The pharmacist at the dispensing facility, or an employee of the dispensing facility under direct supervision of the pharmacist, has the ability to counsel patients and share information concerning the product being dispensed. No changes were made to the proposed regulations as a result of this comment.

COMMENT: A comment was received suggesting the Department change the word "ordering" to "certifying" in § 80-1.12(h)(2) for the practitioner's name.

RESPONSE: The clarification has been made.

COMMENT: A commenter recommends inclusion of the lot number in the patient log at the dispensing facility to assist with inventory control and should the need arise, in the successful recall of a product.

RESPONSE: The Department will take this comment under advisement. No changes were made to the proposed regulations in response to it.

COMMENT: Comments were received concerning the labeling requirements of the dispensing facility. A commenter stated that there is overlap between the data the manufacturer is required to include on a label and what the dispensary is required to include on its label. The commenter recommends a review of the Cannabis Committee labeling considerations for reference.

RESPONSE: The Department will take these comments under advisement. No changes were made to the proposed regulations in response to them.

COMMENT: Further comments were received with respect to labeling requirements. A comment was submitted that requested the Department consider lack of harm when requiring statements on the label. The commenter indicated that no evidence of harm or risk has been shown from driving under the influence of marihuana.

RESPONSE: Public Health Law § 3364 (12) requires that the label to be affixed on medical marihuana dispensed to the patient contain a statement that the product might impair the ability

to drive. The proposed regulations are in line with this statutory requirement. No changes have been made to the proposed regulation as a result of this comment.

COMMENT: A comment was received expressing concern over the use of marihuana by children and adolescents. The commenter stated that the warning "KEEP THIS PRODUCT AWAY FROM CHILDREN" as required in the proposed regulations, should specify the potential harm it can cause to children.

RESPONSE: Public Health Law § 3364 (12) requires the product label to include this warning. The proposed regulations are consistent with this statutory requirement. No changes were made to the proposed regulation as a result of this comment.

COMMENT: A comment was submitted recommending that the label affixed at the dispensing facility should consider or include the maximum daily dose of the product to align with existing regulations for controlled substances and improve patient safety by eliminating ambiguity in directions, and allow for less diversion. The commenter further stated that the Department should add a maximum content per serving, and if added, to list servings per package.

RESPONSE: Public Health Law § 3364(12) requires that medical marihuana be dispensed in a properly labeled package which includes the information required to be maintained on the certificate (which includes dosage for the certified patient) and the amount of individual doses contained within. The proposed regulations are consistent with statute, however, the Department will take these comments under advisement. No changes have been made to the proposed regulation as a result of these comments.

COMMENT: A comment was received asking if medical marihuana product is subject to sales tax.

RESPONSE: The purchase of approved medical marihuana products by a patient or designated caregiver is not subject to sales tax.. However, the registered organization is required to pay an excise tax to the New York State Department of Taxation and Finance which is based upon gross receipts from the sale of medical marihuana by a registered organization.

COMMENT: Several comments were received concerning the limitation on dispensing medical marihuana products in greater than a thirty day supply and until the patient has exhausted all but a seven day supply. Comments stated that registered organizations will have difficulty determining how much medical marihuana a certified patient still possesses. One comment recommended the proposed regulation require some type of due diligence to be conducted by the registered organization and the certified patient be required to sign an attestation as to the amount of medical marihuana product remaining in his or her possession.

RESPONSE: Public Health Law § 3364 (5)(b) prohibits a registered organization from dispensing an amount greater that a thirty day supply to a certified patient until the certified patient has exhausted all but a seven day supply. The statute further provides that, to verify this information, the registered organization must consult the Prescription Monitoring Program Registry. The Department believes that consulting the registry, in conjunction with other efforts short of requiring an attestation, is an adequate means of ensuring compliance with the statute. No changes have been made to the proposed regulation as a result of these comments.

COMMENT: Further comment was received concerning the limitation on dispensing to a thirty day supply. Commenters expressed concern that a thirty day supply was too short and restrictive, especially for patients who will be traveling long distances to reach a dispensing facility. Those comments include:

- Allowing for a sixty day supply.
- Clarification was sought as to how a product will account for a patient's monthly supply, by weight of the final product or by weight of the extract.
- Clarification was sought as to the number of 10 mg THC doses that may be included in a thirty day supply.
- A recommendation that the Department should explicitly encourage and permit registered organizations to issue "reminders" to patients who are due for another thirty day supply. The Department should also permit the registered organization to process an order earlier than when a patient has exhausted all but a seven day supply when the patient experiences access issues.

RESPONSE: Public Health Law § 3364 (5)(a) requires that a registered organization dispense an amount no greater than a thirty day supply to a certified patient until the certified patient has exhausted all but a seven day supply. Similarly, Public Health Law § 3362 (1)(a) states that possession of medical marihuana is lawful provided that the marihuana that may be possessed does not exceed a thirty day supply, except that during the last seven days of any thirty day period, the certified patient may also possess up to such amount for the next thirty day period. The proposed regulations are consistent with these statutory requirements. The thirty day supply is based upon the dosing recommendations that are included by the practitioner for the brand in the patient's certification. The supply may be calculated based upon number of units or volume

of the product for the authorized forms. For example, a capsule form taken three times per day would require 90 capsules for a 30 day supply. Similarly, oil or liquid based product volume would be measured in milliliters for each dose multiplied by the number of doses per day multiplied by 30 days. The number of 10 mg THC doses per thirty day supply would depend upon the number of units (or mL) that a patient would take per day times 30 days. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: A commenter sought clarification as to whether patients and caregivers will be able to purchase medical marihuana at the dispensing facility of their choice or if they will be limited to the region in which they reside.

RESPONSE: The proposed regulations do not limit patients and caregivers to dispensing facilities located within the region in which they reside.

COMMENT: A comment was received recommending that samples be permitted for device calibration.

RESPONSE: 80-1.10 prohibits a registered organization from distributing products or samples at no cost except as may be allowed by the Commissioner. The Department will take this comment under advisement. No changes were made to the proposed regulation as a result of this comment.

80-1.13 Comments: Security Requirements for Manufacturing and Dispensing Facilities

COMMENT: A comment was received requesting the Department provide a list of approved safes and vaults in light of the requirement in § 80-1.13 (j), which provides that 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.

RESPONSE: The Department will provide guidance on approved safes and vaults that may be used for this purpose. No changes to the proposed regulations are necessary.

COMMENT: Comments were received with regard to the requirement in § 80-1.13 that, prior to transporting any approved medical marihuana product, a registered organization shall complete a shipping manifest using a form determined by the Department. A commenter stated that maintaining a copy of a shipping manifest and transmitting to the dispensing facility is unduly burdensome in some circumstances and restricts a registered organization's ability to meet unexpected situations.

RESPONSE: The shipping manifest is necessary to track transportation of medical marihuana products and ensure that a registered organization's driver has sufficient documentation that may be needed in the event that the driver is questioned about what is being transported. Timely and accurate tracking of the movement of medical marihuana is an appropriate expectation of any registered organization. No changes to the proposed regulation have been made as a result of this comment.

COMMENT: Comments were received concerning the shipping manifest. A commenter stated that the manifest should be approved by the Department before it is considered valid to prevent confusion when law enforcement encounters marihuana in transit. A commenter further stated that employees should be identified by a Department approved identification card that can be verified by law enforcement.

RESPONSE: The proposed regulations authorize the Department to determine the appropriate form to be used as the shipping manifest. The Department will take these comments under advisement. No changes to the proposed regulation have been made as a result of these comments.

COMMENT: A comment was received stating that the proposed regulations should explicitly authorize registered organizations to use security guards employed and supplied by security guard companies.

RESPONSE: The registered organization may not contract for the provision of security services, including in relation to transportation. Core functions directly related to manufacturing and dispensing of the medical marihuana product must be performed by a registered organization's employees. No changes have been made to the proposed regulation as a result of this comment.

COMMENT: A commenter recommended that the proposed regulations require that each manufacturing facility have secured fencing, or similar structure.

RESPONSE: The Department will take this comment under advisement. No changes to the proposed regulation have been made as a result of this comment.

COMMENT: A commenter sought clarification as to whether transportation staff of the registered organization can carry side arms if they are authorized in NYS to have a pistol permit.

RESPONSE: This comment is beyond the scope of the proposed regulations. The individual granted a pistol permit should review the applicable law under which such permit was granted to

determine whether the same may be carried while performing the functions of their employment. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A commenter sought clarification as to what is required to satisfy the requirement in the proposed regulation that 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 when the vehicle contains medical marihuana products.

RESPONSE: "Secure forms of communication", required for the transport team member, is a form of communication that would allow the transport team member to communicate with an employee of the registered organization or contact 911 in the event of an emergency.

COMMENT: A comment was submitted recommending that the proposed regulations should allow for transport using one driver in a secured vehicle, instead of two as required in the proposed regulations. The commenter would like the Department to remove the requirement that one member stay with the vehicle at all times.

RESPONSE: Marihuana is a Schedule I controlled substance according to both the federal Controlled Substance Act and Article 33 of New York's Public Health Law. Strong and effective controls must be in place to ensure that medical marijuana is secured during transport. No changes to the proposed regulation have been made as a result of this comment.

COMMENT: A comment was received suggesting the addition of "or as soon as possible in the case of unusual circumstances" to § 80-1.13(n)(1), to read "[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 or as soon as possible in the case of unusual circumstances."

RESPONSE: The Department will take this comment under advisement. No changes have been made to the proposed regulation as a result of this comment.

COMMENT: Several comments were received concerning the requirement in proposed regulations that the registered organization have a security system in place with the ability to remain operational during a power outage. Those comments include:

- Clarification is needed as to the length of time the surveillance and security equipment must remain operational.
- Whether all security requirements must remain operational during a power outage.
- That a large gas-powered generator would be required during significantly prolonged power outages, which poses safety concerns.
- Questioning the need for a back-up alarm system, particularly when the facility is supported by an emergency power supply.

RESPONSE: The Department will take these comments under advisement, and will provide guidance on security requirements that must be met during times of prolonged power outages. No changes have been made to the proposed regulation as a result of these comments.

COMMENT: A commenter recommended that the Department allow a registered organization to utilize motion detection security devices in lieu of video surveillance, as long as the licensee can demonstrate that monitored activities are adequately recorded.

RESPONSE: Marihuana is a Schedule I controlled substance according to both the federal Controlled Substance Act and Article 33 of New York's Public Health Law. Strong and effective controls must be in place to ensure that medical marijuana is secured at manufacturing and dispensing facilities. No changes to the proposed regulation have been made as a result of this comment.

COMMENT: A commenter recommended that the requirement that registered organizations maintain a copy of video recordings only apply when the registered organization is provided notice and request by law enforcement or other government agency of a pending investigation. The commenter further suggested that a registered organization should be required to maintain all unaltered recordings in existence for a period of 90 days prior to the notification. Finally, the commenter also suggested removing the requirement that a registered organization retain an unaltered copy of a recording if the registered organization is aware of pending litigation, as the Civil Practice Law and Rules prohibits destruction of evidence related to matters in litigation.
RESPONSE: The Department will take these comments into advisement. No changes were made to the proposed regulation as a result of these comments.

COMMENT: A comment was submitted concerning the requirement in § 80-1.13(a)(3) to maintain video cameras at all points of entry and exit. The commenter sought clarification on exterior camera needs if the registered organization's leased area of operation is only a portion of an entire structure. The commenter also asked whether exterior cameras will be required to capture video of adjoining walls and/or the entire outer perimeter of the building.

RESPONSE: Section 80-1.13(a)(3) requires the manufacturing facility or dispensing facility to angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility. The proposed regulations do not require the entire outer perimeter to be recorded, provided that security cameras are installed to capture clear and certain identification of any person entering or exiting the premises. No changes to the proposed regulation have been made as a result of these comments.

COMMENT: A commenter noted that the security requirements for manufacturing and dispensing facilities essentially requires that the processing facility have the product under constant lock within the facility. The commenter felt that this goal can be effectively accomplished with other systems such as a personal access system and stated that requesting a registered organization to have a security plan would be a more balanced way to achieve security goals and be consistent with current state and federal requirements.

RESPONSE: The security requirements take into account that marihuana is a schedule I controlled substance according to the federal Controlled Substance Act, as well as New York State schedules of controlled substances defined in Section 3306 of the Public Health Law. No changes to the proposed regulation were made as a result of this comment.

80-1.14 Comments: Laboratory Testing Requirements for Medical Marihuana

COMMENT: A comment was received recommending that all cannabis grown in this State should be tested for mold, pesticides, herbicides, and any other chemicals that could harm patients.

RESPONSE: Each lot of all final medical marihuana products will be tested for cannabinoid profile, contaminants, and residual solvents. The testing includes aflatoxins and ochratoxins,

which are mold toxins. Registered organizations will be required to develop an extraction method that results in no significant residual solvent or other contaminants in the medical marihuana products. Any final medical marihuana products that do not pass testing will not be approved for distribution to patients. Registered Organizations, in developing all methods, should consider the quality of any product used to generate the final medical marihuana product. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: Several comments were received in relation to the requirement in § 80-1.14 that marihuana testing laboratories must be licensed by the federal Drug Enforcement Agency (DEA). Those comments include:

- A commenter questioned whether it would be impossible for a marihuana testing laboratory in New York to obtain a DEA license until marihuana is rescheduled at the federal level.
- A commenter stated that the DEA has not issued a license to any laboratories that conduct cannabis testing, and raised concerns that existing DEA licensed laboratories are not equipped to conduct agricultural testing e.g., heavy metals, microbials, etc.
- A commenter recommended that, if a DEA license is a prerequisite, the Department should consider having those laboratories manage sample custody and oversee testing by a State certified subcontractor properly equipped and experienced in cannabis testing.

RESPONSE: Laboratories must be licensed by the DEA in order to receive samples for proficiency testing from the Department of Health, Wadsworth Laboratories. The Department believes that laboratories will be able to obtain the required DEA and state licensure to analyze

schedule I controlled substances. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: A commenter sought clarification as to whether New York State will be licensing third party analytical laboratories to test marihuana so that they may apply with the DEA and comply with New York State law.

RESPONSE: The Department will be issuing permits to laboratories, through the Wadsworth Center Environment Laboratory Approval Program, for medical marihuana and contaminant testing. The laboratory must also be licensed with the Department of Health, Bureau of Narcotic Enforcement.

COMMENT: A comment was received recommending the language in § 80-1.14(a) be revised to replace the word "produced" with "manufactured" as follows: Medical Marihuana products manufactured by a registered organization shall be inspected in a laboratory located in NYS that is licensed by the federal DEA and approved for the analysis of medical marihuana by the Department in accordance with Article 5 of the PHL and subpart 55-2 of this title."

RESPONSE: The Department will take this comment under advisement. No changes have been made to the proposed regulation as a result of this comment.

COMMENT: A comment was received stating that independent laboratory testing of every lot manufactured is unnecessary and burdensome. The commenter recommends periodic in-house laboratory testing of medical marihuana, with a requirement for periodic independent laboratory testing.

RESPONSE: Public Health Law § 3364 (3) requires that each registered organization contract with an independent laboratory to test the medical marihuana produced by the registered organization. The laboratory testing requirements set forth in the proposed regulations ensure that quality products, free of contaminants, are available for certified patients in New York State. The Department will monitor program operations and will consider whether the currently required frequency of laboratory testing is appropriate to ensure patient safety. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: Several comments were received concerning the sample retention requirements in the proposed regulations. Those comments include:

- Maintaining samples for two years would increase operating costs.
- The length of time the product is in storage may impact the product's stability and would require an expensive cold chain pharmaceutical storage process.
- Seeking clarification as to how much product is expected to be kept on site for testing, and whether the Department would issue a schedule for testing.
- Recommending that registered organizations be prohibited from self-select the samples to be tested, and recommended that sampling be done either on a random or regular basis, by agents of the testing laboratories.
- Commenter sought clarification on what a statistically representative number of samples will mean. Comment also sought clarification as to whether measures must be taken to preserve the samples against regularly occurring spoilage.

RESPONSE: The availability of samples of each lot of medical marihuana product offered to certified patients is important for further evaluation in the event that a serious adverse event or

side effect is reported. Such adverse events or side effects may not be immediately apparent. The registered organization, in its application for registration, must describe in its operating plan, its method of sampling each lot of medical marihuana product. The operating plan must be approved by the Department. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Comments were received concerning laboratory testing and contaminants. Those comments include:

- A recommendation that testing for contaminants should define the permitted levels of microbials in finished products, and the allowable limits in food products and not synthetic pharmaceutical products which the commenter recommends modeling these limits after FDA and EPA requirements.
- There should be reasonable microbial assessment, the Department's microbiological roster was derived from USP 61 and 62. However, those lists have no bearing on Cannabis.

RESPONSE: The Department will take these comments under advisement. The Department will consider whether clarification on this issue is needed in guidance or in future revisions to the regulations. No changes were made to the proposed regulation as a result of these comments.

COMMENT: A commenter recommended that the Department define the pricing for the independent lab analysis of each sample, in order to provide a uniform, defined lab testing cost. The commenter stated that a uniform lab testing cost would enable each registered organization to accurately budget their operations, and further, more precisely specify their product(s) costs.

RESPONSE: The comment is beyond the scope of the proposed regulations and suggests an action that exceeds the Department's authority.

COMMENT: A comment was received stating that testing for contaminants in the final medical marihuana product list was not accurately labeled. The first set of contaminants are microorganisms, not analytes.

RESPONSE: The Department has made this clarifying change.

COMMENT: A comment was received recommending that § 80-1.14 (h) be revised to replace the word "consumed" with "utilized" in the following statement: The laboratory shall track and destroy any quantity of medical marihuana product that is not utilized in sample testing.

RESPONSE: The definition of "consumed" encompasses utilization. No changes were made to the proposed regulation as a result of this comment.

COMMENT: A commenter sought clarification as to whether DEA licensed laboratories will undertake stability studies and, if so, whether the stability studies would be true shelf-life studies that look at the stability of all ingredients, and not just the active ingredients.

RESPONSE: The Department intends on providing guidance on the issue of stability studies. Verification of the stability of a brand will be provided by testing at a Department of Health approved laboratory. No changes to the proposed regulation have been made as a result of this comment.

COMMENT: A commenter recommended that registered organizations be allowed to reprocess and reconstitute lots with issues that are redressable, to eliminate waste, expense, documentation and resources required to dispose of problematic products.

RESPONSE: The Department will take this comment under advisement. No changes have been made to the proposed regulation as a result of this comment.

COMMENT: Comment was received suggesting that the Department consider a provision that directs registered organizations to provide stability data when they submit their product proposals to the Commissioner. The Commenter recommended ongoing testing to validate the data provided and to determine whether product modifications are required.

RESPONSE: The Department will take this comment under advisement. No changes have been made to the proposed regulation as a result of this comment.

COMMENT: A comment was received requesting that the Department provide guidance on the acceptable limits for identified anylates. The commenter suggested the American Herbal Pharmacopoeia as a reference in establishing the limits. The commenter also recommended that the Department review the AHPA Cannabis Committee's recommendations for further considerations on returned product.

RESPONSE: The Department will take this comment under advisement. No changes have been made to the proposed regulation as a result of this comment.

COMMENT: Comments were received concerning typographical errors when referencing section numbers in the proposed regulations. The comments include:

- Section 80-1.14(f) references § 80-1.11(h)(2), when only § 80-1.11(c)(2) would be appropriate.
- Section 55-2.15(c)(2)(iii)(a) should be updated to reflect that contaminants are listed in § 80-1.14(g), and not in § 80-1.11(h)(2).

RESPONSE: These minor revisions have been made.

80-1.15 Comments: Pricing

COMMENT: Several comments were received concerning the price and affordability of medical marihuana. Those comments include:

- Recommending that the proposed regulations be revised to address access by low income patients, such as discounted rates, subsidized rates, a sliding fee scale, or free medicine or equipment, and travel and transportation stipends.
- Requiring a compassionate use program as one of the components for entities applying for registration as a registered organization, and incentives for applicants who become registered organizations to offer a charity care program or provide a sliding scale fee or dispense the medicine and equipment for free.
- Allow exemptions in cases where qualified low income patients may take advantage of give-back programs created by the dispensing facilities as profits increase.
- Recommending that the State subsidize expenses for medical marihuana, or that the State should use a portion of the revenue from the program (from fees and taxes) to fund grants to help low income patients purchase medical marihuana products, and to provide transportation to dispensing facilities.

RESPONSE: Public Health Law § 3369-d requires the Commissioner to set the price per dose for each form of medical marihuana sold by any registered organization, and must take into account the fixed and variable costs of producing the form of marihuana in approving such price. The statute does not provide for differentiation of price based on income of the certified patient. Although the regulations prohibit distribution of products or samples at no cost, they allow exceptions to be authorized by the Commissioner, including authorization for a registered organization to implement a charity program. The Department will seek to ensure geographic distribution of dispensing facilities; however, no travel stipends or other state financial support is available at this time. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Comments were received generally against the proposed regulations which authorize the Commissioner to set the price per dose of medical marihuana products, and recommending instead that the price should be determined by the market and provided the benefits of this approach. Those comments include:

- If the Commissioner approves the price per dose of medical marihuana product, more than 5 registered organizations should be licensed.
- What does the Department intend to do if one registered organization is able to produce a product that costs substantially less than the product produced by other registered organizations.
- A recommendation that pricing information be submitted by all applicants as part of a registered organization application, with the opportunity to make revisions prior to

Departmental approval. The Department should consider setting prices for a two year period to provide stability.

- The proposed regulations should provide a registered organization the right to respond to administrative action refusing or reducing a proposed price.
- Seeking clarification as to whether the price for the product will be statewide or vary by the cost to bring it to the market in a particular region.
- Approved prices should be able to be modified, especially early in the program lifecycle when registered organizations will be facing potentially unexpected costs.
- Pricing will be an area of exposure for the Department as participation in an activity that violates the CSA.

RESPONSE: Pursuant to Public Health Law § 3369-d, every sale of medical marihuana must be at a price determined by the Commissioner. Every charge made or demanded for medical marihuana not in accordance with the price determined by the Commissioner is prohibited. The statute further authorizes the Commissioner to set the price per dose of each form of medical marihuana and, in doing so, to consider the fixed and variable costs of producing the form of marihuana and any other factor the Commissioner, in his discretion, deems relevant in determining the price. The proposed regulations are in accord with the requirements of statute. Section 80-1.15 requires a cost analysis, defined to 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. In determining whether to approve a registered organization's proposed price, the proposed regulations require the registered organization to submit information and documentation on its fixed and variable

costs in producing each brand of medical marihuana, and its proposed profit. If the Commissioner approves a proposed price, the price is effective for that registered organization for the duration of the registration; however, the regulations do allow a review of the approved price at the conclusion of the first year, or earlier based on documented exceptional circumstances. The Department believes the proposed regulations sufficiently clarify the requirements of statute and no further revisions have been made. However, the Department has considered the remaining comments and will evaluate whether further guidance is needed in this area, or whether clarification is needed in future revisions to the regulation.

COMMENT: Comments were also received concerning what components should be factored in when determining "costs". Those comments include:

- The excise tax value should be included as part of an applicant's projected cost information.
- The costs should take into account research and development, start-up and capital expenditures, and the cost of capital and provide a reasonable period of time to recoup such costs.

RESPONSE: In determining whether to approve a registered organization's proposed price, section 80-1.15 of the proposed regulations require the registered organization to submit information and documentation on its fixed and variable costs in producing each brand of medical marihuana, and its proposed profit. The registered organization will be expected to provide sufficient information and justification as to what should be included as its costs, and the reasonableness of its proposed profit. The Department will then carefully review each

component of the proposed price. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Additional comments were received concerning the allowable profit a registered organization could include in its proposed price. Those comments include

- Discouraging any cap on profit.
- Seeking clarification as to what constitutes a "reasonable profit" to allow applicants to prepare a business plan for submission. The commenter stated that proposed regulations do not provide a legal standard by which the Department shall determine a reasonable profit after evaluating cost to manufacture, market and distribute medical marihuana.
- Seeking clarification on the allowable minimum price the registered organization would be allowed to sell medical marihuana product, and allowable profit.
- That a median price per dose must be established.

RESPONSE: Section 80-1.15 requires a cost analysis, defined to 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, efficiency and profit. In determining whether to approve a registered organization's proposed price, the proposed regulations require the registered organization to submit information and documentation on its fixed and variable costs in producing each brand of medical marihuana, and its proposed profit. Determination of a reasonable price will be made for each product sold by the registered organization. A minimum price, median price or cap on profit are not set forth in

the proposed regulation. The Department will evaluate whether further guidance is needed in this area, or whether clarification is needed in future revisions to the regulation.

COMMENT: Further comments were received concerning the requirement in the proposed regulations for the Commissioner to determine the reasonableness of the proposed costs, and, in making this determination, consider whether the costs represent inefficient and uneconomical practices. Those comments include:

- What criteria the Department would utilize in determining whether practices were "inefficient or uneconomical."
- Staffing levels, wages and employee benefits should not be factored into the analysis related to inefficiencies and uneconomical practices. In determining inefficiencies and uneconomical practices, the regulations should be amended to include a consideration of the varying quality practices employed by the registered organization.

RESPONSE: The Department will take these comments under advisement and will determine whether clarification is needed with respect to this issue. No changes have been made as a result of these comments.

80-1.16 Comments: Medical Marihuana Marketing and Advertising by Registered Organizations

COMMENT: Several comments were received concerning the marketing and advertising requirements in § 80-1.16. Those comments include:

- The advertising restriction limiting a sign to black and white was too restrictive. The commenter stated that the registered organization would not be able to positively brand

their company with a professional sign if all dispensing facilities are limited to one black and white sign.

- A suggestion of submitting a proposed sign to the Department for prior approval in lieu of this requirement.
- Recommended allowing colors consistent with local zoning ordinances.
- Advertising standards are stricter than the models used for other pharmacy regulations and continued to stigmatize the use of marihuana.

RESPONSE: Although the proposed regulations restrict the signage to a black and white sign, there is not a restriction on a positively branded professional design, provided that the design does not include any graphics related to marihuana or paraphernalia. No changes were made to the proposed regulations as a result of these comments.

COMMENT: Commenters objected to the prohibition on illuminating a sign with the company's name and logo. Those comments included:

- Restricting the sign from illumination would cause confusion to patients trying to find the facility, especially at night.
- Non-illuminated sign appears to be in conflict with the security requirements for manufacturing and dispensing facilities, which require the registered organizations to keep illuminated the outside perimeter of any manufacturing and dispensing facility.
- Restrictions far exceed constitutionally permissible regulation of commercial speech under time, place and manner restrictions. The commenter noted that similar restrictions are not imposed on pharmacies or other facilities that market medicines in general or for specific afflictions.

RESPONSE: The advertising standards related to a facility's signage of its location take into account that marihuana is a schedule I controlled substance according to the federal Controlled Substance Act, as well as New York State schedules of controlled substances defined in Section 3306 of the Public Health Law. The demand for medical marihuana products will be limited to certified patients, and due to all the preliminary steps required to become a certified patient, the need to advertise to walk-in customers has no role in this program. Although the sign will not be illuminated, the exterior of the facility will be illuminated and could have its address number clearly visible on the exterior of the facility. The outside perimeter of the facility may also be illuminated without illuminating the sign. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Several comments were received recommending removal of most restrictions on advertising, as well as eliminating the requirement for prior approval by the Department of any advertisement for an approved medical marihuana product. The commenter recommended this be replaced with clear guidance and defined boundaries for registered organizations seeking to advertise publicly. Those comments include:

- The proposed regulations prohibit patient education, the ability of registered organizations to provide important educational material and information to physicians, patients and their families.
- The proposed regulations will increase ambiguity and uncertainty amongst registered organizations.
- The regulations should parallel the standards related to the prohibition of unfair or deceptive acts as set forth in the Federal Trade Commission Act, sections 5 and 12

indicating that advertising must be truthful and non-deceptive, must have evidence to back up their claims and cannot be unfair.

- Any material given to the patient might also include the fact that these formulations have not been fully evaluated and that they need to report to their doctor any adverse effects.

RESPONSE: Public Health Law § 3364 authorizes the Commissioner to make rules and regulations restricting the advertising and marketing of medical marihuana, which must be consistent with the federal regulations governing prescription drug advertising and marketing. The advertising requirements in the proposed regulations are consistent with federal regulations. In addition, the dispensing facility is required to provide a Department approved package safety insert to the certified patient or designated caregiver when the product is dispensed. This insert will contain information that addresses responsible and safe consumption of approved products, including warnings, contraindications, adverse effects, information on tolerance, dependence, and withdrawal, securing the product and disposal instructions. The Department will take these comments under advisement. No changes to the proposed regulations have been made as a result of these comments.

COMMENT: Several comments were received concerning the requirement in the proposed regulations that advertisements document the accuracy of statements made therein. The comments include:

- There is limited scientific information about long term effects of various preparations, especially when used consistently for long periods of time.
- The requirement that any claim of effectiveness be fair and balanced and supported only by demonstrable medical research and reports that are widely accepted in the medical profession

are unduly burdensome. Rather, an insert that states what is known about the short term risks is more appropriate.

RESPONSE: The proposed regulations state that all advertisements that make a statement relating to effectiveness, side effects, consequences and contraindications shall present a true and accurate statement of such information. The proposed regulations also authorize the Department to require a specific disclosure if the Department determines that the advertisement would be false or misleading without such a disclosure or require that changes be made to the advertisement that are necessary to protect the public health, safety and welfare or consistent with dispensing information for the product under review. The Department believes that the proposed regulations further an important goal to ensure accurate and reliable information is provided to certified patients. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: A commenter recommended that language in § 80-1.16(f)(1) be revised to make clear that a claim must be demonstrated by substantial scientific or "documented" clinical experience, to ensure that anecdotal-only evidence is insufficient. Another comment received stated that the requirement that no promotion of a particular strain or brand for the treatment of particular symptom is unduly restrictive and that the proposed regulations should permit promotion of strain effectiveness based on anecdotal evidence, and allow reliance on research that is founded upon accepted methodologies regardless of whether the theory is widely accepted in the medical community.

RESPONSE: Anecdotal evidence does not constitute substantial evidence or substantial clinical data and will not be accepted. The Department believes that the proposed regulations further an important goal to ensure accurate and reliable information is provided to certified patients.

COMMENT: A comment was received stating that there wasn't an appropriate limit to advertising in print, billboards, public transit or visual media. The commenter recommended that dispensing facilities should only be allowed to advertise location and business hours as this would also eliminate the need for State approval of each advertisement.

RESPONSE: Public Health Law § 3364 (13) authorizes the Commissioner to make rules and regulations restricting the advertising and marketing of medical marihuana, which must be consistent with the federal regulations governing prescription drug advertising and marketing. The proposed regulations strike an importance balance between advertisement and marketing of medical marihuana products and ensuring that certified patients obtain true and accurate information. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A comment was received stating that the regulations prohibit an ad from including any statement, design, representation, picture or illustration portraying anyone under the age of 18. The commenter sought clarification as to whether this prohibits the ad from stating that medical marihuana can be recommended for someone under the age of 18 in appropriate situations.

RESPONSE: Section 80-1.16 (d) requires that 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. The Department will take this comment under advisement in determining whether clarification is needed in future regulations or guidance related to this issue.

COMMENT: The regulations require 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. The Department will have to decide what is a true and accurate statement of such information. Advertisements should also be clearly designed to not appeal to children such as cartoons or the use of images from games, television shows, movies or other media that appeal to children. An additional comment was received concerning the warning regarding child care. A warning regarding child care without basis may have unintended future policy consequences in regard to the ability for parents with disabilities to safely and effectively care for their children.
RESPONSE: The Department will consider these comments and whether clarification is needed in guidance or in future revisions to the regulations.

COMMENT: A comment was received seeking clarification on § 80-1.16(m),which prohibits a registered organization from cooperating, directly or indirectly, in any advertisement if such advertisement 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. The commenter asked whether this section allows a registered organization to advertise itself, but not its individual medical marihuana product.

RESPONSE: "Influencing patient or caregiver choice" in § 80-1.16 (m) refers to an advertisement that has the purpose or effect of steering or influencing patient or caregiver choice in the selection of a practitioner, or approved medical marihuana product. Each advertisement would necessarily have to be evaluated on a case by case basis to determine whether the advertisement seeks to influence patient or caregiver choice. An advertisement for a registered organization, as opposed to a specific product could also have the purpose or effect of steering or influencing patient or caregiver choice.

COMMENT: A comment was received in support of the advertising and marketing requirements set forth in the proposed regulations. The commenter stated that advertisements are a significant variable in perception of risk and other factors that influence the likelihood of addictions (tobacco, alcohol and marihuana).

RESPONSE: The comment is noted.

80-1.17 Comments: Reporting Dispensed Medical Marihuana Products

COMMENT: A comment was received indicating that 24-hour notice after dispensing to the certified patient is too rigid and should allow for additional time. The commenter stated that it may be difficult in some situations to meet the requirement that a record of all approved medical marihuana products that have been dispensed are filed electronically with the Department no later than 24 hours after the marihuana is dispensed.

RESPONSE: Public Health Law § 3364(4)(b) requires that the proprietor of a registered organization shall file or cause to be filed any receipt and certification information with the

Department by electronic means on a real time basis. The proposed regulations are consistent with this requirement.

COMMENT: Comments were received seeking clarification concerning HIPAA. One commenter asked whether a registered organization is a health care facility such that it must comply with HIPAA and state consent requirements. Commenters would like to see waivers or lessened requirements in regard to reporting to protect patient confidentiality.

RESPONSE: Confidentiality and reporting requirements are provided for in statute. Public Health Law § 3371 was amended to provide statutory authority for an individual employed by a registered organization to consult the Prescription Monitoring Program Registry. Public Health Law § 3364(4)(b) requires a registered organization to file any receipt and certification information with the Department, electronically on a real-time basis. With respect to confidentiality, Public Health Law § 3363 (13) states that the Department shall maintain a confidential list of people to whom it has issued a registry identification card. Public Health Law § 3369 (4) states that certification applications, certification forms, and any certified patient information cards are exempt from public disclosure under sections 87 and 89 of the Public Officer's Law. The proposed regulations include a requirement in 80-1.2 (a)(15) that the practitioner has obtained patient consent if required by law. The Department will take these comments under advisement as it develops its patient registry identification card application.

80-1.18 Comments: Prohibition of the Use of Medical Marihuana in Certain Places

COMMENT: Several comments were received concerning the prohibition of the use of approved medical marihuana products in certain places as set forth in § 80-1.18 of the proposed

regulations, and recommended that the proposed regulations be revised to allow the use of medical marihuana products in a variety of places. Those comments include:

- The restrictions would prohibit patients from taking medical marihuana at school or college, work or while passengers in a car.
- Children and students would not be able to utilize medical marihuana products when they need to or where they reside, including while in any child care setting, residential facilities, day cares, foster care, group homes, and for college students, on campus in a dormitory. The Department should consider reasonable exceptions to allow the use of medical marihuana vaporizers in appropriate domiciles.
- Recommendation that the Department avoid establishing categories of consumption (vaporized) and stated that the word "consumed" is more encompassing.

RESPONSE: Public Health Law § 3362 (2)(a) provides that possession of medical marihuana shall not be lawful if it is consumed or vaporized in a public place, regardless of the form of medical marihuana stated in the patient's certification. No changes have been made to the proposed regulations in response to these comments.

COMMENT: A commenter stated that the exception to the prohibition on vaporization in public places related to "separate, enclosed rooms" provided for in § 80-1.18 should be applied to all public spaces that provide such quarantined facilities, similar to the state's law on designated smoking areas. The commenter recommended that the proposed regulations be revised to require statement that all public and private college universities shall provide a place for use of medical marihuana at a campus health facility.

RESPONSE: Public Health Law § 3362 (2)(a) provides that possession of medical marihuana shall not be lawful if it is consumed or vaporized in a public place, regardless of the form of medical marihuana stated in the patient's certification. The proposed regulations are in line with the requirements of statute. Section 80-1.18 prohibits vaporization in all public and private colleges, universities and other educational and vocational institutions. This prohibition furthers a public health goal of minimizing exposure to second-hand vapor and is in line with Public Health Law § 3362 (2)(a). No changes have been made to the proposed regulations in response to these comments.

COMMENT: A comment was received in support of the prohibition of vaporization in public places. The commenter recommended that the proposed regulations be revised to authorize the use of sprays in lieu of vaporization, unless there is a documented determination that vaporization is required.

RESPONSE: Section 80-1.11(g) of the proposed regulations allow for the following forms of medical marihuana as alternatives to vaporization: liquid or oil preparations for metered oromucosal, sublingual, or administration per tube, as well as capsules for oral administration. The Commissioner may approve additional forms and routes of administration. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A comment was received seeking clarification as to whether medical marihuana product is allowed on school grounds, and if it can be administered by the school nurse. The commenter recommended against allowing use of medical marihuana product in school unless administered by a nurse, and recommended a prohibition on use of vaporizers in a school.

RESPONSE: Public Health Law § 3362 (2)(a) provides that possession of medical marihuana shall not be lawful if it is consumed or vaporized in a public place, regardless of the form of medical marihuana stated in the patient's certification. The proposed regulations are in line with the requirements of statute. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: Numerous comments were received recommending that the distance from a school for vaporization of approved medical marihuana products should be 1000 feet, not 100 feet as required in § 80-1.18 (b).

RESPONSE: The 100 feet restriction aligns with section thirteen hundred ninety-nine-o of the Public Health Law which prohibits smoking within one hundred feet from entrances, exits or outdoor areas of schools. The 1000 feet restriction is specific to the location of the registered organization. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: Several comments were received concerning the safety of vaporization, some stating that inhaling medication, even in vaporized form, can be extremely irritating and harmful to epithelium that protects the lungs, oropharyngeal region, nasal passages, and even the brain. Those comments include:

- A commenter noted that the use of vaporizers to dispense medical marihuana seems to conflict with FDA guidelines, and recommended that the Department provide guidance on this issue.
- Requesting that the Department define "what are acceptable vaporizing devices."

- A commenter stated that medical devices are strictly regulated by the FDA and in order for a vaporizer or other such device to be used, it will have to be approved as a medical device by the FDA and properly labeled under federal law.
- Recommending that a patient be provided adequate directions for use in layman's terms.

RESPONSE: Pursuant to Public Health Law § 3361 (3) in making a patient certification, the practitioner shall consider the form of medical marihuana the patient should consume, including the method of consumption and any particular strain, variety and quantity or percentage of marihuana or particular active ingredient, and appropriate dosage. The practitioner shall state in the certification any recommendation or limitation the practitioner makes, in his or her professional opinion, concerning the appropriate form or forms of medical marihuana and dosage. Whether vaporization should be recommended for a particular patient is left to the discretion of the patient's practitioner taking into account the patient's condition. The regulations require applicants for registration as a registered organization to include a detailed description of any devices to be used with approved medical marihuana products that are offered or sold by the registered organization. The remaining comments are noted. Public Health Law 3360 (8) and (16) provide authority to the Commissioner to approve the form of medical marihuana which includes its method of consumption. The proposed regulations authorize vaporization as a method of consumption. No changes to the proposed regulations are necessary as a result of the comments.

COMMENT: A few comments were received recommending that private or public insurance cover the cost of medical marihuana products.

RESPONSE: Pubic Health Law § 3368 (2) provides that nothing within Title V-A shall be construed to require an insurer or health plan, including a governmental insurance program, to provide coverage for medical marihuana. No changes have been made to the proposed regulations as a result of this comment.

80-1.19 Comments: Reporting Requirements for Practitioners, Patients and Designated Caregivers

COMMENT: Comments were received in support of the adverse event reporting requirements. Comments were also submitted recommending that the proposed regulations be revised to provide a definition of "adverse event", consistent with that defined by the FDA. Additional comments include:

- Recommending that the regulations specify the reporting elements in relation to each adverse event.
- Recommending that the proposed regulations define "serious adverse event" in relation to the physician's requirement to report a serious adverse event not more than one business day after the physician becomes aware.
- Recommending that the proposed regulations require reporting where the adverse event is "reasonably related to the use of the medical marihuana product."
- A commenter stated that reporting of adverse events should occur within 24 hours of "the registered organization's knowledge of" the occurrence.
- One commenter stated that there should be a penalty for not reporting complaints and adverse events.

RESPONSE: The Department will take these comments under advisement, and will provide guidance concerning adverse event reporting. Public Health Law § 12 provides for a penalty for violations of statute or regulations. A person who violates, disregards or disobeys a provision of statute or regulation shall be liable for a civil penalty up to $2000.00. No changes to the proposed regulations have been made as a result of these comments.

80-1.22 Comments: Practitioner Prohibitions

COMMENT: A comment was received seeking clarification on the basis for which the proposed regulations restrict a practitioner from being the patient's caregiver.

RESPONSE: Practitioners are prevented from being their own certified patient's designated caregiver to protect against any potential conflict of interest. These regulations seek to create a system with appropriate checks and balances that will ensure marihuana is only dispensed to a patient or caregiver after an appropriately trained independent practitioner certifies it is appropriate. Allowing any individual to serve in more than one distinct role undermines the goals of this regulatory scheme. No changes have been made to the proposed regulation as a result of this comment.

COMMENT: A comment was received concerning the practitioner prohibitions and the requirement in § 80-1.22 (a)(1) which prohibits a practitioner from obtaining any item of value from the registered organization. Those comments include:

- Practitioners will be prevented from acting as principal investigators or consultants in any future clinical trials or research with a registered organization. The commenter suggests retention and reporting of practitioner compensation data similar to the transparency

regulations in place for pharmaceutical and device manufacturing industries and physicians.

- Recommending that the proposed regulations include a fair market value exception and an exception for services offered to all regional physicians. In the alternative, the commenter requests a specific exception for continuing medical education courses offered by registered organizations regarding medical marihuana.

RESPONSE: The Department will take these comments under advisement. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: A comment was received seeking clarification that § 80-1.22(a)(2), which prohibits a practitioner from offering a discount or any other item of value to a certified patient based on the patient's agreement to use a particular practitioner, registered organization, brand or form of medical marihuana product, only applies to advertising and does not limit the ability to provide economic assistance to established patients in need.

RESPONSE: This proposed regulation seeks to ensure that a registered practitioner will recommend the product that is appropriate for a patient by ensuring that the practitioner will receive no benefit for steering a patient to a particular registered organization. A practitioner does not have the authority to obtain medical marihuana from a dispensing facility for distribution to patients as free samples. If the practitioner seeks to provide economic assistance to the patient, the practitioner would be prohibited from offering a discount or other item of value to the certified patient to induce a patient to obtain the services of that practitioner, a particular registered organization, or utilize a brand or form of approved medical marihuana product.

80-1.23 Comments: Designated Caregiver Prohibitions

COMMENT: Comments were received concerning the provision in § 80-1.23(b) that authorizes a designated caregiver to charge the certified patient for reasonable costs incurred in the transportation and delivery of medical marihuana product to the certified patient. A commenter stated that it would be difficult to determine if a designated caregiver was charging a patient a "reasonable cost". A commenter also sought clarification on the specific duties that must be performed in order to be considered a designated caregiver.

RESPONSE: A certified patient may designate up to two designated caregivers either on the application for issuance or renewal of a registration identification card or in another manner determined by the Department. [§ 80-1.3] Upon issuance of a registry identification card to a designated caregiver in accordance with proposed regulations at § 80-1.4, the designated caregiver would be authorized to obtain the medical marihuana product at a dispensing facility on behalf of the patient. The proposed regulations at § 80-1.23 provides that the designated caregiver may only charge the certified patient a reasonable fee for the transportation and delivery of medical marihuana to the certified patient. If the fee charged is excessive, the designated caregiver may be subject to penalties under Public Health law section 12 and 3363(15) for violations of statute and regulations, including the imposition of unreasonable fees. These provisions, taken together, seek to ensure that a designated caregiver performs his or her services in compliance with law and regulation. No changes to the proposed regulations have been made as a result of these comments.

Miscellaneous Comments

COMMENT: A commenter recommended that the Department work with other departments, banking institutions, and the federal government to ensure that in New York State the medical marihuana industry is bankable and businesses in the industry won't face prosecution or raids. Another commenter recommended the establishment of a state run credit union to assist in the operation.

RESPONSE: These comments are beyond the scope of the proposed regulations. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Several commenters indicated that the proposed regulations fail to address the urgent need for expedited access to medical marihuana for patients who suffer life-threatening or terminal illnesses. Several comments sought expedited access for children who suffer from intractable epilepsy. Some commenters requested a provision be added to the regulations to allow for patient registration cards to be issued to critically ill patients on an emergency basis and to allow for a limited number of physicians to register to immediately certify such patients. The commenters said that a provision to fast track the application of one or more registered organizations should also be created. One comment was received seeking expedited adoption of the regulations.

RESPONSE: Title V-A of Article 33 of the Public Health Law establishes a comprehensive system for the manufacture, dispensing, obtaining and use of medical marihuana in this State. The system seeks to ensure access to safe and reliable medical marihuana by certified patients. The proposed regulations further this goal by setting forth in greater detail the requirements for practitioners, certified patients, designated caregivers, registered organizations and laboratories. The Department is moving forward aggressively to implement the provisions of Title V-A of

Article 33 of the Public Health Law. No changes to the proposed regulations have been made as a result of these comments.

COMMENT: Comments were received requesting temporary importation of medical marihuana, including from Colorado or Washington.

RESPONSE: The comments are beyond the scope of the proposed regulations and suggests an action that exceeds the Department's authority.

COMMENT: A comment was received seeking clarification as to the Department's authority to regulate marihuana consumption. Other commenters do not believe regulation should be necessary.

RESPONSE: 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 Article 33 of the Public Health Law sets forth the requirements for manufacturing, dispensing and making available to certified patients, medical marihuana. Title V-A also authorizes the Department to issue regulations regarding the medical use of marihuana in this State. The other comments are noted. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Several comments were received recommending that the regulations be revised to authorize patients to grow their own marihuana plants. It was suggested that a fee could be charged for cultivating one's own plants to make up for the loss of tax revenue. Another commenter suggested the Department allow for cultivation of a limit of 6 mature marihuana plants per qualifying patient.

RESPONSE: Title V-A of Article 33 of the Public Health Law authorizes a registered organization as defined in such law, to grow and dispense medical marihuana in New York State. The statute does not authorize a certified patient to grow marihuana for his or her own consumption. The proposed regulations are consistent with the requirements of statute. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: Comments were received requesting that the Department use different states, such as Washington, Maine and Colorado as models for New York's medical marihuana program. One commenter suggested the Department look at a specific website for additional information.

RESPONSE: New York State's Compassionate Care Act sets forth the statutory framework for the medical marihuana program in this State. The proposed regulations are consistent with the requirements of the Act. No changes to the proposed regulations have been made as a result of these comments.

COMMENT: Comments were received indicating that recreational marihuana should be legal.

RESPONSE: These comments are beyond the scope of the proposed regulations and suggest an action that exceeds the Department's authority.

COMMENT: A number of comments were received indicating that the proposed regulations are generally too restrictive, and some felt the proposed regulations left little financial incentive to participate in the program.

- Some commenters further stated that medical marihuana is being treated as an illegal drug.
- A commenter stated that treating medical marihuana differently from other medication is a form of discrimination and that long term use of marihuana comes with fewer side effects. The commenter felt that by limiting access, the State can ensure massive contributions.
- Commenters stated that the scope of distribution, variety of strains, number of conditions covered, and several other components of the proposed regulations are needlessly limited under the pretense of caution and seem to be guided by criminal concerns.
- Commenters stated that marihuana has proven benefits medicinally, is far less likely to lead to violent behavior unlike alcohol or mind-altering drugs and is far less addictive than other substances.

RESPONSE: Marihuana is a Schedule I controlled substance under both the federal Controlled Substance Act and Article 33 of New York's Public Health Law. The Compassionate Care Act and the proposed regulations represent a strong and effective regulatory system that ensures that medical marijuana is dispensed only to certified patients and their designated caregivers. No changes have been made to the proposed regulations in response to these comments.

COMMENT: Several comments were submitted recommending that medical marihuana be legalized in New York State.

RESPONSE: Public Health Law § 3362 (1) provides that the possession, acquisition, use, delivery, transfer transportation, or administration of medical marihuana by a certified patient or designated caregiver possessing a valid registry identification card, for certified medical use,

shall be lawful under the Act, subject to certain conditions specified in the statute. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: A comment was received asking for clarification regarding the illegality of marihuana when marinol is already legal.

RESPONSE: This inquiry is beyond the scope of the regulations.

COMMENT: A comment was received suggesting the Department implement a medical model and methodology of service delivery to evaluate the proposed regulations.

RESPONSE: The Department will be performing ongoing evaluations of the medical marihuana program, which will be handled outside of the regulatory process.

COMMENT: A comment was received asking if the word "employee" in the regulations encompasses independent contractors and consultants.

RESPONSE: The word "employee" is not defined in the proposed regulations, however the ordinary meaning of this word refers to an employment relationship as opposed to a contractual relationship between the parties. No changes to the proposed regulations are necessary.

COMMENT: Comments were received stating that there were no provisions for an outside, independent evaluator to monitor and/or report on the program so that the public, as well as appointed and elected officials, could learn from the experience and refine the program going forward.

RESPONSE: These comments are beyond the scope of the proposed regulations. No changes have been made to the proposed regulations as a result of the comments.

COMMENT: Several comments were received regarding the interplay between federal law and NYS regulations regarding marihuana. Those comments include:

- A comment was received stating that the program violates federal law in that "medical" marihuana dispensaries or persons such as physicians, government employees, landlords and others acting under state "medical" marihuana laws may be subject to prosecution by the U.S. Government under the federal Controlled Substances Act (CSA) because the state "medical" marihuana laws are preempted by the CSA. 21 U.S.C. § 801 et seq.
- A commenter stated that, although the current federal administration has not been enforcing these laws in medical marihuana states, this may change and the Department should insure that registered organizations and physicians be made aware of them.
- A comment was received recommending that the State indemnify doctors in the event the federal government decides to prosecute.
- A commenter also stated that the program should be halted if the federal government decides to prosecute.

RESPONSE: The proposed regulations set forth a strong and effective regulatory system that ensures that medical marijuana is dispensed only to certified patients and their designated caregivers for medical use of marihuana. The system also seeks to put in place strong controls to prevent diversion. The comments are beyond the scope of the proposed regulations. No changes to the proposed regulations have been made as a result of these comments.

COMMENT: A comment was received stating that the revenue generated from production and sale of medical marihuana should be distributed in order to rebuild the infrastructure of communities that have been disproportionately impacted by the war on drugs.

RESPONSE: Distribution of funds associated with the sales of medical marihuana is beyond the scope of the proposed regulations. No changes to the proposed regulations have been made as a result of this comment.

COMMENT: A comment was received recommending that the Department address the stigma associated with the usage of medical marihuana.

RESPONSE: The proposed regulations further the State's goal in making medical marihuana available for certified medical use. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A commenter requested that the Department add a statement that "No licensed attorney shall be in violation of any state disciplinary rule by providing advice consistent with the provisions of the Laws of 2014, Chapter 90" to the general prohibitions.

RESPONSE: Public Health Law § 3369 (1) provides protections to certified patients, designated caregivers, practitioners, registered organization and the employees of registered organizations from arrest or prosecution, including by a professional licensing board solely for the certified medical use or manufacture of marihuana, or for any other action or conduct in accordance with the Act. This section would apply to advice and assistance provided by attorneys to the extent they were employed by a registered organization. Furthermore, the statute

and proposed regulations do not seek to alter the practice of law in any fashion. No changes to the proposed regulations have been made as a result of this comment.

COMMENT: A comment was received recommending the State legalize industrial hemp in order to obtain a CO2 neutral fuel source.

RESPONSE: The comment is beyond the scope of the proposed regulations and suggests an action that exceeds the Department's authority.

COMMENT: A comment was received seeking clarification concerning how hospitals would obtain a supply of medical marihuana for use by certified patients admitted at the hospitals, and further asked what types of contracts would be available for supplying medication to hospitals in which a patient may be residing. A comment was received urging that priority be given to registering hospitals as registered organizations.

RESPONSE: In accordance with the Compassionate Care Act, a registered organization is authorized to dispense medical marihuana to a certified patient or designated caregiver. A designated caregiver must be an individual and not an entity, such as a hospital. The proposed regulations do not govern any type of hospital contract. With respect to granting priority to registering hospitals, the proposed regulations do not grant priority to any class of applicants. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: A commenter asked if, in the event a Native American Nation chose to legalize medical marihuana on their reservation and started up a program of their own, it would be illegal

for a resident of this State to use marihuana on the reservation, and would such resident face prosecution once they re-entered State land, even if not in possession of any cannabis.

RESPONSE: Legalization of medical marihuana on a Native American reservation is beyond the scope of the proposed regulations. No changes to the proposed regulations are necessary.

COMMENT: A comment was received asking for each regulatory requirement to be scrutinized to determine necessity in light of a balancing of costs and benefits.

RESPONSE: The Department must consider a balance between ensuring the availability of quality products for certified patients authorized to use medical marihuana and protecting the public against risks to its health and safety. The Compassionate Care Act and the proposed regulations strikes this balance by implementing a strong and effective medical marihuana program in this State. The Department considered the needs and benefits of the regulatory requirements, as set forth fully in the Regulatory Impact Statement. The Department will evaluate all aspects of the program and consider whether revisions are required to regulations in the future. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A comment was received recommending that the regulations set forth stated goals, which should include minimizing known risks of cannabinoids to consumers, including addiction, overdose, and accidents.

RESPONSE: The proposed regulations further the purpose of the Compassionate Care Act, which includes striking the right balance between potentially relieving the pain and suffering of those in desperate need of a treatment and protecting the public against risks to its health and safety. There are several requirements in the regulations which should minimize known risks of cannabinoids to consumers, including but not limited to the requirements set forth in the

following sections of the regulations: § 80-1.2 (a) for patient certification, § 80-1.12(k) for a Department approved package safety insert to be provided with each product package dispensed to a patient, and § 80-1.11 for manufacturing requirements. No changes to the proposed regulations are necessary.

COMMENT: A comment was submitting recommending that the proposed regulations should be revised to minimize the appearance of providing support for the use of marihuana for non-approved or recreational purposes.

RESPONSE: The proposed regulations do not support the use of marihuana for non-approved purposes, including recreational use. No changes to the proposed regulations are necessary.

COMMENT: A comment was received recommending that the Department provide education to the public on how to access medical marihuana in the State.

RESPONSE: The Department will consider different methods to provide education concerning the medical marihuana program. No changes to the proposed regulations are necessary.

COMMENT: A comment was received stating that the proposed regulations do not provide criteria and standards for Department decision making, including in areas concerning practitioner registration and patient certification. The commenter recommended that the proposed regulations be revised to set forth standards, and an evaluation and selection process for registered organizations.

RESPONSE: The Compassionate Care Act and proposed regulations provide a sufficient framework concerning the manner in which approvals, certifications and registrations will be granted. No changes to the proposed regulations are necessary.

COMMENT: A comment was received recommending that, for clarification purposes, the proposed regulations be revised to incorporate the definitions in Public Health Law § 3360.

RESPONSE: The definitions set forth in Public Health Law § 3360 apply to the terms as set forth in the proposed regulations. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A comment was received stating that the term "approved marihuana product" is redundant and should be removed throughout.

RESPONSE: The proposed regulations delineate a distinction between medical marihuana that has not met laboratory testing standards versus final laboratory approved product. No changes to the proposed regulations have been made as a result of this comment.

COMMENT: A commenter stated that Regulatory Impact Statement inadequately describes the financial impact these regulations will place upon the Department. The comment requests that the Regulatory Impact Statement should make a clear and detailed estimate of the Department staff and resource needed to implement these regulations.

RESPONSE: The Regulatory Impact Statement adequately addresses the costs to the Department. The Regulatory Impact Statement provides that the Department "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."

COMMENT: Comments were received in support of the proposed regulations. A commenter stated that the proposed regulations may prevent what the commenter referred to as "storefront doctors" or those operating out of dispensaries.

RESPONSE: The comment is noted. No changes to the proposed regulations are necessary.

COMMENT: Several comment were received concerning the research and evaluation of the implementation of medical marihuana in our state. Those comments include:

- A commenter stated a lack of studies will diminish the ability to make improvements to the program in the future. The commenter recommended that a portion of the revenue from the excise tax on the sale of medical marihuana should be used for information and research into effectiveness of therapy in ameliorating conditions.
- Recommending a collaborative effort in collecting real-time patient experience survey data at the point of care.

- A comment sought clarification regarding the ability of each registered organization to participate in studies with universities and hospitals for the use of medical marihuana to treat epilepsy and other diseases.
- Recommending that peer reviewed research should take into account the federal Institute of Medicine Recommendations on researching marihuana as medicine as it pertains to non-smoked marihuana and include efficacy for conditions, risks, benefits, dosage, interactions, impact on other pre-existing conditions, and alternatives.
- Recommending that the Department establish multicenter prospective clinical trials with centralized data collection and analysis. Registered organizations and academic medical centers or universities would be involved.
- Recommending that those wishing to prescribe medical marihuana could propose research protocols so that the dosages and effects, positive and negative, would be better known.
- A comment was also received stating that ongoing evaluation is critical and recommended implementation of evaluation protocols at the onset of the prescribing of medical marihuana. The commenter stated that evaluation and limited research can occur simultaneously.

RESPONSE: Public Health Law § 3367 authorizes the Commissioner to provide for the analysis and evaluation of the operation of the Compassionate Care Act, and authorizes the Department to develop, seek any necessary federal approval for, and carry out research programs relating to the medical use of marihuana. The Department does not believe that research and evaluation methods require specificity in regulation. The Department will take these comments into advisement when developing any evaluation or research programs.

COMMENT: A comment was received stating that the proposed regulations do not address the timeframe for registering practitioners, certifying patients and registration of organizations. Another commenter recommended revisions to the proposed regulations to provide detail on how the Department will employ available IT tools and systems to implement and support the actions and processes under the proposed regulation, and what connectivity requirements will be required from practitioners, patients and Registered Organizations.

RESPONSE: Once the proposed regulations are adopted, the Department will work expeditiously to implement the processes that will allow for practitioner education, practitioner registration, patient certification, certified patient and designated caregiver registration, and selection of registered organizations. Information will be provided to better assist relevant parties with these processes. No changes to the proposed regulations are necessary.

COMMENT: A comment was received recommending that the Department require independent agents, approved by the State, to act as onsite quality assurance officers to further enhance the QA/QC program.

RESPONSE: The proposed regulations impose strict quality control requirements. The Department does not believe revisions to the proposed regulations are necessary at this time but will monitor quality control practices as the program is implemented. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A comment was received seeking clarification as to how the Department is estimating the number of patients per county that will seek to obtain medical marihuana.

RESPONSE: This comment is beyond the scope of the proposed regulations. No changes to the proposed regulation are necessary as a result of this comment.

COMMENT: A commenter sought clarification as to how the Department will determine who will be allowed to grow marihuana under the medical marihuana program.

RESPONSE: The application process for registered organizations will be shared on the Department's web page. The applicant must submit the information and documentation required in § 80-1.5. The Department will review the application and consider the criteria set forth in § 80-1.6 when deciding whether to grant a registration. No changes to the proposed regulations have been made as a result of this comment.

COMMENT: A commenter stated that the proposed regulations do not set forth a time table for all the processes contained therein, such as practitioner registration, and patient certification. The commenter stated that these processes could take months or years to implement before patients will have meaningful access to medication, and asked that practitioner courses and registered organization and patient/caregiver registry application processes necessary for purchase of medication be implemented immediately.

RESPONSE: The effective dates for the Compassionate Care Act are set forth in statute. The details concerning the supporting technology to be implemented will be provided outside of the regulatory process. No changes to the proposed regulations have been made as a result of these comments.

COMMENT: A comment was received seeking the ability for low income individuals and communities to be more involved in the oversight of the entire medical marihuana program. Comment was received in support of creating a mechanism through which patients denied access to the program can appeal through the Department.

RESPONSE: The proposed regulations do not create a mechanism for any class of individuals to have a preferred role in the oversight of the medical marihuana system. The Public Health Law and proposed regulations set forth the conditions and symptoms associated with such conditions (defined in the statute as 'serious conditions") for which a patient may be certified for the medical use of marihuana. It is at the practitioner's clinical discretion to determine whether a patient has a serious condition and a certification should be issued to the patient. No changes to the proposed regulations have been made as a result of this comment.

COMMENT: A comment was received stating that the proposed regulations are more protective of patients and the public than other states. The commenter supported the requirements in the proposed regulations concerning practitioner education and patient certification, the ban on smoking and edibles, cannabinoid profile testing, the inclusion of a pharmacist at the dispensing facility, and the limitation of serious conditions until successful implementation can be achieved.

RESPONSE: The comments are noted. No changes to the proposed regulations are necessary.

COMMENT: A comment was received expressing concern that the medical use of marihuana is not well studied, and that measures should be put in place to ensure excellent care by physicians. The commenter recommended that the Department review registered doctors'

records for abnormalities and encouraged the development of best practices and guidance from DOH in the implementation of those best practices.

RESPONSE: Public Health Law § 3360 (12) defines "practitioner" as a physician who has completed a two to four hour course as determined by the Commissioner. For practitioners who wish to certify their patients for use of medical marihuana, the proposed regulations at § 80-1.1 requires a four hour course that includes the following content: 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. The proposed regulations at § 80-1.19 imposes reporting requirements on a practitioner, including a requirement that the practitioner report patient deaths and adverse events. The Department will perform ongoing monitoring for compliance, and will evaluate any factors which may improve the program. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: A comment was received concerning Section 80-1.2 (a) (14) and (15) and patients who cannot give consent. The commenter stated that OPWDD may wish to establish research protocols.

RESPONSE: The proposed regulations at § 80-1.2(a)(14) provides that, to the extent that a practitioner is seeking to authorize the use of an approved medical marihuana product by 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. The practitioner must document in the patient's medical record that such explanation

has been provided. Establishment of research protocols are beyond the scope of the proposed regulations. No changes to the proposed regulations are necessary.