SUMMARY OF EXPRESS TERMS

Pursuant to the authority vested in the Commissioner of Health by Section 3369-a of the Public Health Law (PHL), Part 1004 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, and pursuant to Section 502 of the PHL, Subpart 55-2 of Title 10, are 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. Section 1004.1(a) and (b) are amended to align with the statute, which requires practitioners to complete a two to four-hour course and register with the department before certifying patients for medical marihuana.

§ 1004.2 Practitioner issuance of certification. Section 1004.2(a) is amended to clarify the department's expectation that practitioners adhere to new section 1004.2(e) which details the statutory requirement to consult the Prescription Monitoring Program Registry. Section 1004.2(a) is further amended to require registered practitioners to indicate on patient certifications whether a patient is temporarily residing in New York State for the purpose of receiving care and treatment from the practitioner.

§ 1004.3 Application for registration as a certified patient. Section 1004.3(b) is amended to clarify that New York State residents must show proof of residency. Section 1004.3(b) is amended to remove the requirement that applicants include a statement in their application if
they are temporarily residing in New York State for purposes of receiving care and treatment in the state, as this requirement will now be documented by the certifying practitioner.

§ 1004.4 Designated caregiver registration. Section 1004.4(b) is amended to indicate that acceptable proof of residence for a caregiver includes a New York State non-driver identification card.

§ 1004.5 Application for initial registration as a registered organization. Section 1004.5(b) is amended to clarify the requirement to submit a prepared financial statement upon initial application for designation as a registered organization.

§ 1004.6 Consideration of registered organization applications. Section 1004.6(a) is amended to allow forms of payment other than a certified check. Section 1004.6(e) is amended to clarify that a registered organization's registration may be amended instead of the application for registration.

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§ 1004.10 Registered organizations; general requirements. Section 1004.10(a) is amended to include a process in which the department will provide a statement of findings to a registered organization, and that the registered organization must respond and implement a plan of correction to address any deficiencies identified by the department. Section 1004.10(a) is also amended to allow manufacturing materials to be submitted to the department upon request and to reduce sample retention duration from two years to thirty days after the date of expiration. Further, this section is amended to clarify that registered organizations must notify
department of adverse events and other incidents within 24 hours and must inventory and maintain records of medical marihuana products or by-products which are disposed. Section 1004.10(a) is also amended to account for records that may need to be maintained for a time period other than five years and to require registered organizations to post a registration certificate in a conspicuous location on the premises of each manufacturing and dispensing facility site. Section 1004.10(b) is amended to clarify criminal history requirements for registered organization managers or employees.

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

Section 1004.11(a)(2) is amended to update the allowable range of THC and CBD concentration per dose and brand for potency testing purposes, and is amended to remove the term “extraction” from the definition of a brand. Section 1004.11(c) is modified to remove the prohibition on the use of unprocessed whole flower, to coincide with amendments to section 1004.11(g) and the allowable forms of administration. Section 1004.11(c) is also amended to clarify reporting requirements for other cannabinoid components at >0.1%. Section 1004.11(e) is amended to update the allowable range of THC and CBD concentration per dose and brand for potency testing purposes and is updated to clarify that the New York State Department of Environmental Conservation is the authority which registers acceptable pesticides. In addition, section 1004.11(e) is modified to add a requirement that registered organizations shall ensure continual environmental monitoring of harvested plant material awaiting additional processing. Section 1004.11(g) is modified to allow registered organizations to produce medical marihuana products in new forms of administration. Section 1004.11(h) is amended to allow registered organizations to break the seal of an approved medical marihuana product for internal quality control testing or
destruction. Section 1004.11(k) is amended to clarify labeling requirements related to stability studies. Section 1004.11(m) is amended to clarify stability testing requirements and to account for initial stability testing limitations. Section 1004.11(n) is amended to make clear that registered organizations may not use any cannabinoid preparation not produced by a registered organization in an approved manufacturing facility.

§ 1004.12 Requirements for dispensing facilities. Section 1004.12(a) is amended to clarify that medical marihuana products may not be dispensed or handled unless an individual with an active New York State pharmacist license is on the premises and supervising. Section 1004.12(a) is further revised to clarify that dispensing facility pharmacists must complete a four hour course approved by the commissioner pursuant to section 1004.1(b). Section 1004.12(b) is amended to allow dispensing facilities to sell additional items. Section 1004.12(d) is stricken to allow food or beverages to be consumed on the premises of a dispensing facility. Section 1004.12(f) is changed to section 1004.12(d) and new section 1004.12(d) is amended to include a requirement that the Prescription Monitoring Program (PMP) Registry be consulted prior to dispensing approved medical marihuana products. Section 1004.12(g) is changed to section 1004.12(e) and new section 1004.12(e) is amended to clarify dispensing facility access restrictions. Section 1004.12(h) is changed to section 1004.12(f) and new section 1004.12(f) is revised to clarify that labels shall include the expiration date of the product once opened. Section 1004.12(m) is changed to section 1004.12(k) and new section 1004.12(k) is modified to clarify the documentation requirements for dispensing facilities that accept returns of approved medical marihuana products and to ensure secure storage until returned products can be properly disposed.
§ 1004.13 Security requirements for manufacturing and dispensing facilities. Section 1004.13(a) is revised to clarify that production and harvesting are included in the definition of manufacturing and a video surveillance requirement is also added to the disposal process. Section 1004.13(a)(8) is amended to allow registered organizations to use an automatic voice dialer, digital dialer or other acceptable industry standard equivalent. Section 1004.13(c) removes the requirement that a back-up alarm system needs to be provided by a different company than the primary alarm. Section 1004.13(g) reduces the frequency of alarm system testing that must be conducted by the registered organization. Section 1004.13(h) addresses visitors at the manufacturing facility. Section 1004.13(i) is amended to clarify the requirements for storage of marihuana. Section 1004.13(j) is amended to clarify that registered organizations must store medical marihuana in such a manner as to protect against physical, chemical and microbial contamination and deterioration. Sections 1004.13(n)-(p) are modified to remove the requirement that registered organizations only transport approved medical marihuana products from a manufacturing facility to dispensing facilities.

§ 1004.14 Laboratory testing requirements for medical marihuana. Section 1004.14(b) is amended to add the requirement that no immediate family members of a board member, officer, manager, owner, partner, principal stakeholder or member of a registered organization shall have an interest or voting rights in the lab performing testing on medical marihuana. Section 1004.14(c) is amended to clarify final product testing sample requirements. Section 1004.14(d) is modified to clarify that registered organizations may test final products that have been packaged. Section 1004.14(e) is amended to add the requirement that sampling methodologies
must be approved by the department. Section 1004.14(g) is amended to clarify the list of contaminants for which testing must occur and to clarify that pesticides include herbicides and fungicides. Section 1004.14(h) is amended to clarify stability testing requirements for open and unopened products. Section 1004.14(i) is added to include a disposal requirement for laboratories. Section 1004.14(j) is added to include a requirement for laboratories to return medical marihuana products deemed unsuitable for testing to the registered organization.

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§ 1004.16 Medical Marihuana marketing and advertising by registered organizations.

Section 1004.16(a) is amended to remove the requirement that only a single black and white sign may be allowed on the external structures of a registered organization. Section 1004.16(a) is also amended to remove the restriction that external signs not be illuminated. Section 1004.16(m) is amended to clarify that registered organizations may educate practitioners about medical marihuana brands or devices offered by the registered organization.

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§ 1004.20 Proper disposal of medical marihuana products by patients or designated caregivers. Section 1004.20 is amended to allow patients and caregivers to return approved medical marihuana products to the dispensing facility from which they were purchased or any dispensing facility associated with the registered organization. Section 1004.20(b) is also amended to clarify that the New York State Department of Environmental Conservation provides guidance on proper drug disposal.
§ **1004.21 General prohibitions.** Section 1004.21(d) is amended to allow physicians, nurse practitioners and physician assistants, employed by registered organizations, to counsel certified patients and designated caregivers on medical marihuana product use, administration and risks.

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§ **1004.24 Registered Organizations disposal of medical marihuana.** Section 1004.24 is added to provide guidance on acceptable processes for disposing of medical marihuana products and by-products.

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§ **55-2.15 Requirements for laboratories performing testing for medical marihuana.** Section 55-2.15(b) is amended to correct the agency name and to include a disposal requirement for laboratories. Section 55-2.15(c) is also amended to include a disposal requirement for laboratories.
Pursuant to the authority vested in the Commissioner of Health by Section 3369-a of the Public Health Law (PHL), Part 1004 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended, and pursuant to 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:

Subdivisions (a) and (b) of section 1004.1 are amended to read as follows:

(a) No practitioner shall be authorized to issue a patient certification as set forth in section 1004.2 unless the practitioner:

* * *

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

* * *

(b) The commissioner shall approve at least one, if not more, courses for practitioners seeking to become registered, which shall be two to 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.

Subdivision (a) of section 1004.2 is amended and new subdivision (e) is added to read as follows:
(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 **subject to completion of subpart (e) of this section.** Such certification shall contain:

* * *

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

(16) to the extent that a practitioner seeks to authorize the use of an approved medical marihuana product by a patient who temporarily resides in New York State for the purpose of receiving care and treatment from the practitioner, the practitioner shall so state on the patient’s certification.

* * *

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

Subdivisions (b) and (c) of section 1004.3 are amended to read as follows:

(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:

* * *

(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:

* * *

(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].

Subdivision (b) of section 1004.4 is amended to read as follows:

(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:

* * *

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

* * *

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

Subdivision (b) of section 1004.5 is amended to read as follows:

(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:

* * *

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

Subdivisions (a) and (e) of section 1004.6 are amended to read as follows:

(a) Applicants for approval to operate as registered organizations shall submit an application to the department, containing the information required in section 1004.5 of the Part, in a manner and format determined by the department.

* * *

(2) The registration fee for the registration period shall be $200,000. Applicants shall submit the registration fee by certified check, or another method approved by the Department, 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] fee for $200,000 to all applicants who are not granted a registration.

* * *

(e) [An application] Upon application to the department, a registered organization’s registration may be amended to allow the registered organization to relocate within the state or to add or delete permitted registered organization activities or facilities. The 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 $250.

Subdivisions (a) and (b) of section 1004.10 are amended to read as follows:

(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;

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

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

(b) contain a procedure addressing how the registered organization intends to correct each area of noncompliance;
(c) contain an explanation of how proposed corrective actions will be implemented and maintained to ensure noncompliance does not recur;

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

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

(ii) Upon written approval of the department, the registered organization shall implement the plan of correction.

* * *

(4) submit approved medical marihuana product samples and manufacturing materials to the department upon request, [including] for but not limited to, 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 two times and shall be retained by the registered organization for at least two years thirty days following the date of expiration;

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

(i) any adverse events;

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

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

and

(iv) any vehicle accidents or incidents occurring during transport of medical marijuana products.

(6) Within ten days of the occurrence of one of the above events, the registered organization shall submit a complete written incident report to the department detailing the circumstances of the event, any corrective actions taken, and where applicable, confirmation that appropriate law enforcement authorities were notified
([6]7) 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]8) 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] pursuant to section 1004.24 of this Part;

([8]9) maintain records required by article 33 of the Public Health Law and this Part for a period of five years, unless otherwise stated, and make such records available to the department upon request. Such records shall include:

* * *

(10) post the certificate of registration issued by the department in a conspicuous location on the premises of each manufacturing facility and dispensing facility.

(b) Registered organizations shall not:

* * *

(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]

* * *

(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[.]; or

(8) be managed by or employ anyone who has been convicted of any felony of sale or possession of drugs, narcotics, or controlled substances provided that this provision only applies to:

(i) managers or employees who come into contact with or handle medical marihuana; and

(ii) a conviction less than ten years (not counting time spent in incarceration) prior to being employed, for which the person has not received a certificate of relief from disabilities or a certificate of good conduct under article 23 of the correction law.

* * *

Subdivisions (a), (c), (e), (g), (h), (k), (l), (m) and (n) of section 1004.11 are amended to read as follows:

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

* * *

(2) “Brand” means a defined medical marihuana [extraction] product that has a homogenous and uniform cannabinoid concentration (total THC and total CBD) 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 [that form of the brand].
(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:

(x) Any other cannabinoid component at > 0.12 percent, for which there is a certified standard available at a customary cost.

(3) The final medical marihuana product shall not contain less than 90 percent or more than 110 percent of the concentration of total THC or total CBD indicated on the label for this brand. Each brand and shall have no more than [a maximum of] 10mg total THC per dose. However:

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

(iii) the concentration of total THC and CBD in milligrams per single dose for each sample of a brand lot submitted for testing must be within 25 percent of the mean concentration of total THC and CBD in milligrams per single dose for that submitted lot with the exception that, for brands with a specified total THC and CBD concentration less than 2 milligrams per single dose, the concentration of each sample for that low concentration cannabinoid shall be within 0.5 milligrams per dose of the mean concentration.

(e) A registered organization shall:

(3) upon prior written notice to the department, only use [only] pesticides[, fungicides, and herbicides] that are [approved] registered by the New York State Department of [Agriculture and Markets] Environmental Conservation or that specifically meet the United States Environmental Protection Agency registration exemption criteria for Minimum Risk Pesticides, and only in accordance with section 325.2(b) of title 6 of the NYCRR;

(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[.]; and
(7) provide continual environmental monitoring for temperature, ventilation and humidity at all locations in the manufacturing facility where unprocessed leaf and flower material is stored, until further extraction or other processing is completed.

* * *

(g) Approved medical marihuana products shall be limited to the [following] forms [and routes] of administration approved by the Department, including but not limited to:

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

(2) [metered liquid or oil preparations for vaporization] solid and semisolid preparations (e.g. capsules, chewable and effervescent tablets, lozenges);

(3) [capsules for oral administration; or] metered ground plant preparations; and

(4) [any additional form and route of administration approved by the commissioner. Smoking is not an approved route of administration] topical forms and transdermal patches.

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

(6) Smoking is not an approved route of administration.

(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, or by the registered organization for internal quality control testing or disposal.

* * *

(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:

* * *

(7) the date of expiration of the unopened product, based on stability studies in accordance with section 1004.11(m)(2) of this title, or a tentative expiration date approved by the department;

* * *

(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] section 1004.24 of this Part.

(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] reported to the department and not dispensed by a registered organization without prior written approval from the department.

* * *

(m) The registered organization shall demonstrate the stability of each approved medical marihuana product produced (each brand in each form) by testing both the unopened and opened product at an approved laboratory in accordance with section 1004.14(h) of this title:

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

(2) [shelf-life] the stability of unopened [medical marihuana] products (e.g., sealed 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:]

*  *  *

(n) No synthetic marihuana additives nor any cannabinoid preparation not produced by a
registered organization in an approved manufacturing facility shall be used in the production of
any medical marihuana product.

Subdivisions (a), (b), (d), (e), (f), (g), (h), (i), (j), (k), (l) and (m) of section 1004.12 are amended
to read as follows:

(a) [Dispensing facilities shall not be open or in operation] Medical marihuana products shall not
be dispensed or handled unless an individual with an active New York State pharmacist license,
as defined in article 137 of the Education Law, who has completed a four-hour course pursuant
to section 1004.1 of this part, 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] only 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] and items that promote health
and well-being subject to disapproval of the department and only in such a manner as does not
increase risks of diversion, theft or loss of approved medical marihuana products or risk physical,
chemical or microbial contamination or deterioration of approved medical marihuana products.

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[(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:

* * *

(4) ensure the prescription monitoring program registry is consulted pursuant to 3343-a and section 3364 of the Public Health Law, prior to any sales transactions and dispensing of any approved medical marihuana products by the facility.

* * *

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

(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.] registered organization employees;

(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.

employees of the department or its authorized representatives;

(3) emergency personnel responding to an emergency, and;

(4) other persons authorized by a manager of the registered organization for the sole purpose of maintaining the operations of the facility.

(i) The dispensing facility shall maintain a visitor log of all persons, other than registered organization employees or emergency personnel responding to an emergency, that access these secured areas, which shall include the name of the visitor, date, time and purpose of the visit. The visitor log shall be available to the 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)g] 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:
(5) the quantity and date dispensed; [and]

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

and

(7) the expiration date of the product once opened pursuant to section 1004.11(m)(1) of this Part.

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

([jj]i) 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.

([kl]j) 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:

* * *

([ll]k) 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.

* * *

([ml]l) 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.]:

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(1) dispose of such product pursuant to section 1004.24 of this part;

(2) provide the following information to the department:

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

(ii) the date of the return;

(iii) the brand and form being returned;

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

(v) the reason for the return;

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

(vii) any other information required by the department;

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

Subdivisions (a), (c), (g), (h), (i), (j), (n), (o) and (p) of section 1004.13 are amended to read as follows:

(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:
(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, or disposed of. 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;

(8) an automatic voice dialer or digital 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, or other department approved industry standard equivalent;

(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].

(g) A registered organization shall keep all security equipment in full operating order and shall test such equipment no less than [monthly] semi-annually at each manufacturing facility and
dispensing facility that is operated under the registered organization’s registration. Records of security tests must be maintained for five years and made available to the department upon request.

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

(1) The registered organization shall be responsible for ensuring the integrity of the security of the manufacturing facility and the maintenance of sanitary operations when permitting access to the facility.

(2) The manufacturing facility shall maintain a visitor log of all persons other than registered organization employees or emergency personnel responding to an emergency that access any secured areas, which shall include the name of the visitor, date, time and purpose of the visit. The visitor log shall be available to the department at all times during operating hours and upon request.

(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 and in such a manner as approved by the department in advance, to prevent diversion, theft or loss.

(1) Registered organizations shall return marihuana to its secure location immediately after completion of manufacture, distribution, transfer or analysis.
(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 protect against physical, chemical and microbial contamination and deterioration of the product [prevent diversion, theft or loss].

*   *   *

(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] destination that will receive the products and to the department at least two business days prior to transport unless otherwise expressly approved by the department.

*   *   *

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

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

(2) and 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] to his or her destination(s) and shall not make any unnecessary stops in between.
Subdivisions (b), (c), (d), (e), (g) and (h) of section 1004.14 are amended and new subdivisions (i) and (j) are added to read as follows:

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

(c) For final product testing, [T]he registered organization shall submit to the laboratory[, and testing shall only be performed on,] a statistically significant number of samples containing the final medical marihuana product equivalent to the sealed medical marihuana product dispensed to the patient (e.g., liquid extract in a sealed [vial] bottle or intact sealed bottle of capsules). Upon prior written approval of the department, a registered organization may submit to the laboratory the final medical marihuana product sample packaged in a quantity less than that which would be provided to the patient if the sample is prepared and packaged in the identical manner as the product provided to the patient.

(d) Testing of the final medical 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, approved by the
department, 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.

*   *   *

(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

   [Klesbsiella]

   Pseudomonas species (for products to be vaporized)

   Salmonella species

   [Streptococcus] Enterococcus species

   Bile tolerant gram negative bacteria, specifically including Klebsiella species

   Clostridium botulinum

   Aspergillus species

   Mucor species

   Penicillium species

   Thermophilic Actinomycetes species

   [Aflaltoxin] Aflaltoxins A1, B1, B2, G1, G2

   Ochratoxin A

   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) Stability testing shall be performed on each brand and form of medical marihuana product as follows:

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

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

(3) For stability testing of both opened and unopened products, each brand shall retain a total
THC and total CBD concentration in milligrams per single dose that is consistent with section 1004.11(c)(3). If stability testing demonstrates that a product no longer retains a consistent concentration of THC and CBD pursuant to section 1004.11(a)(2), the product shall be deemed no longer suitable for dispensing or consumption. The department may request further stability testing of a brand to demonstrate the ongoing stability of the product produced over time.

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

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

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

Subdivisions (a), (d), (h), (i), and (m) of section 1004.16 are amended to read as follows:

(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][1]) Not advertise medical marihuana brand names or utilize graphics related to marihuana or paraphernalia on the exterior of the physical structures; and 
([4][2]) Not display [approved] medical marihuana products and paraphernalia so as to be clearly visible from the exterior of a physical structure.

* * *

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

* * *

(i) Any advertisement for an approved medical marihuana product, which makes any claims or statements regarding efficacy, shall be submitted to the department at least [30] 10 business days prior to the public dissemination of the advertisement.

* * *

(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]. Nothing contained within this section prevents a registered organization from educating practitioners about approved medical marihuana products offered by the registered organization.

Subdivision (b) of section 1004.20 has been amended to read as follows:

(b) A certified patient or designated caregiver shall complete disposal of approved medical marihuana [product] products by one of the following methods:
(1) rendering the approved medical marihuana product non-recoverable beyond reclamation in accordance with [the department’s proper disposal instructions, which are available on the department’s Internet web site] the Department of Environmental Conservation’s guidance; or

(2) [disposing of the approved medical marihuana product at a department-recognized drug takeback program located in New York.] returning the approved medical marihuana product to the dispensing facility from which it was purchased or any dispensing facility associated with the registered organization which manufactured the approved medical marihuana product, to the extent that the registered organization accepts product returns.

Subdivision (d) of section 1004.21 has been amended to read as follows:

(d) No employee of a registered organization shall counsel [the] a certified patient or designated caregiver on the use, administration of, and the risks associated with approved medical marihuana products, unless the employee is a physician, nurse practitioner, physician assistant or pharmacist with an active New York State license who has completed a four hour course pursuant to section 1004.1 of this Part, or the employee is under the direct supervision of, and in consultation with, such physician, nurse practitioner, physician assistant, or pharmacist on-site in the dispensing facility.

Section 1004.24 is added to read as follows:

§ 1004.24 Registered organizations; disposal of medical marihuana

(a) The disposal of medical marihuana shall mean that the medical marihuana has been rendered unrecoverable and beyond reclamation.
(b) Registered organizations shall dispose of any medical marihuana that is outdated, damaged, deteriorated, contaminated or otherwise deemed not appropriate for manufacturing or dispensing, or any plant-based waste created as a by-product of the manufacturing processes. Registered organizations shall:

(1) obtain department approval of disposal methods; and

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

(c) Registered organizations shall maintain records of disposal, which shall include:

(1) the type of plant material being disposed, if the material is a by-product of the manufacturing process;

(2) the brand and form of approved medical marihuana product being disposed, if a finished product;

(3) the weight of the disposed material, the number of plants, or in the case of a finished product, the quantity of the disposed product; and

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

(d) All records of disposal shall be retained for at least five years and be made available for inspection by the department.
Subdivisions (b) and (c) of section 55-2.15 are amended to read as follows:

(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 Administration registration. 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 disposal of 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, disposal of and storage of medical marihuana, medical marihuana product or final medical marihuana product as defined in section 55-2.15(a) of this subpart including any validation summaries or data as requested; and

*  *  *
REGULATORY IMPACT STATEMENT

Statutory Authority:
The Commissioner is authorized pursuant to Section 3369-a of the Public Health Law (PHL) to promulgate rules and regulations necessary to effectuate the provisions of Title V-A of Article 33 of the Public Health Law. The Commission is authorized pursuant to Section 502 of the PHL to promulgate rules and regulations relating to environmental laboratories.

Legislative Objectives:
The legislative objective of Title V-A is 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.

Needs and Benefits:
These proposed regulations promote the safe and effective use of approved medical marihuana products while, improving patient access, and 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. The regulations will serve the following needs:

1. Practitioner registration – The proposed regulations modify the duration of the Department approved course to allow for courses that are two to four hours in duration.
2. Practitioner issuance of certifications to patients – The proposed regulations add the practitioner’s statutory requirement to consult the Prescription Monitoring Program Registry. If the practitioner issues a certification to a patient who is a non-resident of New York but who is temporarily residing in the State for purposes of receiving care and treatment, such information must be indicated on the certification.

3. Certified patient and designated caregiver registrations – Clarify that an acceptable proof of residence for a caregiver includes a New York State non-driver identification card.

4. Application for initial registration as a registered organization – The requirement for the prepared financial statement upon initial application for a registered organization is clarified.

5. Registered organization requirements for manufacturing and dispensing facilities – Reporting requirements for other cannabinoid components at >0.1% are clarified. The allowable range of THC and CBD concentration per brand and dose for potency testing purposes is amended. Registered organizations shall ensure continual environmental monitoring of harvested plant material awaiting additional processing. Registered organizations may produce products in new forms including, but not limited to, solid and semisolid preparations (e.g. capsules, chewable and effervescent tablets, lozenges), metered ground plant preparations, and topical forms and transdermal patches. Registered organizations may break the seal of an approved medical marihuana product for internal quality control testing or destruction. Labeling requirements related to stability studies are clarified for registered organizations. Stability testing
requirements and initial stability testing limitations are further defined. Registered organizations may not use any cannabinoid preparation in any of its medical marihuana products that has not been produced by a registered organization. Dispensing facility pharmacists must complete a Department approved four-hour course. The Prescription Monitoring Program (PMP) Registry must be consulted prior to dispensing approved medical marihuana products. Dispensing facility access restrictions are amended to allow individuals who are not certified patients or designated caregivers into the dispensing facility. Labels on all medical marihuana products shall include the expiration date of the product once opened. Dispensing facilities that accept returns must document the returns and ensure secure storage until disposal.

6. General registered organization requirements – The Department may provide a statement of findings to a registered organization and registered organizations must respond to implement a plan of correction to address deficiencies identified by the Department. Manufacturing materials may be submitted to the Department upon request and sample retention duration is reduced from two years to thirty days following the date of expiration. Registered organizations must notify the Department of adverse events and other incidents within 24 hours. Registered organizations must maintain records of medical marihuana products or by-products which are disposed of. Registered organizations must post a Department issued certificate of registration in a conspicuous location on the premises of each manufacturing and dispensing facility. Criminal history requirements for registered organization managers or employees are clarified.
7. Laboratory testing requirements – No immediate family members of a board member, officer, manager, owner, partner, principal stakeholder or member of a registered organization shall have an interest or voting rights in the independent laboratory performing testing on medical marihuana. Registered organizations may test final products that have been packaged. The list of contaminants for which testing must occur and stability testing guidance for open and unopened products is further defined. A disposal requirement for laboratories and a requirement for laboratories to return medical marihuana products deemed unsuitable for testing to the registered organization has been included.

8. Security requirements for manufacturing and dispensing facilities – A video surveillance requirement was added to the disposal process. Registered organizations must store all marihuana in a secure area or location within the registered organization as approved by the Department. Restrictions on where and how registered organizations transport medical marihuana were clarified. Manufacturing facility access restrictions are further clarified.

9. Medical marihuana marketing and advertising by registered organizations – Requirements for approved signage are amended. The regulations clarify the type of advertisements requiring Department approval.

10. Proper disposal of medical marihuana products by patients or designated caregivers – A clarification is made that the Department of Environmental Conservation provides guidance on proper drug disposal and patients and caregivers may return approved medical marihuana products to certain dispensing facilities.
11. General prohibitions – A physician, nurse practitioner, physician assistant or pharmacist employed by a registered organization, who has completed the four-hour course, may counsel certified patients or designated caregivers at a registered organization dispensing facility on medical marihuana product use, administration and risks.

12. Registered Organizations disposal of medical marihuana - Acceptable processes for disposing of medical marihuana products and by-products are defined.

**Costs**

**Costs to the Regulated Entity:**

The proposed streamlined visitor access requirements will result in a simplification of staff responsibilities for registered organizations where visitors to the dispensing facility, including, but not limited to emergency personnel and persons performing regular maintenance, will not require prior authorization by the Department.

Registered organizations will also benefit from the easing of the cannabinoid concentration variability requirements, which are amended to be consistent with pharmaceutical industry standards. Increasing the cannabinoid concentration variability may result in reduced costs to registered organizations related to relabeling of final products falling outside of concentration estimates.

Registered organizations will further benefit from decreased costs related to submitting samples for testing which are packaged in a quantity less than what would be provided to the patient but in a sufficient amount for laboratory confirmation of safety and potency. Registered
organizations will realize savings by reducing the amount of product needed for testing. In addition, a savings may be experienced by registered organizations due to decreased sample retention requirements.

Registered organizations may have additional costs in staffing related to responding to a statement of findings identified by the Department where a written plan of correction is required by the registered organization. These costs are necessary to ensure the program is administered in a manner that protects the public health and safety. Any increase in costs to registered organizations related to the proposed amendments will be offset by additional savings from the proposed amendments.

**Costs to Local Government:**

The proposed rule does not require the 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 the review of additional brands and dosage forms will require the commitment of Department staff resources. The Department also anticipates an increased administrative cost to support ongoing monitoring and compliance of the medical marihuana program, and for laboratory services provided by Wadsworth Center laboratories for testing of medical marihuana products.
Local Government Mandates:

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

Paperwork:

Deficiencies identified by the Department will result in the issuance of a written statement of findings issued by the Department and registered organizations will be required to submit a written plan of correction.

Duplication:

No relevant rules or legal requirements of the Federal and State governments duplicate, overlap or conflict with this rule.

Alternatives:

The Department could have made this regulation final as previously proposed. However, the substantive changes proposed in this revised rulemaking will help to further enhance the medical marihuana program.

Federal Standards:

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

Compliance Schedule:

There is no compliance schedule imposed by these amendments, which shall be effective upon publication of a notice of adoption.
Contact Person:

Ms. Katherine Ceroalo
New York State Department of Health
Bureau of House Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (Fax)
regsqna@health.ny.gov
REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES
AND LOCAL GOVERNMENTS

Effect of Rule:
This proposed rule will amend regulations for registered organizations who manufacture, distribute and sell approved medical marijuana products in New York State, as well as expand access to patients by authorizing new dosage forms and improving regulations pertaining to visitors. 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 on 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:
No new compliance costs will be required of small business entities and local governments.

Economic and Technological Feasibility:
This proposal is economically and technologically feasible. Statute requires the registered organization to pay an excise tax to the Commissioner of Tax and Finance. This tax will help to
provide funds to the counties in New York State where medical marihuana is manufactured and dispensed.

**Minimizing Adverse Impact:**

To minimize the potential for patient adverse effects associated with the use of medical marihuana, the regulations continue to provide for Department authorization of approved brands (cannabinoid profiles) and dosage forms that registered organizations may manufacture. In addition, the regulations continue to 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 also discussed the regulations and received input from various advocacy organizations. There will be a 30-day public comment period with the regulations that will allow for additional comments to be considered.
STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

No Rural Area Flexibility Analysis is required pursuant to Section 202-bb(4)(a) of the State Administration Procedure Act (SAPA). It is apparent from the nature of the proposed regulation that it will not impose any adverse impact on rural areas, and the rule does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.
STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.
SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

The Department of Health (“Department”) received comments from various stakeholders, including but not limited to healthcare providers, registered organizations and legislators. Comments received included, but were not limited to, topics concerning manufacturing requirements, dispensing facility operations and laboratory testing. Based on the comments received, no changes are being made to the proposed rulemaking.
ASSESSMENT OF PUBLIC COMMENT

The Department of Health ("Department") received comments from various stakeholders, including patients and their family members, healthcare providers, advocacy groups, registered organizations and legislators. Comments received included topics concerning advertising, manufacturing requirements, dispensing facility operations, practitioner education and laboratory testing. These comments and the Department’s responses are summarized below.

§ 1004.1 Practitioner registration.

COMMENT: Several commenters wrote in support of the proposed amendment to allow practitioners to choose to take a two-hour practitioner education course, rather than requiring a four-hour course. Commenters stated that this change would make it easier for patients’ primary practitioners and specialists to certify patients for the program, thus allowing more patients to qualify for the program. Commenters also stated that it is unreasonable to require a physician to take a four-hour course on marihuana when there is no similar requirement for other medications.

RESPONSE: The comments are noted. No changes to the proposed regulations have been made as a result of these comments.

COMMENT: Several commenters opposed allowing a two-hour practitioner education course rather than the currently required four-hour course. Commenters supported the four-hour course, stating that it gives practitioners appropriate information to enable them to safely recommend medical marihuana. Commenters suggested that reducing the required number of hours will limit the essential information needed by practitioners and jeopardize the health and safety of patients. One commenter stated that physicians who become certified to prescribe
buprenorphine must complete eight hours of education and that the complexities of medical marihuana prescribing and usage should be no less.

**RESPONSE:** This proposed regulation aligns with Public Health Law (PHL) § 3360(12), which allows for a two- to four-hour practitioner education course. The proposed regulation does not alter the educational content requirements of the course detailed in Section 1004.1(b) of the regulations, which 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. Rather, the proposed amendment allows the Department to offer such educational content in a condensed format, thereby making the practitioner education course available to learners with potential time constraints. No changes to the proposed regulations have been made as a result of these comments.

**COMMENT:** A commenter encouraged the Department to make available a free, online two-hour practitioner education course, so that the cost of taking the required course does not deter practitioners from participating in the Medical Marihuana Program. The commenter also suggested that the requirement for practitioners to take a course should be removed; however, the commenter acknowledged that this is not within the purview of the Department.

**RESPONSE:** PHL § 3360(12) requires practitioners to complete a two- to four-hour course before they can register with the Department to certify patients for medical marihuana. No changes to the proposed regulations were made as a result of this comment.
COMMENT: A commenter encouraged the Department to develop content so that the required practitioner education course is tailored to physicians who are less familiar with medical marihuana. The commenter suggested that interested physicians should be educated about the statute, regulations, and qualifying conditions. The commenter further stated that physicians should be reassured that their involvement in New York State’s Medical Marihuana Program would not adversely affect their status with the federal Drug Enforcement Agency or medical licensure.

RESPONSE: The required practitioner education course includes information regarding: 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. In addition, the course provides practitioners with information about the qualifying serious conditions. The Medical Marihuana Program and Compassionate Care Act are firmly established in state law, as are many other medical marihuana programs around the nation. Possible ramifications with respect to the federal Drug Enforcement Agency are not within the purview of the Department. No changes to the proposed regulations were made as a result of these comments.

COMMENT: Comments were received requesting that the required practitioner education course be mandatory for all practitioners in New York State.

RESPONSE: The Department encourages all practitioners in New York State to take the practitioner education course; however, the Compassionate Care Act only requires practitioners seeking to register with the Medical Marihuana Program to take the course. No changes to the proposed regulations were made as a result of these comments.
COMMENT: Several commenters wrote in support of allowing practitioners more autonomy in the Medical Marihuana Program. One commenter suggested that physicians should be allowed to determine the best method and amount of delivery, rather than limiting the amount of THC per dose. Another commenter suggested that practitioners should be able to prescribe a trial period for any medical condition so that patients could determine if medical marihuana addresses their pain. The commenter stated that marihuana, which is not addictive, might treat such pain as effectively and with fewer side-effects.

RESPONSE: These comments are outside the scope of the existing statute and the proposed regulations. No changes to the proposed regulations were made as a result of these comments.

COMMENT: Comments were received in support of simplifying the process by which practitioners certify patients. In addition, commenters stated that more information should be made available to educate the public and practitioners about medical marihuana, and that the Department should initiate an education campaign. Commenters also mentioned the opioid epidemic and the need for additional practitioners to continue growing the Medical Marihuana Program.

RESPONSE: The Department will continue its ongoing efforts to educate practitioners about the benefits of the Medical Marihuana Program. No changes to the proposed regulations were made as a result of these comments.

§ 1004.2 Practitioner issuance of certification.

COMMENT: A commenter stated that requiring practitioners to consult the Prescription Monitoring Program (PMP) Registry could cause practitioners to be hesitant to recommend
medical marihuana to patients who previously received a prescription in New York State for an opioid. The commenter stated that a patient may seek medical marihuana as an alternative to opioids or to free herself from an opioid-dependency. The commenter suggested that the Department ensure that the required practitioner education courses inform practitioners about the pain management benefits of medical marihuana, as well as medical marihuana’s effect of decreasing opioid dependence. The commenter also suggested that the Department revise Section 1004.2(e) to specify that a practitioner may recommend medical marihuana for a patient despite the patient’s opioid history.

**RESPONSE:** Consultation of the PMP registry is a requirement set forth in Section 3361 of the PHL, and the proposed regulation is consistent with this statutory requirement. No changes were made to the proposed regulation as a result of this comment.

**COMMENT:** A commenter sought clarification related to Section 1004.2(a)(16) of the proposed regulations and asked whether the Department will require temporary New York State residents who are undergoing treatment in the state to be certified by particular practitioners.

**RESPONSE:** Section 3360 of the PHL requires that, to be certified as a patient in the Medical Marihuana Program, patients must be either a resident of New York State or receiving care and treatment in New York State. The proposed regulation is consistent with the statute and only requires the certifying practitioner to indicate on the patient’s certification that the patient is temporarily residing in the state. No changes were made to the proposed regulation as a result of this comment.
COMMENT: Numerous comments were received asking the Department to allow more qualifying conditions to the Medical Marihuana Program. Commenters sought the addition of conditions such as: autism, glaucoma, anxiety, irritable bowel syndrome (IBS), Rheumatoid Arthritis, depression, schizophrenia, bipolar disorder, End Stage Renal Disease (ESRD) and advanced Chronic Kidney Disease (CKD), Alzheimer's Disease, dementia, arthritis, post-traumatic stress disorder (PTSD) and insomnia. Commenters also suggested broadening the list to include any condition, symptom or complication for which a practitioner finds it is likely that a patient will receive therapeutic or palliative benefit from treatment with medical marihuana. A commenter also suggested that the Department implement transparent procedures for the addition of new qualifying conditions.

RESPONSE: On November 11, 2017, Governor Andrew M. Cuomo signed legislation adding PTSD as a qualifying condition for medical marihuana. In addition, on March 22, 2017, the Department adopted regulations adding chronic pain as a qualifying condition. The Department will continue to consider additional conditions as more information becomes available. No changes to the proposed regulations were made as a result of these comments.

COMMENT: A commenter stated that the Department should not allow PTSD to be added to the list of qualifying conditions because there may be evidence that marihuana is dangerous to an individual suffering from PTSD.

RESPONSE: As noted above, legislation was recently enacted that adds PTSD as a qualifying condition for medical marihuana. Virtually every state with a medical marijuana program allows for treatment of PTSD. It is estimated that approximately 19,000 patients with PTSD in New York could benefit from the use of medical marijuana. No changes to the proposed regulations were made as a result of this comment.
COMMENT: A commenter suggested that the Department remove the “clinically associated with” or “complication of” requirement in Section 1004.2(a)(9), as it prevents patients from receiving the health benefits of medical marihuana, including neuroprotective properties.

RESPONSE: This comment is beyond the scope of the regulatory amendments. No changes to the proposed regulations were made as a result of this comment.

§ 1004.3 Application for registration as a certified patient.

COMMENT: Several comments were received regarding non-resident patients. Commenters noted that the proposed regulation excludes patients from the program if they are visiting New York State. Commenters also suggested that New York State should offer reciprocity to visitors who hold valid out-of-state medical marihuana cards.

RESPONSE: Section 3360(3) of the PHL defines a “certified patient” as “a patient who is a resident of New York state or a patient receiving care and treatment in New York state as determined by the commissioner in regulation, and is certified under Section 3361 of this title.” The current regulations already require non-New York State residents to be temporarily residing in New York State for purposes of receiving care and treatment. The proposed regulation requires the certifying practitioner, rather than the patient, to indicate on the patient’s certification that the patient is temporarily residing in the state. Additionally, Section 3364 of the PHL authorizes a registered organization to dispense medical marihuana to a certified patient or designated caregiver upon presentation to the registered organization of a valid registry identification card for that certified patient or designated caregiver. Therefore, registered organizations are not permitted to dispense to a patient with an out-of-state medical marihuana card.
§ 1004.4 Designated caregiver registration.

COMMENT: A commenter expressed support for the proposed change to Section 1004.4, which would allow designated caregivers to use a New York State non-driver identification card as proof of residence. The commenter also suggested allowing patients and designated caregivers to use identification cards issued by a municipality, such as New York City's NYC ID card, because this is important for New Yorkers whose immigration status may make it difficult to obtain a non-driver identification card.

RESPONSE: The Department will take these comments under advisement and continue to study the risks and benefits of these proposals. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A commenter stated that medical marihuana patients may depend on out-of-state family members or friends to provide assistance, but these non-New York State residents would not be able to act as designated caregivers under the current regulations. The commenter suggested that the Department waive the residency requirement for non-New York State residents who care for medical marihuana patients, and that it should allow non-New York State designated caregivers to use an out-of-state driver's license or other state or federally-issued ID card.

RESPONSE: The Department will take these comments under advisement and continue to study the risks and benefits of these proposals. No changes were made to the proposed regulations as a result of these comments.
§ 1004.6 Consideration of registered organization applications.

COMMENT: A commenter stated that Section 1004.6(b)(1)-(3), which refers to "initial applicants," applies only to registered organizations manufacturing marihuana, and not to those performing only the more limited functions for which a registered organization may exist (e.g., dispensary-only registered organizations). The commenter requested clarification of these provisions.

RESPONSE: Section 1004.6(b)(1)-(3) applies to all registered organizations, all of which are licensed to manufacture and dispense medical marihuana. No changes to the proposed regulations were made as a result of this comment.

COMMENT: A commenter asked whether Section 1004.6(e) should be removed to avoid confusion, since the proposed language now references the amendment of an existing registration, rather than modifying a registration application.

RESPONSE: The intent of the proposed amendment to Section 1004.6(e) is to clarify that a registered organization’s “registration” may be amended, rather than its application for registration. No changes to the proposed regulation were made as a result of these comments.

§ 1004.10 Registered organizations; general requirements.

COMMENT: A commenter suggested removing, reducing, or allowing exceptions to the 1,000-foot setback requirement in Section 1004.10(b)(7). The commenter stated that New York State does not require a setback between pharmacies and schools or places of worship, yet the regulations governing medical marihuana require a 1,000-foot setback between dispensaries and
these locations if they are located on the same street. The commenter stated that restrictions on location make it harder for patients to access dispensing facilities by public transit.

**RESPONSE:** This comment is beyond the scope of the regulatory amendments. No changes to the proposed regulations were made as a result of this comment.

**COMMENT:** Comments were received regarding Section 1004.10(b)(8), which prohibits a registered organization from being managed by or employing anyone who has been convicted of any felony of sale or possession of drugs, narcotics, or controlled substances, except in certain circumstances. One commenter requested that the language be modified to be as specific as possible and include specific references to criminal convictions at the state and/or federal level, if this is the intent. Another commenter stated that individuals convicted of nonviolent felonies for the sale or possession of marihuana should be permitted to participate in the management or workforce of a registered organization. The commenter also encouraged the Department to establish equity initiatives for the allocation of a certain percentage of jobs in New York State’s medical marihuana industry for people convicted of non-violent felonies for the sale or possession of marihuana. One commenter asked what the Department considers an “unreasonable risk” pursuant to the New York State employment guidelines relating to the employment of persons with prior criminal conviction records.

**RESPONSE:** The regulatory amendment, which prohibits registered organizations from being managed by or employing anyone who has been convicted of a felony concerning the sale or possession of drugs, is consistent with Section 3364(7) of the PHL. With respect to employment of people convicted of non-violent felonies, such an initiative is beyond the scope of these proposed regulations. With respect to convictions that are not subject to PHL § 3364(7), registered organizations are responsible for determining if employment of a person with a prior
criminal conviction record poses an “unreasonable risk” pursuant to New York State Correction Law § 752. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A commenter requested that the 15-calendar day timeframe established by Section 1004.10(a)(1)(i) run from the date of the registered organization's receipt of such statement of findings rather than its issue date. The commenter stated that this would be consistent with the timeframe in Section 1004.10(a)(1)(e) for submission of corrective action plans running from the date of notification, which the commenter assumed meant receipt of notification and not the date of issuance.

RESPONSE: In cases where the Department determines it is necessary to communicate deficiencies pursuant to this provision, the Department will take measures to ensure such communications are received by the registered organization on the same day they are issued. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A commenter asked the Department to define the term “adverse events,” as referred to in Section 1004.10(a)(5)(i).

RESPONSE: The Department considers an adverse event to include any untoward medical occurrence associated with the use of an approved medical marihuana product in humans. The Department considers such an adverse event to be “serious” if it results in outcomes including, but not limited to: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly or birth defect.
§ 1004.11 Manufacturing requirements for approved medical marihuana product(s).

COMMENT: A commenter asked for clarification of the phrase “certified standard available at a customary cost” in the proposed amendment to Section 1004.11(c)(2)(x).

RESPONSE: This subdivision generally requires testing of additional cannabinoid components, if there is an established standard for such analysis available at a reasonable price.

COMMENT: Numerous commenters wrote in support of the proposed language in Section 1004.11(g) that would allow for access to additional forms of products. Commenters stated that the proposed changes are a dramatic improvement over existing regulations and would result in many more patients obtaining a safe product from registered organizations, rather than purchasing marihuana from the illicit market. Comments were received in support of the use of topical tinctures, lotions and salves, and rectal suppositories.

RESPONSE: Section 1004.11(g)(4) of the proposed regulations allows for topical formulations of medical marihuana, including transdermal patches. Rectal suppositories are allowed as a solid or semisolid preparation pursuant to Section 1004.11(g)(2) of the proposed regulations. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: A commenter expressed support for the proposed changes to Section 1004.11(g), which address product types and quality control. The commenter stated that while the proposed regulations are good and should be adopted, the Department should consider a process for approving additional forms of administration without the need for a regulatory change that identifies each new delivery method as it is approved.

RESPONSE: This comment is beyond the scope of the regulatory amendments. No changes to the proposed regulations were made as a result of this comment.
COMMENT: Numerous comments were received suggesting that additional forms of medical marihuana should be permitted, including edible preparations and marihuana in whole plant form.

- Commenters in support of edible preparations stated that edible preparations provide patients with long-lasting relief.
- Commenters in support of whole plant marihuana preparations stated that such form would prevent further refining costs from being passed on to patients. The commenters stated that drawing in patients who are currently smoking marihuana purchased from the criminal market will allow them to purchase a healthier, tested, and regulated product.
- Commenters stated that it would be more appealing to potential medical users if the marihuana flower was intact and if there was a selection of strains, because different strains produce different effects that may be helpful for different medical conditions.
- A commenter stated that all but three other states that have medical marihuana programs allow whole plant material to be purchased. The commenter noted that numerous studies have shown the efficacy of whole plant marihuana and that whole plant marihuana does not have to be “ground” because some patients administer flower raw in salads or smoothies.
- A commenter stated that while the pharmaceutical Marinol has been available and is prescribed by some physicians, it does not have the same level of efficacy as the whole plant and that the process of making pharmaceutical grade THC products strips away important co-elements in the plant that create the overall therapeutic effects.

RESPONSE: No changes to the proposed regulation were made as a result of these comments. Section 1004.11(g)(2) allows for solid and semisolid preparations (e.g. capsules, chewable and effervescent tablets, lozenges), which may be consumed orally, providing patients with similar
long-lasting relief to that obtained from incorporating medical marihuana into food products. Further, pursuant to PHL § 3360(1), a certified medical use of marihuana does not include smoking. Patients may also obtain additional information regarding the strains used to manufacture approved medical marihuana products from the registered organizations. The Department also notes that Marinol is synthetic and not plant-derived. Although medical marihuana in New York State is manufactured into approved, metered, medical marihuana products, all products are plant-based and may contain many different cannabinoids and terpenes that contribute to an “entourage effect.”

**COMMENT:** One commenter expressed concerns that the regulations force patients to expose themselves to excipients that may cause respiratory issues or cancer and that some patients may want to avoid such potentially toxic substances.

**RESPONSE:** Pursuant to Section 1004.11(d), all excipients must be pharmaceutical grade and approved by the Department. Section 1004.12(k)(2) requires that a safety insert, with a list of all excipients used in the manufacturing process, be provided to patients with every purchase of an approved medical marihuana product. No changes have been made to the proposed regulations as a result of these comments.

**COMMENT:** Comments were received seeking clarification regarding the changes to the allowable forms of administration of marihuana. Specifically, one commenter requested clarification on the term "metered ground plant material." Another commenter asked whether "solid and semisolid preparations" include sublingual strips, similar to a Listerine strip. A commenter also asked whether "chewables" include products popularly called "edibles."
**RESPONSE:** Metered ground plant material is plant material that, once harvested, dried and cured, is milled or ground into fine particulate plant matter with high surface area, divided into individual measured dosage units, and packaged in a manner that meets the regulatory requirement of no more than 10mg of THC per dose. Section 1004.11(g)(5) of the proposed regulations states that medical marihuana may not be incorporated into food products by the registered organization, unless approved by the Commissioner of Health. Therefore, a solid or semisolid form that is manufactured as a chewable product may not be incorporated into food by the registered organization without such approval. A sublingual strip dosage form may be considered a solid or semisolid preparation, with the understanding that all approved medical marihuana products must be reviewed and approved by the Department.

**COMMENT:** Comments were received stating that smoking medical marihuana should be allowed. One commenter expressed concern that patients are being forced to purchase concentrated, non-smokable marihuana preparations, which children may accidentally consume. Another commenter noted the immediate effect of smoking marihuana versus taking it in a pill form.

**RESPONSE:** Pursuant to PHL § 3360, smoking is not included as a certified medical use. PHL § 3362 requires that medical marihuana be kept in the original, child resistant packaging in which it was dispensed and may only be removed for immediate consumption. Patients desiring fast onset dosage forms are encouraged to work with their practitioner and dispensing facility pharmacist to find a product that best meets their needs. Sublingual administration and vaporization, which are approved dosage forms, may provide faster onset, shorter acting relief than dosage forms taken orally. Different dispensing facilities may carry different dosage forms,
and patients have the freedom to choose which dispensing facility they visit. No changes have been made to the proposed regulations as a result of this comment.

**COMMENT:** A commenter asked whether there will be a maximum allowable weight of dried flower product that can be possessed.

**RESPONSE:** Pursuant to PHL § 3362, a patient may obtain up to a 30-day supply of medical marihuana, based on the dosage recommended by the certifying practitioner. Section 1004.11(c)(3) of the proposed regulations provides that each brand shall have a maximum of 10mg total THC per dose. Products at registered organization’s dispensing facilities are dispensed based on practitioner recommendations and are not labeled by weight, but by milligrams of THC and CBD per metered dosage unit.

**COMMENT:** A commenter wrote in support of the proposed regulations at Section 1004.11(c)(2)(x) and asked why the smaller dosing is now going to be held to significantly lower standards than more substantial dosing.

**RESPONSE:** At dosages of 5mg, 0.5mg represents the 10% variation that is allowed by the proposed language in Section 1004.11(c)(3). However, at less than 4mg, small variations in the amount of THC or CBD in a product result in a proportionally larger percentage variation. Therefore, using a percentage variation is not appropriate where the variation in actual content is so small. No changes to the proposed regulations were made as a result of this comment.

**COMMENT:** A commenter asked whether there will be an acceptable deviation range with regard to testing for plant material.
RESPONSE: Pursuant to Section 1004.11(c)(3) of the proposed regulations, final medical marihuana product shall not contain less than 90 percent or more than 110 percent of the concentration of total THC or total CBD indicated on the label for the brand. Section 1004.11(c)(3)(i)-(ii) further specify that the allowable variances for THC and CBD concentrations less than 5mg per dose must be within 0.5mg per dose. No changes to the proposed regulations were made as a result of this comment.

COMMENT: A commenter asked whether the Department will consider permitting topical products with greater than 10mg THC, considering that the products will not be ingested. The commenter asked whether the 10mg maximum dosing for THC applies to topical applications if the active ingredients do not enter the bloodstream.

RESPONSE: Section 1004.11(c)(3) provides that each brand shall have a maximum of 10mg total THC per dose, and this requirement applies to topical applications. Registered organizations will need to indicate grams of active ingredient (i.e. THC) per single application, and the size or inches of the single application. No changes were made to the proposed regulations as a result of this comment.

COMMENT: Commenters wrote in support of proposed changes to Section 1004.11(e)(3) regarding the pesticides that a registered organization may use. Commenters also recommended that product labels disclose any pesticides used, as well as other information pertaining to the laboratory testing conducted on the product.

RESPONSE: The Department works closely with the New York State Department of Environmental Conservation when reviewing pesticide use on medical marihuana plants. Registered organizations are required to document pesticide use and are subject to on-site
inspections by the Department. Pursuant to PHL § 3364(10), registered organizations must provide documentation of the quality, safety and clinical strength of medical marihuana to any person to which it is sold or dispensed. Patients should inquire with registered organizations about what, if any, pesticides they use on their plants. No changes have been made to the proposed regulations as a result of these comments.

COMMENT: A commenter wrote in support of Section 1004.11(l)(1)-(2), which establishes the procedures for products failing to meet minimum standards. The commenter suggested that registered organizations be allowed to reuse any non-compliant lot of medical marihuana for other purposes, including research and development or reprocessing to achieve compliance.

RESPONSE: Section 1004.11(l)(2) of the proposed regulation allows registered organizations to request approval to dispense products not meeting minimum standards or specifications for brand consistency. However, this is only applicable if the lot has met the minimum standards or specifications for safety referred to in Section 1004.11(l)(1). Lots that do not meet the minimum standards or specifications for safety could potentially pose a threat to public health and safety and must be destroyed by the registered organization. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A commenter asked whether the registered organization cultivation manager is required to maintain a climate monitoring log once the chain of custody of the ground plant material is transferred to manufacturing.

RESPONSE: Section 1004.11(e)(7) of the proposed regulations requires “continual environmental monitoring for temperature, ventilation and humidity at all locations in the manufacturing facility where unprocessed leaf and flower material is stored, until further
extraction or other processing is completed.” Section 1004.10(a)(8)(ii) of the regulations requires registered organizations to maintain cultivation and manufacturing records, including a climate monitoring log. Registered organizations may determine which of their employees will maintain these records. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A commenter opposed allowing registered organizations to produce medical marihuana products in new forms, stating that as there is no evidence that new forms are needed for the conditions for which medical marihuana may be recommended.

RESPONSE: Additional forms of medical marihuana products may make administration of the product easier for patients with serious conditions, and for pediatric patients who may have difficulty consuming certain dosage forms. In addition, additional forms may provide lower cost alternatives to patients. No changes have been made to the proposed regulations as a result of this comment.

COMMENT: A commenter expressed concern with Sections 1004.11(m) and 1004.14(h), regarding product stability testing. The commenter suggested that "in-use" stability testing should be conducted on a representative batch or lot product sample for each product, rather than on each extract lot. The commenter stated that, if the batch composition and process does not change from the approved formulation and stability is demonstrated on a representative sample, testing of every lot should not be required. The commenter asserted that there is no scientific rationale for testing every lot manufactured and that this policy is burdensome.

RESPONSE: The Department will take these comments under advisement. The Department anticipates issuing guidance to the registered organizations to help clarify the regulatory
requirements with regard to stability testing. No changes were made to the proposed regulations as a result of these comments.

**COMMENT:** A commenter stated that Section 1004.11(g) appears to be inconsistent because it permits liquids, chewables and lozenges but prohibits food products.

**RESPONSE:** Registered organizations may manufacture these specific dosage forms, but are prohibited from incorporating medical marihuana into other food products without approval of the commissioner. No changes have been made to the proposed regulations as a result of this comment.

**COMMENT:** A commenter asked what devices the Department will allow for administering metered ground plant preparations.

**RESPONSE:** Neither the Compassionate Care Act nor the Department’s regulations require devices for administering medical marihuana to be approved by the Department. However, packaging and labeling of all medical marihuana brands and forms must meet the requirements set forth in the regulations.

**COMMENT:** A commenter expressed concerns with metered ground plant material as an allowable form of medical marihuana. The commenter’s concerns included: an accelerated rate of decomposition; a lack of medically acceptable containers for administering such material; practitioners not being familiar with how to dose plant material; a lack of product stability; an increased propensity for abuse and diversion; and that it would detract from the current high standards of the program.
RESPONSE: The proposed regulation does not eliminate any of the currently available medical marihuana products derived from chemicals extracted from plant material. In addition, the same standards apply to registered organizations that choose to manufacture metered ground plant material products as apply to any other approved dosage form. These standards include researching appropriate containers and packaging, conducting internal stability testing to determine expiration dating of both opened and unopened packaging, and educating pharmacists and patients on proper handling and use of this new dosage form. Further, Section 1004.11(c)(7) requires registered organizations to ensure the availability of at least a one-year supply of any offered brand, unless otherwise allowed by the Department. Section 1004.11(m) requires registered organizations to demonstrate the stability of each approved medical marihuana product produced by testing at an approved laboratory. Registered patients with concerns about this product form should work with their practitioners and dispensing facility pharmacists to find an alternate product form that most appropriately meets their needs. The Department will continue its outreach to federal, State and local agencies to increase awareness about the availability of this product form. No changes to the proposed regulation were made as a result of these comments.

§ 1004.12 Requirements for dispensing facilities.

COMMENT: Comments were received regarding the proposed language in Section 1004.12(a), which requires that where medical marihuana products are dispensed or handled at a dispensing facility, a licensed pharmacist must be on the premises and supervise the activity. Commenters suggested that the regulations should allow pharmacists to provide consults through telemedicine or video chat, and should allow other trained employees to supervise the dispensing or handling
of medical marihuana. Commenters also expressed concern that the regulations may unnecessarily burden dispensing facilities and increase costs to patients.

**RESPONSE:** The intent of this amendment is to remove the requirement that a pharmacist be on the premises of a dispensing facility at all times that the facility is open, while maintaining the security of medical marihuana products under the supervision of a licensed pharmacist. Certified patients that have one or more serious condition often take several different medications. Although other employees may have specialized training related to marihuana, licensed pharmacists have the training and skills necessary to identify any drug interactions that patients may experience. No changes have been made to the proposed regulations as a result of these comments.

**COMMENT:** A commenter wrote in support of Section 1004.12(b) of the proposed regulation and asked for clarification as to what items constitute the promotion of “health and well-being.” The commenter further asked whether such items include dietary supplements, books, fitness supplies and inspirational products such as greeting cards. The commenter asked whether every item for sale would require prior approval of the Department, or if the Department would only reserve the right to disapprove items.

**RESPONSE:** In general, registered organizations will be able to decide what items they believe meet the criteria set out in Section 1004.12(b) and offer such items for sale. However, the Department reserves the right to disapprove items that the Department determines do not promote health and well-being, that may contribute to product diversion, theft or loss, or that risk contamination to approved medical marihuana products. Registered organizations should consult with the Department if they have any questions about the appropriateness of a particular item.
COMMENT: Multiple commenters wrote in support of allowing patients to consume food and water in dispensing facilities.

RESPONSE: The comments supporting this amendment have been noted.

COMMENT: A commenter stated that the proposed change to Section 1004.12(j) should be eliminated because it would require patients to purchase their 30-day supply in no more than two transactions. The commenter stated that this is unnecessarily burdensome to patients and restricts patients’ ability to split up their 30-day supply between a number of dispensaries to efficiently find out what product works best for them.

RESPONSE: Section 1004.12(j) of the current regulations, and Section 1004.12(i) of the proposed regulations, requires dispensing facilities to ensure that each patient that purchases product receives their product from no more than two distinct lots for any 30-day supply dispensed. The regulations seek to ensure the Department’s ability to trace a specific lot, in the event of a product recall or adverse event. Nothing in the proposed regulations prohibits a patient from making multiple trips to a dispensing facility to obtain product within a 30-day timeframe. Likewise, nothing in the proposed regulations prohibits a patient from visiting multiple registered organization dispensing facilities within a 30-day timeframe. The applicable limitation is PHL § 3362(1)(a), which prohibits a certified patient from possessing more than a 30-day supply of medical marihuana based on the patient’s dosage, as determined by the certifying practitioner. No changes to the proposed regulation were made as a result of these comments.
COMMENT: Several comments were received in support of the proposed regulations pertaining to visitors in dispensing facilities. Commenters noted that the proposed language will be particularly helpful for patients who need to bring their children with them to dispensing facilities. Commenters also stated that the changes will allow prospective patients to learn about medical marihuana products and that the changes will help reduce the stigma associated with going to a dispensing facility.

RESPONSE: The comments supporting this amendment have been noted.

COMMENT: A commenter asked whether the proposed amendment to Section 1004.12(g)(1) means that any registered organization employee is allowed in the dispensing facility storage and security areas.

RESPONSE: No. Section 1004.13(i) of the proposed regulations states that all marihuana “must be stored in a secure area or location within the registered organization accessible to the minimum number of employees essential for efficient operation and in such a manner as approved by the department in advance, to prevent diversion, theft or loss.” Section 1004.13(d) of the current regulations states that 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.” Further, registered organizations are required to make available to the Department, upon request, a list of authorized employees who have access to any surveillance room. No changes to the proposed regulation were made as a result of this comment.
COMMENT: A commenter expressed concern that referencing the Prescription Monitoring Program (PMP) Registry seems to suggest that medical marihuana is a prescribed medicine, though in actuality it is only recommended to patients with qualifying serious conditions. The commenter further stated that having a New York State-licensed pharmacist on site at a dispensing facility seems to suggest that a pharmacy is dispensing the medical marihuana, and that this normalizes marihuana by implying that it is a prescribed drug.

RESPONSE: The law is clear that medical marihuana is not “prescribed”; rather, it may be dispensed to a certified patient or designated caregiver with a valid registry identification card. Further, pursuant to PHL § 3364(5)(b), all registered organizations must consult the PMP Registry prior to dispensing medical marihuana to a certified patient. Accordingly, the regulations require dispensing facilities to submit dispensing data to the PMP Registry. No changes to the proposed regulation were made as a result of these comments.

§ 1004.13 Security requirements for manufacturing and dispensing facilities.

COMMENT: Many commenters expressed support for proposed changes to sections 1004.13(a), 1004.13(a)(8) and 1004.13(g). The commenters stated that the proposed changes to the security requirements will ease the burden on registered organizations while preserving a commitment to security. Commenters suggested the Department continue to look for other ways to make the manufacturing and dispensing processes easier for registered organizations and less costly because overly onerous requirements drive up costs to patients.

RESPONSE: The comments supporting this amendment have been noted. The Department will continue its efforts to support the Medical Marihuana Program while protecting health and safety.
**COMMENT:** A comment was received in support of Section 1004.13(j), stating that allowing marihuana to be stored in a secure way other than a safe or vault will reduce costs while preserving security. The commenter encouraged the Department to allow an open floor plan where patients can view the different products.

**RESPONSE:** Nothing in the PHL or Part 1004 prevents a registered organization’s dispensing facility from having an open floor plan. Some registered organizations currently use “display products” which do not contain any medical marihuana but assist in counseling a patient on the appropriate use of a product or device. No changes to the proposed regulation were made as a result of this comment.

**COMMENT:** A commenter expressed support for the proposed changes to Sections 1004.13(n)-(p), which remove the requirement that registered organizations only transport approved medical marihuana products from a manufacturing facility to a dispensing facility. The commenter also suggested that the Department be more explicit in its authorization of home delivery services by placing express language in the regulations or in the impact statement.

**RESPONSE:** The Department provided home delivery service guidance to the registered organizations in late 2016. Since that time, home delivery transactions have been occurring in accordance with the guidance. Additional regulatory amendments are not necessary to authorize registered organizations to provide home delivery services. No changes were made to the regulations as a result of this comment.

**COMMENT:** A commenter suggested amending Section 1004.13(r) to allow for the transport of medical marihuana without the need for two registered organization employees. The commenter stated that this requirement unnecessarily drives up costs to patients and is
incongruent with the treatment of other medications. The commenter stated that registered organizations should be allowed to hire third-party contractors to transport medical marihuana and only one person should be required for transport.

**RESPONSE:** PHL § 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. To ensure security and accountability, employees must be used for the provision of services directly related to these activities, and a registered organization may not contract out for these services. No changes were made to the proposed regulation as a result of this comment.

**COMMENT:** Several commenters opposed the loosening of any security requirements for manufacturing and dispensing facilities. Commenters stated that the Department has done an admirable job of minimizing diversion and illegal distribution of medical marihuana and any loosening of security procedures could result in increased illegal activity, availability of marihuana and product contamination.

**RESPONSE:** The Department has a continued interest in ensuring that all aspects of the Medical Marihuana Program serve to maintain the health and safety of patients, while preserving the safety and security of registered organizations and the general public. The proposed regulations seek to balance the need for stringent security requirements while allowing registered organizations to conduct their business operations. No changes to the proposed regulations have been made as a result of these comments.
§ 1004.16 Medical Marihuana marketing and advertising by registered organizations.

COMMENT: A commenter questioned the need for marketing and advertising if a certified patient can get medical marihuana products only at a dispensing facility. The commenter stated that marketing should not occur in the following locations: public media, radio, TV, billboards, near schools, churches, day care, parks and family gathering spots.

RESPONSE: Although a patient can purchase approved medical marihuana products only at a registered organization’s dispensing facility, patients have a choice when deciding which dispensing facility to visit. Marketing and advertising can inform patients of the types of products available and of any discount programs or delivery services offered. No changes to the proposed regulations were made as a result of these comments.

COMMENT: Several commenters opposed the removal of the requirement that only a single black and white sign be allowed on the external structures of a registered organization and the removal of the restriction that external signs not be illuminated. Commenters noted that patients seeking to purchase medical marihuana know the address of the registered organization and do not need to help finding them. A commenter also stated that lighting and bold colors may make medical marihuana products more attractive to youth.

RESPONSE: Allowing registered organizations to have illuminated external color signage will help patients to locate dispensing facilities. Only a certified patient or his or her designated caregiver, with a valid registry identification card, may purchase approved medical marihuana products from a dispensing facility. Additionally, patients under the age of eighteen are required to have a designated caregiver. No changes to the proposed regulations were made as a result of these comments.
**COMMENT:** Commenters asked what, if any, limitations there are on a registered organization’s ability to educate practitioners pursuant to the proposed language in Section 1004.16(m). Specifically, a commenter asked whether registered organizations can discuss how marihuana affects the body with practitioners, or whether registered organizations are limited to discussing only their specific products. Another commenter asked whether there are any limitations on how the education is conducted (e.g. through a website, videos, one-pagers, presentations at dispensing facilities, etc.).

**RESPONSE:** The proposed amendments to Section 1004.16(m) allow registered organizations to educate practitioners about approved medical marihuana products without the education being considered “steering or influencing patient or caregiver choice with regard to selection of an approved medical marihuana product.” This regulatory amendment allows for general discussions of marihuana and its benefits and effects. Educational delivery is not limited to any specific format. No changes to the proposed regulation were made as a result of this comment.

**COMMENT:** Several commenters opposed the proposed amendments to Section 1004.16(m). Commenters noted the possibility that allowing registered organizations to educate health care providers could result in misinformation and the over-recommendation of medical marihuana, with harmful individual and societal consequences. Commenters also suggested that practitioners should learn about medical marihuana from the required State-mandated practitioner education course, peer reviewed medical journals, and presentations at professional conferences.

**RESPONSE:** Marketing and advertising can help practitioners understand the types of products and dosage forms available, before deciding on which products to recommend to a patient. Section 1004.16(d) requires that any advertisements for approved medical marihuana products
that make statements related to effectiveness, side effects, consequences or contraindications must be true and accurate. Additionally, Section 1004.16(i) requires Department review and approval of all advertisements that make claims or statements regarding efficacy. No changes to the proposed regulations were made as a result of these comments.

**COMMENT:** A commenter requested that additional information be disseminated about the program via advertising on TV, billboards, through local seminars for patients and doctors.

**RESPONSE:** These comments are outside the scope of the proposed regulations. No changes to the proposed regulations were made as a result of this comment.

§ 1004.21 General prohibitions.

**COMMENT:** Several commenters opposed allowing physicians, nurse practitioners, and physician assistants employed by registered organizations to counsel certified patients and designated caregivers on medical marihuana products, administration and risks. Commenters stated that this is a conflict of interest because the practitioners are employed by the registered organization. Commenters suggested that only the certifying practitioner, who is familiar with the patient’s full medical condition and history, should counsel patients and designated caregivers. One commenter suggested that counseling should be performed by substance abuse professionals. Another commenter asserted that the warning labels on dispensed medical marihuana products may be inadequate and that a consultation between registered organization staff and patients is insufficient.

**RESPONSE:** The proposed language in Section 1004.21(d) allows a pharmacist, physician, nurse practitioner, or physician assistant employed by the registered organization to counsel a patient or supervise the counseling of a patient within the dispensing facility. Under the current
regulation, only pharmacists are permitted to counsel or supervise the counseling of patients within the dispensing facility. Expanding the types of practitioners authorized to conduct this activity will help patients receive information concerning the appropriate use, administration, warnings and precautions associated with approved medical marihuana products. PHL § 3364(6) requires registered organizations to provide patients with a Department-approved safety insert whenever medical marihuana products are dispensed. The safety insert includes information on the potential risks associated with marihuana, recognition of problematic usage and information on services or treatment for problematic usage. No changes to the proposed regulations were made as a result of these comments.

Miscellaneous Comments

COMMENT: Several commenters wrote regarding the cost of getting certified by a practitioner and purchasing approved medical marihuana products. Comments included:

- Insurance companies should cover the cost of medical marihuana to improve access to the medication.
- There is wide variation in the cost of practitioner visits and the costs of products across dispensing facilities.
- The prices in New York State are very high compared to other states and that whole flower products for vaporization would help reduce costs.
- Financial assistance should be provided so that medical marihuana products are not prohibitively expensive.

RESPONSE: These comments address issues beyond the scope of the regulatory amendments. No changes to the proposed regulations were made as a result of these comments.
COMMENT: Comments were received requesting that patients be allowed to grow their own marihuana at home.

RESPONSE: PHL § 3364 limits the manufacture of medical marihuana to registered organizations. No changes to the proposed regulations were made as a result of this comment.

COMMENT: Comments were received concerning the length of time it takes for patients and caregivers to receive registry identification cards. Commenters stated that registry identification cards take too long to receive and that processing should be expedited.

RESPONSE: The Department continues to work on enhancements to the registration process to help expedite the time it takes for certified patients and designated caregivers to received their registry identification cards.

COMMENT: Comments were received suggesting that New York State should make its Medical Marihuana Program more like that of Colorado. Commenters advised that they would like the New York State program to legalize marihuana, lower taxes, and allow patients to use hemp oil as well as marihuana oil to treat conditions.

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

COMMENT: Numerous commenters shared the struggles they, or their family members, have experienced when trying to obtain medical marihuana. Many expressed hope that increased access to dispensing facilities, practitioners and products would come from the proposed regulatory package.
RESPONSE: The Department notes these concerns and expects that these regulatory amendments will expand access to medical marihuana. No changes to the proposed regulations were made as a result of these comments.

COMMENT: Multiple comments were received expressing concern about the use of medical marihuana and potentially legalizing recreational marihuana. Commenters expressed concern about the risk of addiction, particularly for teenagers, and about the perception that there is no harm in using marihuana. Commenters mentioned Marinol as an alternative option and stated that efforts should be placed into removing THC from products, because CBD contains the majority of marihuana’s medical properties. One commenter stated that recent studies show that protracted use of crude marihuana can lead to physiological dependence and serious damage to vital organ systems, and that marihuana has been linked to elevated rates of myocardial infarction, cardiac arrhythmias, cancers, and neuro-psychiatric disorders. The commenter suggested that the Department and legislators convene public hearings with medical experts to examine the health benefits of marihuana and its side effects.

RESPONSE: The regulatory amendments do not legalize marihuana for recreational use. The Compassionate Care Act and Department regulations are designed to protect health and safety while providing an alternative treatment option to patients suffering from severe debilitating or life-threatening conditions. In particular, PHL § 3364(6) requires registered organizations to provide patients with a Department-approved safety insert when medical marihuana products are dispensed that includes, but is not limited to, information on the method of administration, any potential risks, recognition of problematic usage and information on services or treatment for problematic usage. PHL § 3364(3) also requires an independent laboratory to test the medical marihuana produced by the registered organization. Section 1004.14 of the regulations requires
concentration testing, as well as contaminant testing, and Section 1004.11 provide numerous requirements for the manufacture and labeling of approved medical marihuana products by registered organizations. No changes to the proposed regulations were made as a result of these comments.

**COMMENT:** Comments were received requesting that home delivery be authorized in specific locations.

**RESPONSE:** Registered organizations are permitted to provide home delivery services. Patients interested in home delivery should contact the registered organizations to determine if they fall within a serviced area. No changes to the proposed regulations were made as a result of this comment.

**COMMENT:** A commenter asked what is being done to educate medical students studying in New York State on the medical benefits of marihuana.

**RESPONSE:** Although the Department is not engaged in any efforts that specifically target medical students, the Department encourages all medical students and physicians to take the practitioner education course. No changes to the proposed regulations were made as a result of this comment.

**COMMENT:** A commenter stated that the Department should provide guidance to residential facilities, including private and state-run facilities, OPWDD facilities, nursing homes and adult homes, because many of the residents in those facilities may be eligible for certification to use medical marihuana. The commenter expressed concern that many facilities do not allow medical marihuana use on site, refuse to allow staff to handle or assist patients with medical marihuana,
do not allow staff to administer medical marihuana to patients who cannot self-administer, and have concerns about storage or security. The commenter noted that these concerns often prevent patients living in these facilities from accessing medical marihuana.

**RESPONSE:** On October 5, 2017, the Department filed emergency regulations that give facilities, as defined in the emergency regulation, the ability to be a patient’s designated caregiver, thereby enabling such facilities to register with the program and assist the patient with the possession, acquisition, delivery, transfer, transportation, and administration of approved medical marihuana products. No changes to the proposed regulations were made as a result of this comment.

**COMMENT:** Several commenters expressed that they had difficulty travelling to dispensing facilities or that the nearest dispensing facility was too far away.

**RESPONSE:** The Department recently doubled the number of registered organizations from five to ten, to make it easier for patients across the state to access medical marihuana. In addition, the Department has authorized registered organizations to offer home delivery services. No changes to the proposed regulations were made as a result of this comment.

**COMMENT:** A commenter stated that, given the federal government’s position with respect to marihuana and the difficulties in conducting clinical trials, the Department should collect data about medical marihuana, including enrollment statistics and retention rates. The commenter also suggested implementing a public use data set and recordkeeping systems, to assist the Department in evaluating and facilitating improvements to the Medical Marihuana Program.

**RESPONSE:** This comment is beyond the scope of the regulatory amendments. No changes to the proposed regulations were made as a result of this comment.
COMMENT: Numerous medical marihuana patients and healthcare providers submitted comments describing their success stories regarding the use of medical marihuana.

RESPONSE: The comments supporting New York State’s Medical Marihuana Program have been noted.