

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 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 the

department of adverse events and other incidents within 24 hours and must inventory and maintain records of medical marijuana 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 marijuana 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 marijuana products in new forms of administration. Section 1004.11(h) is amended to allow registered organizations to break the seal of an approved medical marijuana 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 marijuana 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 marijuana 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 marijuana 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 marijuana product by a qualifying patient subject to completion of subpart (e) of this section. Such certification shall contain:

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(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 marijuana 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.

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(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.

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(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.

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(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.

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(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;] of the following:

(i) any adverse events;

(ii) any incident involving theft, loss or possible diversion of medical marihuana 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 marihuana 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:

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(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.

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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:

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(x) Any other cannabinoid component at $> 0.[1]2$ percent, for which there is a certified standard available at a customary cost.

(3) The final medical marihuana product shall not contain less than [95] 90 percent or more than [105] 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:

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(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:

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(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.

* * *

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

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

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(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)f] [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 marijuana 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.

(j)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.

(k)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:

* * *

(l)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.

* * *

(m)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.];

(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]the 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 marijuana product are adequately assessed for contaminants and the cannabinoid profile is consistent throughout.

* * *

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

Analyte:

E. coli

[Klebsiella]

Pseudomonas 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 Actinomyces species

[Aflatoxin] Aflatoxins 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.

([h]i) 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.

(j) 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 [Agency license] 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

* * *