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 read as follows, to be effective upon publication of a Notice of Adoption in the New York State Register.

§ 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(c) 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(e) is amended to clarify that a registered organization's registration may be amended instead of the application for registration.

* * *

§ **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 one year. 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 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 (5) years and to require registered organizations to post the 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 and to include a requirement that registered organizations not steer or influence any individual to a practitioner for the purpose of becoming a certified patient.

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

Section 1004.11(a) is amended to update the allowable range of THC and CBD concentration per dose and brand for potency testing purposes. Section 1004.11(c) is modified to clarify reporting requirements for other cannabinoid components at >0.2 percent. Section 1004.11(c) is also amended to update the allowable range of THC and CBD concentration per dose and brand for potency testing purposes. Section 1004.11(e) 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 products in new forms including tablets, film strips, metered dose inhalation, and rectal administration. Section 1004.11(h) is amended to allow registered organizations to break the seal of an approved medical marihuana product for the purpose of internal quality control testing or disposal. Section 1004.11(l) is amended to require registered organizations to report to the department any lot not meeting the minimum standards or specifications for brand consistency, rather than destroying such lots. 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 the registered organization in any of its medical marihuana products.

§ **1004.12 Requirements for dispensing facilities.** Section 1004.12(a) is revised to clarify the requirement that dispensing facility pharmacists must complete a four hour course. Section 1004.12(d) is amended to clarify that no food or beverages may be sold on the premises of a dispensing facility without prior approval from the department. Section 1004.12(f) is amended to include a requirement that dispensing facility pharmacists or a designated individual shall consult the Prescription Monitoring Program (PMP) Registry prior to dispensing approved medical marihuana products. Section 1004.12(g) is amended to clarify dispensing facility access restrictions. Section 1004.12(h) is revised to clarify that labels shall include the expiration date of the product once opened on all products. Section 1004.12(m) is modified to include a requirement that dispensing facilities must document returns of approved medical marihuana products and ensure secure storage until disposal.

§ 1004.13 Security requirements for manufacturing and dispensing facilities. Section 1004.13(a) is revised to clarify that production and harvesting is included in the definition of manufacturing and a video surveillance requirement is also added to the disposal process. Section 1004.13(a) is amended to allow registered organizations to use a digital dialer or other acceptable industry standard equivalent. Section 1004.13(j) is amended to clarify that registered organizations must use approved safes, vaults or other storage methods approved by the department for medical marihuana products. 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. Section 1004.13(u) is added to restrict visitor access to manufacturing 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 include a disposal requirement for laboratories. Section 1004.14(i) is added to include stability testing guidance for open and unopened products. 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.

* * *

§ **1004.16 Medical Marihuana marketing and advertising by registered organizations.** Section 1004.16(a) is modified to remove the requirement that only signs with black and white colors may be allowed on the external structures owned by registered organizations. Sections 1004.16(a), (d), (h) and (i) are further modified to clarify the difference between a brand and an approved medical marihuana product. 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.

* * *

§ **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 product(s) 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 and nurse practitioners employed by registered organizations to counsel certified patients or designated caregivers at a registered organization's dispensing facility on medical marihuana product use, administration and risks.

* * *

§ 1004.24 Inventory Requirements for registered organizations. Section 1004.24 is added to define inventory requirements for registered organizations.

§ **1004.25 Registered Organizations disposal of medical marihuana.** Section 1004.25 is added to provide guidance on acceptable processes for disposing of medical marihuana products and by-products.

* * *

§ 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:

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 <u>subject to completion of subdivision (e) of this section</u>. Such certification shall contain:

* * *

(14) to the extent that a practitioner is seeking to authorize the use of an approved medical marihuana product by a patient who is under the age of eighteen or a person who is otherwise incapable of consenting to medical treatment, the practitioner shall explain the potential risks and benefits of medical marihuana to the patient's parent or legal guardian, and if appropriate, to the minor patient. The practitioner shall document in the patient's medical record that such explanation has been provided as required herein; [and]

(15) a statement that the patient, or the patient's parent or legal guardian if applicable, has provided informed consent[, if required by law.]<u>; and</u>

(16) to the extent that a practitioner is seeking to authorize the use of an approved medical marihuana product by a patient who is temporarily residing in New York State for the purpose of receiving care and treatment from the practitioner, the practitioner shall indicate such in 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 Article 33 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 Article 33 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 33 of the Public Health Law and this part, and is temporarily residing in New York State for the purpose of receiving care and treatment from a practitioner registered with the department.

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

(i) a copy of a state or government issued identification card that contains the applicant's name and permanent address. If the applicant is under the age of 18, the parent or legal guardian applying on behalf of the applicant shall submit a copy of the parent or legal guardian's state or government issued identification and a copy of the applicant's birth certificate; and

(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 18, 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;

Subdivision (e) of section 1004.6 is amended to read as follows:

(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 10 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 that 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 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 direct the registered organization to implement an alternate plan provided 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 times and shall be retained by the registered organization for at least [two years] one year following the date of expiration.

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

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

Within ten days of the occurrence of one of the above events, registered organizations 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.

* * *

(7) dispose of unusable medical marihuana products that have failed laboratory testing or any marihuana used in the manufacturing process [as per the registered organization's approved operating plan] pursuant to section 1004.25 of this Part.

(8) 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:

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

* * *

(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[.]<u>;</u>

<u>(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:</u>

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

<u>(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; or</u>

* * *

<u>(9) steer or influence any individual with regard to the selection of a practitioner or group of practitioners for the purpose of becoming a certified patient.</u>

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 percent 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:

* * *

(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 > [0.1]0.2 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 [a maximum of] no more than 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;

(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 6 NYCRR 325.2(b);

* * *

(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:

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

(2) metered liquid or oil preparations for metered dose inhalation or vaporization;

(3) capsules, tablets or film strips for oral administration; or

* * *

(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 502 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 1004.25 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 medical marihuana product] opened 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 products shall be determined [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 the registered organization in its approved manufacturing facility shall be used in the production of any medical marihuana product.

Subdivisions (a), (d), (f), (g), (h) and (m) of section 1004.12 are amended to read as follows:

(a) Dispensing facilities shall not be open or in operation unless an individual with an active New York State pharmacist license, as defined in article 137 of the Education Law, who has completed a 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.

* * *

(d) No food or beverages shall be [consumed by certified patients or designated caregivers] sold on the premises of a dispensing facility[, unless necessary for medical reasons] without prior written approval of the department.

* * *

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

* * *

(4) ensure the dispensing facility pharmacist, or an individual employed by a registered organization and designated by the pharmacist, consults the prescription monitoring program registry pursuant to section 3343-a and section 3364 of Article 33 of the Public Health Law prior to any sales transactions and dispensing of any approved medical marihuana products by the facility, to verify the certified patient will not possess an amount greater than that allowed for in section 3362 of Article 33 of the Public Health Law, due to prior transactions at that or any other dispensing facility.

* * *

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

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

(2) [Upon prior written request of a registered organization, 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.] certified patients and designated caregivers possessing a valid registry identification card issued by the department;

(3) employees of the department or its authorized representatives;

(4) emergency personnel responding to an emergency or unforeseen circumstance related to immediate patient care; and

(5) any other person(s) visiting the facility shall require the prior written approval of the department as requested by the registered organization, except persons authorized by a manager of the registered organization to be on the premises of the facility for the sole purpose of maintaining the operations of the facility shall not require the prior written approval of the department. For all persons authorized by this paragraph to enter a facility, a registered organization shall:

(i) [The dispensing facility shall maintain a visitor log, which shall include the name of the visitor, date, time and purpose of the visit. The visitor log shall be available to the department at

all times during operating hours and upon request.] provide a visitor identification badge to the authorized visitor, which must be visible at all times and returned upon exiting the facility;

(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.] escort and monitor authorized visitors at all times while visitors are in the facility;

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

* * *

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

* * *

(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.

* * *

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

(1) dispose of such product pursuant to section 1004.25 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), (j), (n), (o) and (p) of section 1004.13 are amended and new subdivision (u) is added 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;

* * *

(j) All medical marihuana, except unprocessed leaf and flower products, [approved or ready for testing,] including those awaiting testing, must be stored in a department approved safe or vault or other storage method approved by the department, in such a manner as to prevent diversion, theft or loss. Approved safes or vaults include:

(1) those which meet the minimum security standards for non-practitioner handling of Schedule I Controlled Substance set forth in section 80.13 of this Title; or

(2) any other safe, vault or storage method approved by the department.

* * *

(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 approved by the department.

* * *

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

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

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

* * *

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

* * *

(u) Manufacturing facility access shall be restricted, pursuant to section 1004.12(g) of this Part, the same as dispensing facilities; with the exception that certified patients and designated caregivers may not access a manufacturing facility.

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) [The]For final product testing, 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 [capsule] sealed bottle of capsules). Upon prior 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) 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 totally unrecoverable and beyond reclamation.

(i) Stability testing shall be performed on opened and unopened products for each brand and form of medical marihuana product:

(1) For testing of open products, stability testing shall be of three different extract lots each tested, at a minimum, at time zero (0) when opened and then every 30 days for a minimum of 60 days total. This shall establish use of the product 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) of this Part. 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. The department may waive any of the requirements of this subsection upon good cause shown;

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

([4]3) 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] a brand of medical marihuana that make a statement relating to effectiveness, side effects, consequences[, and] or contraindications shall present a true and accurate statement of such information.

* * *

(h) An advertisement for [any approved medical marihuana product] a brand of medical marihuana shall not contain:

* * *

(i) Any advertisement for [an approved medical marihuana product] a brand of medical marihuana that makes a statement relating to effectiveness, side effects, consequences, or contraindications 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 informing a practitioner about medical marihuana brands or devices 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 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.

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

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

Section 1004.24 is added to read as follows:

§1004.24 Inventory requirements for registered organizations.

(a) Upon initiating operations, registered organizations shall conduct an initial inventory. The inventory shall include all marihuana plant stock at any stage of the manufacturing process, including products awaiting disposal, and any other materials as determined by the department.

(b) Registered organizations shall maintain a real time electronic inventory utilizing a system approved by the department, which shall contain data adequately documenting the medical marihuana materials through the manufacturing, transporting, dispensing and disposal processes at any point in time, including but not limited to seeds, plants at every stage, harvested materials and every lot of medical marihuana product.

(c) In addition to the real time electronic inventory, registered organizations shall conduct a complete physical inventory to be performed by at least two registered organization employees or managers annually; which shall include but not be limited to, the quantity of marihuana plants at every stage, marihuana products, and any medical marihuana that is disposed of pursuant to section 1004.25 of this Part.

(d) Any discrepancy identified in a registered organization's real time electronic inventory or physical inventory shall be:

(1) documented and investigated by an authorized manager or employee of the registered organization; and

(2) reported to the department and to the appropriate law enforcement agencies if the discrepancy is due to suspected criminal activity, such as diversion or theft.

(e) Where a registered organization is unable to determine where the discrepancy in inventory has occurred, the registered organization shall notify the department and submit to the department a plan of corrective action.

(f) Registered organizations shall prepare a comprehensive annual report for each calendar year and deliver it to the department within 31 days of the end of the calendar year. The annual report shall include, but not be limited to, a summary of all marihuana manufactured, dispensed and disposed of for the calendar year, in a format approved by the department.

(g) Devices offered by registered organizations for the administration of medical marihuana are subject to the inventory requirements set forth in this Subpart.

(h) All inventory records shall be retained and available for inspection by the department for at least 5 years.

Section 1004.25 is added to read as follows:

§1004.25 Registered organizations; disposal of medical marihuana

(a) The disposal of medical marihuana shall mean that the medical marihuana has been rendered totally 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) The registered organization shall maintain inventory records of disposal pursuant to section 1004.24 of this Part, which shall include:

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

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

(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 inventory records of disposal shall be retained and available for inspection by the department for at least 5 years.

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

* * *

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 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 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 is temporarily residing in the State for purposes of receiving care and treatment, the patient certification shall indicate such.

2. Certified patient and designated caregiver registrations – Patients that are New York State Residents will not be required to show proof of temporary residence. Acceptable proof of residence for a caregiver includes a New York State non-driver identification card.
3. Application for initial registration as a registered organization – The requirement for the prepared financial statement upon initial application for a registered organization is clarified to indicate that a registered organization's registration may be amended and not the application for registration.
4. Registered organization requirements for manufacturing and dispensing facilities – Reporting requirements for other cannabinoid components at >0.2% are clarified. The allowable range of THC and CBD concentration per dose and brand 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 tablets, film strips, metered dose inhalers and rectal products. Registered organizations may break the seal of an approved medical marihuana product for the purpose of internal quality control testing or disposal. 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 not produced by the registered organization in any of its medical marihuana products. Dispensing facility pharmacists must complete a department approved four hour course. No food or beverages may be sold on the premises of a dispensing facility without prior approval from the department. Dispensing facility pharmacists or a

designated individual shall consult the PMP Registry prior to dispensing approved medical marihuana products. Dispensing facility access restrictions are clarified. Labels on medical marihuana products shall include the expiration date of the product once opened on all products. Dispensing facilities must document returns of approved medical marihuana products and ensure secure storage until disposal.

5. 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 one year. Registered organizations must notify the department of adverse events and other incidents within 24 hours. Registered organizations must perform inventory and maintain records of medical marihuana products or by-products which are disposed of. Records may need to be maintained for a time period other than five (5) years. Registered organizations must post the registration certificate in a conspicuous location on the premises of each manufacturing and dispensing facility. Criminal history requirements for registered organization managers or employees are clarified. Registered organizations shall not steer or influence any individual to a practitioner to become a certified patient.
6. 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 lab 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.

7. Security requirements for manufacturing and dispensing facilities – A video surveillance requirement was added to the disposal process. Registered organizations must use approved safes, vaults or other storage methods approved by the department for medical marihuana products. Registered organizations may transport approved medical marihuana products between dispensing facilities, to approved laboratories and waste management facilities. Manufacturing facility access restrictions are further clarified.
8. Medical marihuana marketing and advertising by registered organizations – The regulations clarify the terminology related to brand and approved medical marihuana products. Requirements for approved signage and marketing of registered organizations to practitioners is clarified.
9. 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 product(s) to the dispensing facility where they were purchased or any dispensing facility associated with the registered organization.
10. General prohibitions – A physician or a nurse practitioner 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.

11. Inventory requirements for registered organizations – Inventory requirements for registered organizations are defined.
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 emergency personnel and personnel performing regular maintenance will not require prior authorization by the department. The streamlined visitor access policy will still allow the department to review the names of the individuals visiting dispensing facilities and the purpose of their visits.

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 will result in reduced staffing 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 registration of nurse practitioners, 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:

No alternatives to making the proposed regulatory amendments were considered by the department.

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.

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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 marihuana products in New York State, as well as expand access to patients by authorizing nurse practitioners to register with the department. 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 45-day public comment period with the regulations that will allow for additional comments to be considered.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

Outside of major cities and metropolitan population centers, the majority of counties in New York State contain rural areas. The regulatory amendments do not propose any changes that would decrease access to dispensing facilities or practitioners in rural areas.

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

There are no new reporting, recordkeeping or other compliance requirements imposed on rural areas as a result of these amendments. No new professional services will be required of rural areas. Compliance requirements are limited to the registered organizations and practitioners registered with the department.

Costs:

There are no compliance costs to existing establishments in rural areas since no new compliance activities are imposed upon them. Compliance costs are limited to the registered organizations and practitioners registered with the department.

Minimizing Adverse Impact:

The proposed rule will apply to practitioners who wish to complete the educational requirement in order to issue certifications to patients for medical marihuana. Practitioners in rural areas of the state may complete this course, which is offered online to make the course easily accessible

to all practitioners who wish to issue certifications to patients for approved medical marihuana products.

Rural Area Participation:

The Department consulted with other state agencies, including Department of Environmental Conservation. There will be a 45-day public comment period with the regulations that will allow for additional comments to be considered regarding 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.