

**NEW YORK STATE'S
MEDICAL MARIJUANA PROGRAM:**

10 NYCRR PART 1004

10 NYCRR Part 1004 Notes

This document reflects those changes received from the NY Bill Drafting Commission through July 20, 2018

New York Codes, Rules, and Regulations > TITLE 10. DEPARTMENT OF HEALTH > CHAPTER XIII. MEDICAL USE OF MARIHUANA > PART 1004. MEDICAL USE OF MARIHUANA

Part 1004 Notes

History

Added Part 1004 on 4/15/15.

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10 NYCRR § 1004.1

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§ 1004.1 Practitioner registration

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

(1) is qualified to treat patients with one or more of the serious conditions set forth in subdivision 1004.2(a)(8) of this Part;

(2) is licensed, in good standing as a physician and practicing medicine, as defined in article 131 of the Education Law, in New York State, or is certified, in good standing as a nurse practitioner and practicing, as defined in article 139 of the Education Law, in New York State, or is licensed, in good standing as a physician assistant and practicing in New York State, as defined in article 131-B of the Education Law, under the supervision of a physician registered under this Part;

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

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

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

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

Statutory Authority

Section statutory authority:

Education Law, § T8A131. Section statutory authority: Education Law, § T8A139. Section statutory authority: Education Law, § T8A131-b

History

Added 1004.1 on 4/15/15; amended 1004.1(a)(1) on 3/22/17; amended 1004.1(a)(2) on 11/30/16; amended 1004.1(a)(2) on 3/15/17; amended 1004.1(a)(3) on 12/27/17; amended 1004.1(b) on 12/27/17.

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§ 1004.2 Practitioner issuance of certification

(a) Requirements for patient certification. A practitioner who is registered pursuant to section 1004.1 of this Part may issue a certification for the use of an approved medical marihuana product by a qualifying patient subject to the completion of subdivision (e) of this section. Such certification shall contain:

- (1) the practitioner's name, business address, telephone number and email address;
- (2) the practitioner's license number as issued by the New York State Department of Education;
- (3) the practitioner's Drug Enforcement Administration registration number;
- (4) a statement that the practitioner is licensed and in good standing in New York State and possesses an active registration with the Drug Enforcement Administration;
- (5) a statement that the practitioner is registered with the department to issue the certification;
- (6) a statement that the practitioner is caring for the patient in relation to the patient's serious condition;
- (7) the patient's name, date of birth, address, telephone number and email address if available;
- (8) the patient's diagnosis, limited solely to the specific severe debilitating or life-threatening condition(s) listed below:
 - (i) cancer;
 - (ii) positive status for human immunodeficiency virus or acquired immune deficiency syndrome, provided that the practitioner has obtained from the patient consent for disclosure of this information that meets the requirements set forth in sections twenty-seven hundred eighty and twenty-seven hundred eighty-two of the Public Health Law;
 - (iii) amyotrophic lateral sclerosis;
 - (iv) Parkinson's disease;
 - (v) multiple sclerosis;
 - (vi) damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;
 - (vii) epilepsy;
 - (viii) inflammatory bowel disease;
 - (ix) neuropathies;
 - (x) Huntington's disease;
 - (xi) any severe debilitating pain that the practitioner determines degrades health and functional capability; where the patient has contraindications, has experienced intolerable side effects, or has experienced failure of one or more previously tried therapeutic options; and where there is documented medical evidence of such pain having lasted three months or more beyond onset, or the practitioner reasonably anticipates such pain to last three months or more beyond onset; or

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(xii) any other condition added by the commissioner.

(9) The condition or symptom that is clinically associated with, or is a complication of the severe debilitating or life-threatening condition listed in paragraph (8) of this subdivision. Clinically associated conditions, symptoms or complications, as defined in subdivision seven of *section 3360 of the Public Health Law* are limited solely to:

- (i) Cachexia or wasting syndrome;
- (ii) severe or chronic pain resulting in substantial limitation of function;
- (iii) severe nausea;
- (iv) seizures;
- (v) severe or persistent muscle spasms; or
- (vi) such other conditions, symptoms or complications as added by the commissioner.

(10) a statement that by training or experience, the practitioner is qualified to treat the serious condition, which encompasses the severe debilitating or life-threatening condition listed pursuant to paragraph (8) and the clinically associated condition, symptom or complication listed pursuant to paragraph (9) of this subdivision;

(11) a statement that in the practitioner's professional opinion and review of past treatments, the patient is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical marihuana for the serious condition;

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

- (i) the authorized brand, authorized form, administration method, dosage and any limitations in the use of the approved medical marihuana product; and
- (ii) the total amount of usable approved medical marihuana product that may be dispensed to the patient, in measurable controlled doses, which shall not exceed a thirty (30) day supply, if used as directed;

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

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

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

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

(b) Expiration of certification.

(1) The certification shall state the date upon which the certification shall expire, which shall be no longer than one year after the date it was issued, unless the patient is terminally ill.

(2) If the practitioner issues a certification to a patient who is terminally ill, the certification shall not expire until the patient's death or the practitioner revokes the certification.

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(3) If the practitioner issues a certification to a patient who is not a resident of New York but is receiving care and treatment in this state, the certification shall be valid for a period of time which is no longer than the applicant is reasonably anticipated to be residing in New York State for the purposes of care and treatment, but in no event shall it be valid for more than one year after the date it was issued.

(c) Submission of Certification to the Department. Practitioners shall utilize a form, which may be in an electronic format, developed by the department for the certification required in subdivision (a) of this section. The practitioner shall submit to the department, the information required by subdivision (a) of this section, in a manner determined by the department, including by electronic transmission through a secure website. In the instance that a practitioner submits this information to the department electronically, the practitioner shall retain, for a period of 5 years, a printed copy of the electronic certification that shall contain the information required in subdivision (a).

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

(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.

Statutory Authority

Section statutory authority:

Public Health Law, § 3360. Section statutory authority: *Public Health Law, § 2780.* Section statutory authority: *Public Health Law, § 2782.* Section statutory authority: *Public Health Law, § 3343-A*

History

Added 1004.2 on 4/15/15; added 1004.2(a)(opening paragraph) on 12/27/17; amended 1004.2(a)(8) on 3/22/17; amended 1004.2(a)(15) on 12/27/17; added 1004.2(a)(16) on 12/27/17; added 1004.2(e) on 12/27/17.

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§ 1004.3 Application for registration as a certified patient

(a) A person applying for issuance or renewal of a registration as a certified patient shall:

- (1) be a resident of New York State, or be receiving care and treatment in New York State; and
- (2) possess a certification issued by a registered practitioner.

(b) New York State residents. An applicant shall demonstrate his or her New York State residency by submitting to the department a copy of information concerning his or her New York State Driver's License or New York State Identification Card. If the applicant does not possess or cannot obtain a valid New York State Driver's License or New York State Identification Card, the applicant shall submit a copy of one or more of the following forms of documentation to establish that he or she is a New York resident:

- (1) a copy of a government-issued identification card that contains the applicant's name and New York State address. If the applicant is under the age of eighteen, the parent or legal guardian applying on behalf of the applicant shall submit a copy of the parent or legal guardian's state or government issued identification and a copy of the applicant's birth certificate;
- (2) a copy of a utility bill or other document indicating an applicant's residency issued within the previous two months that contains the applicant's name and address;
- (3) a copy of a current lease or similar document indicating an applicant's residency within New York State; or
- (4) such other documentation as approved by the department containing sufficient information to show proof of 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 eighteen, the parent or legal guardian applying on behalf of the applicant shall submit a copy of the parent or legal guardian's state or government issued identification and a copy of the applicant's birth certificate;
- (ii) proof of temporary residence in New York State, including, but not limited to a copy of a lease, utility bill, hospital bill, or such other documentation as approved by the department containing sufficient information to show proof of temporary residency in New York State. If the applicant is under the age of eighteen, the parent or legal guardian applying on behalf of the applicant shall submit a copy of such documentation to show sufficient proof of the applicant's temporary residency in New York State.

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

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

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

(2) the information required in section 3363 of the Public Health Law;

(3) for new applicants, if the applicant does not have a current valid New York State Driver's License, New York State Identification Card, or government issued identification containing a photograph, the applicant shall provide a recent passport-style color photograph of the applicant's face, taken against a white background or backdrop. The photograph shall be a true likeness of the applicant's actual appearance on the date the photograph was taken and shall not be altered to change any aspect of the applicant's physical appearance. The photograph shall have been taken not more than 30 days prior to the date of the application. The photograph shall be submitted in a form and manner described by the department, including as a digital file (.jpeg) when appropriate, provided, however, the department may waive the requirements of this paragraph upon good cause shown. For amendments and renewal applications, the department may utilize a previously submitted photograph if the applicant attests it is a true likeness of the applicant on the date the amendment or renewal application is submitted;

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

(5) acknowledgement that a false statement in the application is punishable under section 210.45 of the Penal Law.

(e) If the applicant for a registry identification card is under the age of eighteen or a person who is otherwise incapable of consenting to medical treatment, the application shall be made by an appropriate person over twenty-one years of age. In preparing the application, the applicant may designate up to two proposed designated caregivers who shall be either: (i) a parent or legal guardian of the certified patient; (ii) a person designated by a parent or legal guardian; or (iii) an appropriate person approved by the department upon a sufficient showing that no parent or legal guardian is appropriate or available.

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

(2) Once the certified patient who is a minor or is incapable of medical decision-making is registered, the proposed designated caregiver(s) may apply for and, if approved, receive a designated caregiver registration in accordance with the requirements of section 3363 of the Public Health Law and section 1004.4 of this Part.

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

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

(h) The department shall notify the applicant in writing, by email, by telephone, or in another manner as determined appropriate by the department, if an application is incomplete or factually inaccurate, and shall

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explain what documents or information is necessary for the department to consider the application complete and accurate.

(i) An applicant shall have thirty (30) days from the date of a notification of an incomplete or factually inaccurate application to submit the materials required to complete, revise, or substantiate information in the application. If the applicant fails to submit the required materials within such thirty day time period, the application shall be denied by the department.

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

(k) A certified patient may designate up to two designated caregivers either on the application for issuance or renewal of a registry identification card or in another manner determined by the department. A designated caregiver may be either a natural person or a facility. For purposes of this section, a facility shall mean: a general hospital or residential health care facility operating pursuant to article 28 of the Public Health Law; an adult care facility operating pursuant to Title 2 of article 7 of the Social Services Law; a community mental health residence established pursuant to section 41.44 of the Mental Hygiene Law; a hospital operating pursuant to section 7.17 of the Mental Hygiene Law; a mental hygiene facility operating pursuant to article 31 of the Mental Hygiene Law; and inpatient or residential treatment program certified pursuant to article 32 of the Mental Hygiene Law; a residential facility for the care and treatment of persons with developmental disabilities operating pursuant to article 16 of the Mental Hygiene Law; a residential treatment facility for children and youth operating pursuant to article 31 of the Mental Hygiene Law; or a private or public school. Further, within each of the facilities listed above, each division, department, component, floor or other unit of such facility shall be entitled to be considered to be a facility for purposes of this section. The application for issuance or renewal of a registry identification card shall include the following information:

- (1) name of the proposed designated caregiver(s);
- (2) address of the proposed designated caregiver(s);
- (3) date of birth of the proposed designated caregiver(s), unless the proposed designated caregiver is not a natural person;
- (4) any other individual identifying information concerning the proposed designated caregiver(s) required by the department.

Statutory Authority

Section statutory authority:

Public Health Law, § A33. Section statutory authority: Public Health Law, § 3363. Section statutory authority: Penal Law, § 210.45. Section statutory authority: Public Health Law, § A28. Section statutory authority: Social Services Law, § A7T2. Section statutory authority: Mental Hygiene Law, § 41.44. Section statutory authority: Mental Hygiene Law, § 7.17. Section statutory authority: Mental Hygiene Law, § TEA31. Section statutory authority: Mental Hygiene Law, § TEA32. Section statutory authority: Mental Hygiene Law, § TCA16

History

Added 1004.3 on 4/15/15; added 1004.3(b)(4) on 12/27/17; added 1004.3(c)(1) on 12/27/17; amended 1004.3(k)(effective 10, 05, 17) on 10/25/17, expired 60 days after filing; amended 1004.3(k)(effective 01, 03, 18) on 1/24/18, expired 60 days after filing; amended 1004.3(k)(effective 03, 01, 18) on 3/21/18, expired 60 days after filing; amended 1004.3(k)(effective 04, 30, 18) on 5/16/18, expired 60 days after filing; amended 1004.3(k) on 6/06/18.

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§ 1004.4 Designated caregiver registration

(a) A certified patient's designation of a designated caregiver shall not be valid unless and until the proposed designated caregiver successfully applies for and receives a designated caregiver registry identification card.

(b) A facility or natural person selected by a certified patient as a designated caregiver may apply to the department for a registry identification card or renewal of such card on a form or in a manner determined by the department. The proposed designated caregiver shall submit an application to the department which shall contain the following information and documentation:

(1) for a proposed designated caregiver that is a natural person, the individual shall submit:

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

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

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

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

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

(vi) acknowledgement that a false statement in the application is punishable under section 210.45 of the Penal Law;

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

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

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

(viii) if the documentation submitted by the applicant in accordance with paragraph (vii) of this subdivision does not contain a photograph of the applicant or the photograph on the documentation is not a true likeness of the applicant, the applicant shall provide one recent passport-style color photograph of the applicant's face taken against a white background or backdrop. The photograph shall be a true likeness of the applicant's appearance on the date the photograph was taken and shall not be altered to change any aspect of the applicant's physical appearance. The photograph shall have been taken not more than 30 days prior to the date of the application. The photograph shall be submitted in a form and manner as directed by the department, including as a digital file (.jpeg).

(ix) identification of all certified patients for which the applicant serves, has served or has an application pending to serve as a designated caregiver and a statement that the applicant is not currently a designated caregiver for five current certified patients, and that he/she has not submitted an application which is pending and, if approved, would cause the applicant to be a designated caregiver for a total of five current certified patients;

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(2)for a proposed designated caregiver that is an entire facility that is licensed or operated pursuant to an authority set forth in subdivision (k) of section 1004.3 of this Part, the designated caregiver shall submit:

- (i)the facility's full name, address, operating certificate or license number where appropriate, email address, and printed name, title, and signature of an authorized facility representative;
- (ii)if the facility has a registry identification card, the registry identification number;
- (iii)a statement that the facility agrees to secure and ensure proper handling of all approved medical marijuana products; and
- (iv)an acknowledgement that a false statement in the application is punishable under section 210.45 of the Penal Law;

(3)for a proposed designated caregiver that is a division, department, component, floor or other unit pursuant to subdivision (k) of section 1004.3 of this Part, the designated caregiver shall submit:

- (i)the parent facility's full name, address, operating certificate or license number where appropriate, email address, and printed name, title and signature of an authorized representative of the parent facility and of an authorized representative of the division, department, component, floor or other unit;
- (ii)if the parent facility, division, department, component, floor or other unit has a registry identification card, the registry identification number;
- (iii)a statement that the parent facility, and the division, department, component, floor or other unit, agree to secure and ensure proper handling of all approved medical marijuana products; and
- (iv)an acknowledgement that a false statement in the application is punishable under section 210.45 of the Penal Law.

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

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

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

(f)An applicant shall have 30 days from the date of a notification of an incomplete or factually inaccurate application to submit the materials required to complete, revise or substantiate information in the application. If the applicant fails to submit the required materials within such 30-day time period, the application shall be denied by the department.

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

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

- (1)is already a designated caregiver for five currently certified patients or has an application pending that, if approved, would cause the proposed designated caregiver to be a designated caregiver for more than five currently certified patients; or
- (2)in accordance with subdivision (e) of this section, fails to provide complete or factually accurate information in support of his or her initial or renewal application.

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Statutory Authority

Section statutory authority:

Penal Law, § 210.45

History

Added 1004.4 on 4/15/15; amended 2004.4(b)(effective 10, 05, 17) on 10/25/17, expired 60 days after filing; amended 1004.4(b)(7)(ii) on 12/27/17; amended 1004.4(b)(effective 01, 03, 18) on 1/24/18, expired 60 days after filing; amended 1004.4(b)(effective 03, 01, 18) on 3/21/18, expired 60 days after filing; amended 1004.4(b)(effective 04, 30, 18) on 5/16/18, expired 60 days after filing; amended 1004.4(b) on 6/06/18.

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§ 1004.5 Application for initial registration as a registered organization

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

(b) In order to operate as a registered organization, an entity shall file an application on forms or in a manner prescribed by the commissioner. The application shall be signed by the chief executive officer duly authorized by the board of a corporate applicant, or a general partner or owner of a proprietary applicant. The application shall set forth or be accompanied by the following:

- (1) the name, address, phone and email address of the applicant;
- (2) identification of all real property, buildings and facilities that will be used in manufacturing, as defined in section 1004.11 of this Part, and dispensing of the medical marihuana products;
- (3) identification of all equipment that will be used to carry out the manufacturing, processing, transportation, distributing, sale and dispensing activities described in the application and operating plan;
- (4) an operating plan that includes a detailed description of the applicant's manufacturing processes, transporting, distributing, sale and dispensing policies or procedures. The operating plan shall also include:
 - (i) a detailed description of any devices used with approved medical marihuana products to be offered or sold by the registered organization;
 - (ii) policies and procedures related to security and control measures that will be in place to prevent diversion, abuse, and other illegal or unauthorized conduct relating to medical marihuana and are consistent with provisions set forth in this Part;
 - (iii) a standard operating procedure manual for all methods used from cultivation of the medical marihuana through packaging, sealing and labeling of each lot of medical marihuana product. The procedures shall include use of good agricultural practices (GAPs) and must conform to all applicable laws and rules of New York State. Standard operating procedures shall be able to be validated to demonstrate that the applicant will be able to produce and dispense consistent and reproducible medical marihuana product such that, for each form of each brand produced, there is homogeneity, absence of contamination and reproducibility of the brand profile in each lot as defined in section 1004.11 of this Part;
 - (iv) quality assurance plans, including but not limited to plans to detect, identify and prevent dispensing errors;
 - (v) policies and procedures to document and investigate approved medical marihuana product returns, complaints and adverse events, and to provide for rapid voluntary or involuntary recalls of any lot of medical marihuana product. Such policies and procedures shall include a plan for any retesting of returned approved medical marihuana products, storage and disposal of marihuana and any manufactured medical marihuana products not passing requirements, and a requirement

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that adverse events and total recalls are reported to the department within twenty-four hours of their occurrence;

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

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

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

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

(6) the name, residence address and title of each of the board members, officers, managers, owners, partners, principal stakeholders, directors and any person or entity that is a member of the applicant. Each such person (if an individual, or lawful representative, if a legal entity) shall submit an affidavit with the application setting forth: (i) any position of management or ownership during the preceding ten years of a ten percent or greater interest in any other business, located in or outside New York State, manufacturing or distributing drugs; and (ii) whether such person or any such business has been convicted of a felony or had a registration or license suspended or revoked in any administrative or judicial proceeding. In addition, any managers who may come in contact with or handle medical marihuana, including medical marihuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee;

(7) documentation that the applicant has entered into a labor peace agreement, as required by subdivision one of section 3365 of the Public Health Law, with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees. The maintenance of such a labor peace agreement shall be an ongoing material condition of registration;

(8) a statement that the applicant is able to comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the registration;

(9) copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts related to the organization's real property interests, that show that the applicant possesses or has the right to use sufficient land, buildings, and other premises as specified in the application and equipment to properly carry on the activities for which registration is sought. In the alternative, the applicant shall post a bond of not less than two million dollars; provided, however, that if the applicant posts a bond in lieu of providing the documentation requested herein, the applicant's submission of the applicable executed deeds, leases and rental agreements shall be required prior to the issuance of a registration to the applicant, if selected; and, provided further that whenever any applicant proposes to lease premises for the activities described in its operating plan, the lease agreement shall clearly set forth as a purpose the manufacturing and/or dispensing of medical marihuana, as applicable, and include the following language:

"The landlord acknowledges that its rights of reentry into the premises set forth in this lease do not confer on it the authority to manufacture and/or dispense on the premises medical marihuana in accordance with article 33 of the Public Health Law and agrees to provide the New York State Department of Health, Mayor Erastus Corning 2nd Tower, The Governor Nelson A. Rockefeller Empire State Plaza, Albany, N.Y. 12237, with notification by certified mail of its intent to reenter the premises or to initiate dispossession proceedings or that the lease is due to expire, at least 30 days prior to the date on which the landlord intends to exercise a right of reentry or to initiate such proceedings or at least 60 days before expiration of the lease."

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(10)a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation and/or arranging for the assistance in preparing the application;

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

(i)site plans;

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

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

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

(v)the registered organization shall submit detailed floor plans indicating the activities performed in each area and security plans (physical and cyber) consistent with the requirements of section 1004.13 of this Part.

(12)a construction timetable;

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

(14)if any controlling person of the applicant, any manager, any sole proprietor applicant, any general partner of a partnership applicant, any officer and member of the board of directors of a corporate applicant, or corporate general partner or a combination of such persons collectively, maintains a ten percent interest or greater in any firm, association, foundation, trust, partnership, corporation, or other entity or if such entity maintains a ten percent interest or greater in the applicant, and such entity will or may provide goods, leases, or services to the registered organization, the value of which is or would be five hundred dollars or more within any one year, the name and address of the entity shall be disclosed together with a description of the goods, leases or services and the probable or anticipated cost to the registered organization;

(15)if the applicant is a corporate subsidiary or affiliate of another corporation, disclosure of the parent or affiliate corporation including the name and address of the parent or affiliate, the primary activities of the parent or affiliate, the interest in the applicant held by the parent or affiliate and the extent to which the parent will be responsible for the financial and contractual obligations of the subsidiary;

(16)the most recent 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, including a balance sheet as of the end of the applicant's last fiscal year and income statements for the past two fiscal years, or such shorter period of time as the applicant has been in operation;

(17)if construction, lease, rental or purchase of the manufacturing or dispensing facility has not been completed, a statement indicating the anticipated source and application of the funds to be used in such purchase, lease, rental or construction;

(18)a staffing plan for staff involved in activities related to the cultivation of marihuana, the manufacturing and/or dispensing of approved medical marihuana products and/or staff with oversight responsibilities for such activities, which shall include:

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(i)a senior staff member with a minimum of one (1) year experience in good agricultural practices (GAP);

(ii)a quality assurance officer who shall exercise oversight of the organization's practices and procedures and who has documented training and experience in quality assurance and quality control procedures;

(iii)a requirement that all staff be twenty-one (21) years of age or older;

(iv)a requirement that all staff involved in the manufacturing be trained in and conform to general sanitary practices; and

(v)policies and procedures to ensure that the proposed registered organization shall not employ anyone who would come in contact with or handle medical marihuana who has been convicted of any felony of sale or possession of drugs, narcotics, or controlled substances in accordance with the requirements of section thirty-three hundred sixty-four of the Public Health Law.

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

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

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

Statutory Authority

Section statutory authority:

Public Health Law, § A33. Section statutory authority: Public Health Law, § 3365. Section statutory authority: Public Health Law, § 3364

History

Added 1004.5 on 4/15/15; amended 1004.5(b)(16) on 12/27/17.

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10 NYCRR § 1004.6

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§ 1004.6 Consideration of registered organization applications

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

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

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

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

(1) the applicant will be able to manufacture approved medical marihuana products, each with a consistent cannabinoid profile (the concentration of total tetrahydrocannabinol (THC) and total cannabidiol (CBD) will define the brand) and each able to pass the required quality control testing;

(2) the applicant will produce sufficient quantities of approved medical marihuana products as necessary to meet the needs of certified patients;

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

(4) the applicant will be able to comply with all applicable state and local laws and regulations;

(5) the applicant is ready, willing and able to properly carry on the activities set forth in this Part;

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

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

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

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

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

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

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

(d) If the commissioner is not satisfied that the applicant should be issued a registration, he or she shall notify the applicant in writing of those factors upon which further evidence is required. Within 30 days of the receipt of such notification, the applicant may submit additional material to the commissioner or demand a hearing, or both.

(e) 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.

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

History

Added 1004.6 on 4/15/15; amended 1004.6(a)(2) on 12/27/17; amended 1004.6(a)(3) on 12/27/17; amended 1004.6(e) on 12/27/17.

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§ 1004.7 Applications for renewal of registrations as registered organization

(a)An application to renew any registration issued under this Part shall be filed with the department not more than six months nor less than four months prior to the expiration thereof. If a renewal application is not filed at least four months prior to the expiration thereof, the department may determine that the registration shall have expired and become void on such expiration date.

(b)Applications shall be accompanied by a non-refundable application fee in the amount of \$ 10,000. Applications shall also be accompanied by a registration fee in the amount of \$ 200,000 made by certified check. Only applications completed in accordance with this Part as determined by the department and for which the application and registration fees have been submitted shall be considered if submitted in a timely manner. The registration fee shall be returned to the applicant if the applicant is not granted a renewal registration under this section.

(c)The application for renewal shall include such information prepared in the manner and detail as the commissioner may require, including but not limited to:

(1)any material change as determined by the department in the information, circumstances or factors listed in section 1004.5 of this Part;

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

(i)each incident or alleged incidence involving the theft, loss, or possible diversion of medical marihuana manufactured, distributed, or dispensed by the registered organization; and

(ii)compliance by the applicant with local or state laws, or regulations of the department, including but not limited to, with respect to any substance listed in section thirty-three hundred six of the Public Health Law;

(3)information concerning the applicant's ability to carry on the manufacturing and distributing activity for which it is registered, including but not limited to approved medical marihuana product shortages or wait lists occurring during the registration period; and

(4)a summary of quality assurance testing for all medical marihuana products produced in the prior year including but not limited to the percentage of lots of each brand and form passing all required testing, the percentage of lots failing contaminant testing, the percentage of lots failing brand requirements, all recalls of product lots and all adverse events reported.

(d)The department shall consider applications for renewal in accordance with the criteria set forth in section thirty-three hundred sixty-five of the Public Health Law.

(e)If the department determines that the applicant's registration should not be renewed, the department shall serve upon the applicant or his or her attorney of record, in person or by registered or certified mail, an order directing the applicant to show cause why his or her application for renewal should not be denied. The order shall specify in detail the respects in which the applicant has not satisfied the department that the registration should be renewed.

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(1)within ten (10) business days of receipt of such an order, the applicant may submit additional material to the department or demand a hearing, or both. If a hearing is demanded, the commissioner shall fix a date as soon as reasonably practicable.

(2)if the applicant fails to submit additional material to the department within ten (10) business days as requested, and the applicant does not demand a hearing within such time period, the application for renewal of registration shall be denied.

Statutory Authority

Section statutory authority:

Public Health Law, § 3306. Section statutory authority: Public Health Law, § 3365

History

Added 1004.7 on 4/15/15.

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10 NYCRR § 1004.8

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§ 1004.8 Registrations non-transferable

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

- (1) the name and address of the registered organization;
- (2) name of the contact person for the registered organization;
- (3) the activities the registered organization is permitted to perform under the registration for each approved location; and
- (4) the real property, buildings and facilities that may be used for the permitted activities of the registered organization.

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

History

Added 1004.8 on 4/15/15.

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10 NYCRR § 1004.9

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§ 1004.9 Failure to operate

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

(b) A registered organization who is required to surrender its registration in accordance with this section shall not be entitled to any refund of fees paid to the department.

History

Added 1004.9 on 4/15/15.

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10 NYCRR § 1004.10

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§ 1004.10 Registered organizations; general requirements

(a) In addition to the requirements in Public Health Law and as otherwise set forth in this Part, a registered organization shall:

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

(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.

(2) only manufacture and dispense approved medical marihuana products in New York State in accordance with article 33 of the Public Health Law and this Part;

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

(4) submit approved medical marihuana product samples and manufacturing materials to the department upon request, 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

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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 two times and shall be retained by the registered organization for at least 30 days following the date of expiration;

(5)implement policies and procedures to notify the department within 24 hours 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 10 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;

(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;

(8)dispose of unusable medical marihuana products that have failed laboratory testing or any marihuana used in the manufacturing process pursuant to section 1004.24 of this Part;

(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:

- (i)documentation, including lot numbers where applicable, of all materials used in the manufacturing of the approved medical marihuana product to allow tracking of the materials including but not limited to soil, soil amendment, nutrients, hydroponic materials, fertilizers, growth promoters, pesticides, fungicides, and herbicides;
- (ii)cultivation, manufacturing, packaging and labeling production records; and
- (iii)laboratory testing results.

(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:

- (1)dispense approved medical marihuana products from the same location where the marihuana is grown or manufactured;
- (2)grow marihuana or produce medical marihuana at any site other than a facility or site approved by the department and set forth in the registered organization's registration;
- (3)distribute products or samples at no cost except as may be allowed by the commissioner;
- (4)make substantial alterations to the structure or architectural design of a manufacturing or dispensing facility without prior written approval of the department;
- (5)change the composition of the entity which is the registered organization, including but not limited to, a change in sole proprietor, partner, director, stockholder, member or membership interest of the registered organization without the prior written approval of the department;

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(6) materially modify or revise its operating plan, including its policies and procedures related to cultivation, processing, manufacturing, distributing or dispensing policies or procedures, without prior written approval of the department;

(7) locate a dispensing facility on the same street or avenue and within 1,000 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 10 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.

(c) In the event that a registered organization elects to cease operation of all permitted activities and to surrender its registration, the following provisions shall apply:

(1) The registered organization shall notify the department in writing at least 120 days prior to the anticipated date of closure of each manufacturing and dispensing facility.

(2) Such written notice shall include a proposed plan for closure. The plan shall be subject to department approval in accordance with department protocols, and shall include timetables and describe the procedures and actions the registered organization shall take to:

(i) notify affected certified patients and designated caregivers of the closure;

(ii) properly destroy, transfer or otherwise dispose of all the registered organization's supply of medical marihuana and medical marihuana products;

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

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

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

(4) A registered organization's failure to notify the department of intent to cease any operations, failure to submit an approvable plan, and/or to execute the approved plan may result in the imposition of civil penalties, not to exceed \$ 2,000, and shall be a basis for the department to revoke the registration of the registered organization under such terms as the department determines is appropriate based on public health and safety considerations. In addition, the department reserves the right to exercise any other remedies available to it.

(d) If a registered organization's application for renewal of registration is denied, the registered organization shall submit a proposed plan for closure in accordance with this section.

Statutory Authority

Section statutory authority:

Public Health Law, § A33. Section statutory authority: Correction, § A23

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History

Added 1004.10 on 4/15/15; amended 1004.10(a) on 12/27/17; amended 1004.10(b)(5) on 12/27/17; amended 1004.10(b)(7) on 12/27/17; added 1004.10(b)(8) on 12/27/17.

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§ 1004.11 Manufacturing requirements for approved medical marihuana products

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

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

(2) Brand means a defined medical marihuana 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 and shall have the same composition and concentration of inactive ingredients as that defined for that form of the brand.

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

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

(5) Lot unique identifier (Lot number or bar code) means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of manufacturing, testing, holding, distribution or recall of a lot of medical marihuana product can be determined.

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

(b) A registered organization shall use either carbon dioxide (CO₂, super-critical) or alcohol for cannabinoid extraction and shall only perform extraction of the leaves and flowers of female marihuana plants. A registered organization shall only use carbon dioxide that is of a supply equivalent to food or beverage grade of at least 99.5% purity; and alcohol used shall be of a grade that meets or exceeds specifications of official compendiums as defined in section 321 of Title 21 of the United States Code (USC). 21 USC section 321 is available for copying and inspection at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. A registered organization shall obtain prior written approval from the department if it seeks to use other extraction methods.

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

(1) Each registered organization may initially produce up to five brands of medical marihuana product with prior approval of the department. These brands may be produced in multiple forms as approved by the commissioner. Thereafter, additional brands may be approved by the department.

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(2) Each medical marijuana product brand, in its final form, shall be defined as having a specific concentration of total Tetrahydrocannabinol (THC) and total Cannabidiol (CBD) and shall have a consistent cannabinoid profile. The concentration of the following cannabinoids, at a minimum, must be reported:

- (i) Tetrahydrocannabinol (THC)
- (ii) Tetrahydrocannabinol acid (THCA)
- (iii) Tetrahydrocannabivarin (THCV)
- (iv) Cannabidiol (CBD)
- (v) Cannabinadiolic acid (CBDA)
- (vi) Cannabidivarin (CBDV)
- (vii) Cannabinol (CBN)
- (viii) Cannabigerol (CBG)
- (ix) Cannabichromene (CBC)
- (x) Any other cannabinoid component at > 0.2 percent, for which there is a certified standard available at a customary cost.

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

- (i) Where the total THC concentration is less than five 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 five 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 two 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.

(4) The registered organization shall offer and make available to patients at least one brand that has a low THC and a high CBD content (e.g., a 1:20 ratio of THC to CBD).

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

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

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

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

(e) A registered organization shall:

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- (1) use good agricultural practices (GAPs) and must conform to all applicable laws and rules of New York State;
 - (2) use water from a public water supply or present a plan, approved by the department, which demonstrates the ability to obtain sufficient quantities of water of equal or greater quality as that from a public water supply and to monitor the quality of such water on an ongoing basis;
 - (3) upon prior written notice to the department, only use pesticides that are registered by the New York State Department of 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;
 - (4) process the leaves and flowers of the female plant only, in a safe and sanitary manner;
 - (5) perform visual inspection of the harvested plant material to ensure there is no mold, mildew, pests, rot or gray or black plant material;
 - (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.
- (f) Production of any approved medical marihuana product shall be in accordance with general sanitary conditions. Poisonous or toxic materials, including but not limited to insecticides, rodenticides, detergents, sanitizers, caustics, acids and related cleaning compounds must be stored in a separate area from the marihuana and medical marihuana products in prominently and distinctly labeled containers, except that nothing herein precludes the convenient availability of detergents or sanitizers to areas where equipment, containers and utensils are washed and sanitized.
- (g) Approved medical marihuana products shall be limited to the forms of administration approved by the department, including but not limited to:
- (1) metered liquid or oil preparations;
 - (2) solid and semisolid preparations (e.g. capsules, chewable and effervescent tablets, lozenges);
 - (3) metered ground plant preparations; and
 - (4) topical forms and transdermal patches.
- (5) medical marihuana may not be incorporated into 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, by the certified patient or designated caregiver, or by the registered organization for internal quality control testing or disposal.
- (i) The registered organization shall package the approved medical marihuana product such that it is child-resistant, tamper-proof/tamper-evident, light-resistant, and in a resealable package that minimizes oxygen exposure.
- (j) The registered organization shall identify each lot of approved medical marihuana product with a lot unique identifier.
- (k) Each approved medical marihuana product shall be affixed with a product label. Medical marihuana product labels shall be approved by the department prior to use. Each product label shall be applied at the manufacturing facility, be easily readable, firmly affixed and include:

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- (1) the name, address and registration number of the registered organization;
- (2) the medical marihuana product form and brand designation;
- (3) the single dose THC and CBD content for the product set forth in milligrams (mg);
- (4) the medical marihuana product lot unique identifier (lot number or bar code);
- (5) the quantity included in the package;
- (6) the date packaged;
- (7) the date of expiration of the 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;
- (8) the proper storage conditions;
- (9) language stating:
 - (i) "Medical marihuana products must be kept in the original container in which they were dispensed and removed from the original container only when ready for use by the certified patient";
 - (ii) "Keep secured at all times";
 - (iii) "May not be resold or transferred to another person";
 - (iv) "This product might impair the ability to drive";
 - (v) "KEEP THIS PRODUCT AWAY FROM CHILDREN (unless medical marihuana product is being given to the child under a practitioner's care)"; and
 - (vi) "This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the certifying practitioner, and in the case of breastfeeding mothers, including the infant's pediatrician."

(l) For each lot of medical marihuana product produced, the registered organization shall submit a predetermined number of final medical marihuana products (e.g., sealed vials or capsules; with the number of samples submitted, based on statistical analysis, determined to be representative of the lot) to an independent laboratory/laboratories approved by the department. The laboratory verifying the cannabinoid content shall be approved for the analysis of medical marihuana product by the department in accordance with section 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 section 1004.24 of this Part.
- (2) Any lot not meeting the minimum standards or specifications for brand consistency shall be reported to the department and not dispensed by a registered organization without prior written approval from the department.
- (3) The registered organization shall keep and maintain records documenting submission of medical marihuana products to approved laboratories as required herein, and the results of the laboratory testing. The registered organization shall provide the department with such records upon request.

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

- (1) the stability of opened products shall be validated under the conditions (light, temperature and humidity), specified for storage of the product and an expiration date for opened product shall be determined.

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(2)the stability of unopened products (e.g., sealed packages or vials) shall be validated by ongoing stability testing and an expiration date for unopened products shall be determined;

(3)specifications regarding storage conditions must address storage at the manufacturing facility once the package is sealed, during transport, at the dispensing facility, in the patient's home and for samples retained for future testing.

(n)No synthetic marihuana additives 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.

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

History

Added 1004.11 on 4/15/15; amended 1004.11 on 12/27/17.

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§ 1004.12 Requirements for dispensing facilities

(a) 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 supervising the activity within the facility.

(b) Dispensing facilities shall only sell approved medical marihuana products, related products necessary for the approved forms of administration of medical marihuana, and items that promote health and well-being subject to disapproval of the department and only in such 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.

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

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

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

(1) not dispense an amount greater than a thirty (30) day supply to a certified patient, and not until the patient has exhausted all but a seven day supply provided pursuant to any previously dispensed medical marihuana product by any registered organization;

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

(3) provide a patient specific log of medical marihuana products (brand, administration form, and dosage, and dates dispensed and any return of product) to the patient, the patient's designated caregiver, if applicable, or the patient's practitioner upon request;

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

(f) 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) registered organization employees;

(2) 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

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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.

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

- (1) the name and registry identification number of the certified patient and designated caregiver, if any;
- (2) the certifying practitioner's name;
- (3) the dispensing facility name, address and phone number;
- (4) the dosing and administration instructions;
- (5) the quantity and date dispensed;
- (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.

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

(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.

(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:

- (1) the medical marihuana product and brand;
- (2) a list of any recipients used;
- (3) a warning if there is any potential for allergens in the medical marihuana product;
- (4) contraindications;
- (5) more specific dosage directions and instructions for administration;
- (6) warning of adverse effects and/or any potential dangers stemming from the use of medical marihuana;
- (7) instructions for reporting adverse effects as may be determined by the department;
- (8) a warning about driving, operation of mechanical equipment, child care or making important decisions while under the influence of medical marihuana;
- (9) information on tolerance, dependence and withdrawal and substance abuse, how to recognize what may be problematic usage of medical marihuana and obtain appropriate services or treatment;
- (10) advice on how to keep the medical marihuana product secure;
- (11) language stating that the certified patient may not distribute any medical marihuana product to anyone else;
- (12) language stating that unwanted, excess, or contaminated medical marihuana product must be disposed of according to section 1004.20 of this Part; and
- (13) language stating that "this product has not been analyzed by the FDA. There is limited information on the side effects of using this product and there may be associated health risks."

(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.

(l) If an approved medical marihuana product is returned to the dispensing facility, the dispensing facility shall:

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

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(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.

Statutory Authority

Section statutory authority:

Education Law, § T8A137

History

Added 1004.12 on 4/15/15; amended 1004.12 on 12/27/17.

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§ 1004.13 Security requirements for manufacturing and dispensing facilities

(a) All facilities operated by a registered organization, including any manufacturing facility and dispensing facility, shall have a security system to prevent and detect diversion, theft or loss of marihuana and/or medical marihuana products, utilizing commercial grade equipment, which shall, at a minimum, include:

(1) a perimeter alarm;

(2) motion detectors;

(3) video cameras in all areas that may contain marihuana and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The manufacturing facility or dispensing facility shall direct cameras at all approved safes, approved vaults, dispensing areas, marihuana sales areas and any other area where marihuana is being manufactured, stored, handled, 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;

(4) twenty-four hour recordings from all video cameras, which the manufacturing facility or dispensing facility shall make available for immediate viewing by the department or the department's authorized representative upon request and shall be retained for at least 90 days. The registered organization shall provide the department with an unaltered copy of such recording upon request. If a registered organization is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the registered organization shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the registered organization that it is not necessary to retain the recording;

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

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

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

(8) an automatic voice dialer 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;

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(9)a failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the manufacturing facility or dispensing facility within five minutes of the failure, either by telephone, email, or text message;

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

(11)a date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

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

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

(c)In addition to the requirements listed in subdivision (a) of this section, each manufacturing facility and dispensing facility shall have a back-up alarm system approved by the department that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment.

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

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

(f)All video recordings shall allow for the exporting of still images in an industry standard image format (includingjpeg,bmp, andgif). Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A registered organization shall erase all recordings prior to disposal or sale of the facility.

(g)A registered organization shall keep all security equipment in full operating order and shall test such equipment no less than 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 must be stored in a secure area or location within the registered organization accessible to the minimum number of employees essential for efficient operation and in such a manner as approved by the department in advance, to prevent diversion, theft or loss.

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- (1) Registered organizations shall return marihuana to its secure location immediately after completion of manufacture, distribution, transfer or analysis.
- (j) All medical marihuana must be stored in such a manner as to protect against physical, chemical and microbial contamination and deterioration of the product.
- (k) All approved safes, vaults or any other approved equipment or areas used for the manufacturing or storage of marihuana and approved medical marihuana products must be securely locked or protected from entry, except for the actual time required to remove or replace marihuana or approved medical marihuana products.
- (l) Keys shall not be left in the locks or stored or placed in a location accessible to individuals who are not authorized access to marihuana or manufactured medical marihuana products.
- (m) Security measures, such as combination numbers, passwords or biometric security systems, shall not be accessible to individuals other than those specifically authorized to access marihuana or manufactured medical marihuana products.
- (n) Prior to transporting any medical marihuana, 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 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.
- (2) The registered organization shall maintain all shipping manifests and make them available to the department for inspection upon request, for a period of five years.
- (o) Approved medical marihuana products must be transported in a locked storage compartment that is part of the vehicle transporting the marihuana 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 to his or her destination(s) and shall not make any unnecessary stops in between.
- (q) A registered organization shall ensure that all approved medical marihuana product delivery times are randomized.
- (r) A registered organization shall staff all transport vehicles with a minimum of two employees. At least one transport team member shall remain with the vehicle at all times that the vehicle contains approved medical marihuana products.
- (s) A transport team member shall have access to a secure form of communication with employees at the registered organization's manufacturing facility at all times that the vehicle contains approved medical marihuana products.
- (t) A transport team member shall possess a copy of the shipping manifest at all times when transporting or delivering approved medical marihuana products and shall produce it to the commissioner, the commissioner's authorized representative or law enforcement official upon request.

History

Added 1004.13 on 4/15/15; amended 1004.13 on 12/27/17.

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10 NYCRR § 1004.14

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§ 1004.14 Laboratory testing requirements for medical marihuana

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

(b) No board member, officer, manager, owner, partner, principal stakeholder or member of a registered organization, 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, the registered organization shall submit to the laboratory 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 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 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.

(f) Testing of the cannabinoid profile shall include, at a minimum, those analytes specified in section 1004.11(c)(2) of this Part.

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

Analyte:

E.coli

Pseudomonas species (for products to be vaporized)

Salmonella species

Enterococcus species

Bile tolerant gram negative bacteria, specifically including Klebsiella species

Clostridium botulinum

Aspergillus species

Mucor species

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Penicillium species

Thermophilic Actinomycetes species

Aflatoxins A1, B1, B2, G1, G2

Ochratoxin A

Antimony

Arsenic

Cadmium

Chromium

Copper

Lead

Nickel

Zinc

Mercury

Any pesticide 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) 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) of this Part, 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.

(i) The laboratory shall track and 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.

Statutory Authority

Section statutory authority:

Public Health Law, § A5

History

10 NYCRR § 1004.14

Added 1004.14 on 4/15/15; amended 1004.14 on 12/27/17.

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10 NYCRR § 1004.15

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§ 1004.15 Pricing

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

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

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

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

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

(1) Registered organizations shall submit a proposed price per unit for each form of medical marihuana indicated in its registration. Registered organizations shall submit such information and documentation, in a manner and format determined by the department, sufficient for the department to perform a cost analysis of the proposed price. In particular, the registered organization shall, in a manner and format determined by the department, provide a detailed breakdown of, and submit information and documentation concerning, all costs factored to arrive at its proposed price, including but not limited to its fixed and variable costs such as materials and services; direct labor; and indirect costs.

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

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

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

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

(e) Correction of Insufficient Price Data. If the registered organization or department determines that the cost or pricing data submitted is inaccurate, incomplete or noncurrent prior to the department's approval of the price,

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the registered organization shall submit new data to correct the deficiency, or consider the inaccuracy, incompleteness, or noncurrency of the data.

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

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

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

History

Added 1004.15 on 4/15/15.

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End of Document

10 NYCRR § 1004.16

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§ 1004.16 Medical marihuana marketing and advertising by registered organizations

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

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

(b) All restrictions listed in subdivision (a) of this section shall apply to any item located on any real property on which a registered organization's physical structures are located.

(c) All restrictions listed in subdivision (a) of this section shall apply to all vehicles owned, leased or utilized by a registered organization.

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

(e) An advertisement does not satisfy the requirement that it presents a "true and accurate statement" of information relating to effectiveness, side effects, consequences, and contraindications if it fails to present a fair balance between information relating to effectiveness, side effects, consequences, and contraindications in that the information relating to effectiveness is presented in a greater scope, depth, or detail than is the information relating to side effects, consequences and contraindications, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(f) An advertisement is false, lacking in fair balance, or otherwise misleading if it:

- (1) Contains a representation or suggestion that one marihuana brand or form is better, more effective, useful in a broader range of conditions or patients or safer than other drugs or treatments including other marihuana brands or forms, unless such a claim has been demonstrated by substantial scientific or clinical experience;
- (2) Contains favorable information or opinions about a marihuana product previously regarded as valid but which have been rendered invalid by contrary and more credible recent information;
- (3) Uses a quote or paraphrase out of context or without citing conflicting information from the same source, to convey a false or misleading idea;
- (4) Uses a study on persons without a debilitating medical condition without disclosing that the subjects were not suffering from a debilitating medical condition;
- (5) Uses data favorable to a marihuana product derived from patients treated with a different product or dosages different from those recommended in New York State;

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- (6) Contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; or
- (7) Fails to provide adequate emphasis for the fact that two or more facing pages are part of the same advertisement when only one page contains information relating to side effects, consequences and contraindications.
- (g) False or misleading information in any part of the advertisement shall not be corrected by the inclusion of a true statement in another distinct part of the advertisement.
- (h) An advertisement for any approved medical marihuana product shall not contain:
- (1) any statement that is false or misleading;
 - (2) any statement that falsely disparages a competitor's products;
 - (3) any statement, design, or representation, picture or illustration that is obscene or indecent;
 - (4) any statement, design, representation, picture or illustration that encourages or represents the use of marihuana for a condition other than a serious condition as defined in subdivision seven of section thirty-three hundred sixty of the Public Health Law;
 - (5) any statement, design, representation, picture or illustration that encourages or represents the recreational use of marihuana;
 - (6) any statement, design, representation, picture or illustration related to the safety or efficacy of marihuana, unless supported by substantial evidence or substantial clinical data;
 - (7) any statement, design, representation, picture or illustration portraying anyone under the age of 18, objects suggestive of the presence of anyone under the age of 18, or containing the use of a figure, symbol or language that is customarily associated with anyone under the age of 18;
 - (8) any offer of a prize, award or inducement to a certified patient, designated caregiver or practitioner related to the purchase of marihuana or a certification for the use of marihuana; or
 - (9) any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the commissioner, department, New York State or any person or entity associated with New York State provided that this shall not preclude a factual statement that an entity is a registered organization.
- (i) Any advertisement for an approved medical marihuana product, which makes any claims or statements regarding efficacy, shall be submitted to the department at least 10 business days prior to the public dissemination of the advertisement.
- (j) The submitter of the advertisement shall provide the following information to the department in addition to the advertisement itself:
- (1) A cover letter that:
 - (i) provides the following subject line: Medical marihuana advertisement review package for a proposed advertisement;
 - (ii) provides a brief description of the format and expected distribution of the proposed advertisement; and
 - (iii) provides the submitter's name, title, address, telephone number, fax number, and email address;
 - (2) an annotated summary of the proposed advertisement showing every claim being made in the advertisement and which references support for each claim;
 - (3) verification that a person identified in an advertisement as an actual patient or health care practitioner is an actual patient or health care practitioner and not a model or actor;

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- (4) verification that a spokesperson who is represented as an actual patient is indeed an actual patient;
- (5) verification that an official translation of a foreign language advertisement is accurate;
- (6) annotated references to support disease or epidemiology information, cross-referenced to the advertisement summary; and
- (7) a final copy of the advertisement, including a video where applicable, in a format acceptable to the department.

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

(l) No advertisement may be disseminated if the submitter of the advertisement has received information that has not been widely publicized in medical literature that the use of any approved medical marijuana product may cause fatalities or serious damage to a patient.

(m) A registered organization, its officers, managers and employees shall not cooperate, directly or indirectly, in any advertising if such advertising has the purpose or effect of steering or influencing patient or caregiver choice with regard to the selection of a practitioner. Nothing contained within this section prevents a registered organization from educating practitioners about approved medical marijuana products offered by the registered organization.

(n) The department may:

- (1) require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the department determines that the advertisement would be false or misleading without such a disclosure; or
- (2) require that changes be made to the advertisement that are:
 - (i) necessary to protect the public health, safety and welfare; or
 - (ii) consistent with dispensing information for the product under review.

Statutory Authority

Section statutory authority:

Public Health Law, § 3360

History

Added 1004.16 on 4/15/15; amended 1004.16(a) on 12/27/17; amended 1004.16(d) on 12/27/17; amended 1004.16(i) on 12/27/17; amended 1004.16(m) on 12/27/17.

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§ 1004.17 Reporting dispensed medical marihuana products

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

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

- (1) a serial number that will be generated by the dispensing facility for each approved medical marihuana product dispensed to the certified patient or designated caregiver;
- (2) an identification number which shall be populated by a number provided by the department, to identify the registered organization's dispensing facility;
- (3) the patient name, date of birth and sex;
- (4) the patient address, including street, city, state, zip code;
- (5) the patient's registry identification card number;
- (6) if applicable, designated caregiver's name and registry identification card number;
- (7) the date the approved medical marihuana product was filled by the dispensing facility;
- (8) the metric quantity for the approved medical marihuana product;
- (9) the medical marihuana product drug code number, which shall be populated by a number provided by the department, to represent the approved medical marihuana brand that was dispensed to the certified patient or designated caregiver, as applicable;
- (10) the number of days supply dispensed;
- (11) the registered practitioner's Drug Enforcement Administration number;
- (12) the date the written certification was issued by the registered practitioner; and
- (13) the payment method.

(c) When applicable, a registered organization shall file a zero report with the department, in a format acceptable to the department. For the purposes of this section, a zero report shall mean a report that no approved medical marihuana product was dispensed by a registered organization during the relevant period of time. A zero report shall be submitted no later than 14 days following the most recent previously reported dispensing of an approved medical marihuana product or the submission of a prior zero report.

History

Added 1004.17 on 4/15/15.

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§ 1004.18 Prohibition of the use of approved medical marihuana products in certain places

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

- (1) places of employment;
- (2) bars;
- (3) food service establishments, except as provided in subdivision six of section thirteen hundred ninety-nine-q of the Public Health Law;
- (4) enclosed indoor areas open to the public containing a swimming pool;
- (5) public means of mass transportation, including subways, underground subway stations, and when occupied by passengers, buses, vans, taxicabs and limousines;
- (6) ticketing, boarding and waiting areas in public transportation terminals;
- (7) youth centers and facilities for detention as defined in sections five hundred twenty-seven-a and five hundred three of the Executive Law;
- (8) any facility that provides child care services as defined in section four hundred ten-p of the Social Services Law, provided that such services provided in a private home are excluded from this subdivision when children enrolled in such day care are not present;
- (9) child day care centers as defined in section three hundred ninety of the Social Services Law and child day care centers licensed by the city of New York;
- (10) group homes for children as defined in section three hundred seventy-one of the Social Services Law;
- (11) public institutions for children as defined in section three hundred seventy-one of the Social Services Law;
- (12) residential treatment facilities for children and youth as defined in section 1.03 of the Mental Hygiene Law;
- (13) all public and private colleges, universities and other educational and vocational institutions, including dormitories, residence halls, and other group residential facilities that are owned or operated by such colleges, universities and other educational and vocational institutions;
- (14) general hospitals and residential health care facilities as defined in article twenty-eight of the Public Health Law, and other health care facilities licensed by the state in which persons reside; provided, however, that the provisions of this subdivision shall not prohibit vaporization by patients in separate enclosed rooms of hospitals, residential health care facilities, and adult care facilities established or certified under title two of article seven of the Social Services Law, community mental health residences

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established under section 41.44 of the Mental Hygiene Law, or facilities where day treatment programs are provided, which are designated as smoking rooms for patients of such facilities or programs;

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

(16) indoor arenas;

(17) zoos;

(18) bingo facilities.

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

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

Statutory Authority

Section statutory authority:

Public Health Law, § 1399-Q. Section statutory authority: Executive, § 527-A. Section statutory authority: Executive, § 503. Section statutory authority: Social Services Law, § 410-P. Section statutory authority: Social Services Law, § 390. Section statutory authority: Social Services Law, § 371. Section statutory authority: Mental Hygiene Law, § 1.03. Section statutory authority: Public Health Law, § A28. Section statutory authority: Social Services Law, § A7T2. Section statutory authority: Mental Hygiene Law, § 41.44. Section statutory authority: Vehicle & Traffic Law, § 129

History

Added 1004.18 on 4/15/15.

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§ 1004.19 Reporting requirements for for registered practitioners, certified patients and designated caregivers

(a) A practitioner shall report to the department, in a manner determined by the department, the death of a certified patient or change in status of a serious condition involving a certified patient for whom the practitioner has issued a certification if such change may affect the patient's continued eligibility for certification for use of approved medical marihuana product. A practitioner shall report such death or change of status not more than five (5) business days after the practitioner becomes aware of such fact.

(b) If a practitioner re-issues a patient's certification to terminate the certification on an earlier date, then the registry identification card shall expire on such earlier date and shall be promptly returned to the department by the certified patient or designated caregiver.

(c) A practitioner shall report patient adverse events to the department, in a manner determined by the department, not more than five business days after the practitioner becomes aware of such adverse event, except that serious adverse events shall be reported not more than one business day after the practitioner becomes aware of such adverse event.

(d) A certified patient or designated caregiver, who has been issued a registry identification card, shall notify the department of any change in the information provided to the department not later than ten (10) business days after such change. A certified patient or designated caregiver shall report changes that include, but are not limited to, a change in the certified patient's name, address, contact information, medical status. A certified patient or designated caregiver shall report such changes on a form, and in a manner, determined by the department. Should a certified patient cease to have the serious condition noted on his or her certification, the certified patient or designated caregiver shall notify the department of such within 10 days and the certified patient's and designated caregiver's registry identification cards shall be considered void and shall be returned promptly to the department.

(e) If a certified patient's or designated caregiver's appearance has substantially changed such that the photograph submitted to the department does not accurately resemble such certified patient or designated caregiver, such person shall submit, in a timely manner, an updated photograph that meets the requirements set forth by the department.

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

(g) If a certified patient or designated caregiver notifies the department of any change that results in information on the registry identification card being inaccurate or the photograph needing to be replaced, the certified patient or designated caregiver shall obtain a replacement registry identification card. The department shall thereafter issue the certified patient or designated caregiver a new registry identification card. Upon receipt of a new registry identification card, the certified patient or designated caregiver shall destroy in a non-recoverable manner the registry identification card that was replaced.

(h) If a certified patient or designated caregiver becomes aware of the loss, theft or destruction of the registry identification card of such certified patient or designated caregiver, the certified patient or designated caregiver shall notify the department, on a form and in a manner prescribed by the department, not later than ten days of

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becoming aware of the loss, theft or destruction. The department shall inactivate the initial registry identification card upon receiving such notice and issue a replacement registry identification card upon receiving the applicable fee provided the applicant continues to satisfy the requirements of section thirty-three hundred sixty-one of the Public Health Law and section 1004.3 of this Part. Prior to issuance of the first replacement registry identification card, a certified patient or designated caregiver shall submit to the department a fee of \$ 25, transmitted in a fashion as determined by the department. For each subsequent replacement registry identification card a certified patient or designated caregiver shall submit to the department a fee of \$ 50, transmitted in a fashion as determined by the department.

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

(1) The department shall issue a notification, in a format determined by the department, to the designated caregiver and the certified patient that the designated caregiver's registration card is invalid.

(2) In the event that the designated caregiver has no other active certified patients, the designated caregiver's registration card must be returned to the department within 10 business days.

(3) In the event that the certified patient has selected another designated caregiver, the proposed designated caregiver must register with the department as defined in section 1004.4 of this Part.

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

(1) The department shall issue a notification, in a format determined by the department, to the certified patient and the designated caregiver that the designated caregiver has terminated his or her relationship with the certified patient.

(2) In the event that the designated caregiver has no other active certified patients, the designated caregiver's registration card must be returned to the department within ten business days.

Statutory Authority

Section statutory authority:

Public Health Law, § 3361

History

Added 1004.19 on 4/15/15.

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10 NYCRR § 1004.20

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§ 1004.20 Proper disposal of medical marihuana products by certified patients or designated caregivers

(a) A certified patient or designated caregiver shall dispose of all approved medical marihuana product in the certified patient's or designated caregiver's possession no later than ten calendar days after the expiration of the patient's certification, if such certification is not renewed, or sooner should the patient no longer wish to possess medical marihuana.

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

(1) rendering the approved medical marihuana product non-recoverable beyond reclamation in accordance with the Department of Environmental Conservation's guidance; or

(2) 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.

History

Added 1004.20 on 4/15/15; amended 1004.20(b) on 12/27/17.

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§ 1004.21 General prohibitions

(a) No person, except for a certified patient or designated caregiver, or an approved laboratorian shall open or break the seal placed on an approved medical marihuana product packaged by a registered organization and provided to the certified patient.

(b) No person associated with a registered organization shall enter into any agreement with a registered practitioner or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the dispensing facility at which the certified patient or designated caregiver will purchase approved medical marihuana products.

(c) No approved medical marihuana product shall be sold, dispensed or distributed via a delivery service without prior written approval to the registered organization by the department, except that a designated caregiver may deliver the approved medical marihuana product to the designated caregiver's certified patient.

(d) No employee of a registered organization shall counsel 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 the pharmacist on-site in the dispensing facility.

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

History

Added 1004.21 on 4/15/15; amended 1004.21(d) on 12/27/17.

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§ 1004.22 Practitioner prohibitions

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

- (1) directly or indirectly accept, solicit, or receive any item of value from a registered organization;
- (2) offer a discount or any other item of value to a certified patient based on the patient's agreement or decision to use a particular practitioner, registered organization, brand or specific form of approved medical marihuana product produced by a registered organization;
- (3) examine a qualifying patient for purposes of diagnosing a debilitating medical condition at any location owned or operated by a registered organization, or where medical marihuana products or related products necessary for the approved forms of administration of medical marihuana are acquired, distributed, dispensed, manufactured, sold, or produced; or
- (4) directly or indirectly benefit from a patient obtaining a written certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

(b) A practitioner that issues written certifications, and such practitioner's co-worker, employee, spouse, parent, child, or sibling shall not have a direct or indirect financial interest in a registered organization or any other entity that may benefit from a certified patient's or designated caregiver's acquisition, purchase or use of approved medical marihuana products, including any formal or informal agreement whereby a registered organization provides compensation if the practitioner issues a written certification for a certified patient or steers a certified patient to a specific dispensing facility.

(c) A practitioner shall not issue a certification for himself/herself or for the practitioner's family members, employees or co-workers.

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

(e) A practitioner shall not be a designated caregiver for any patients that he or she has certified under section 1004.2 of this Part. However, this shall not prohibit a facility, or a division, department, component, floor or other unit from being a designated caregiver pursuant to section 1004.4 of this Part.

History

Added 1004.22 on 4/15/15; amended 1004.22(e)(effective 10, 05, 17) on 10/25/17, expired 60 days after filing; amended 1004.22(e)(effective 01, 03, 18) on 1/24/18, expired 60 days after filing; amended 1004.22(e)(effective 03, 01, 18) on 3/21/18, expired 60 days after filing; amended 1004.22(e)(effective 04, 30, 18) on 5/16/18, expired 60 days after filing; amended 1004.22(e) on 6/06/18.

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§ 1004.23 Designated caregiver prohibitions and protections

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

(b)A designated caregiver may only obtain payment from the certified patient to be used for the cost of the approved medical marihuana product purchased for the certified patient in the actual amount charged by the registered organization; provided, however, that a designated caregiver may charge the certified patient for reasonable costs incurred in the transportation, delivery, storage and administration of approved medical marihuana products.

(c)Designated caregivers, including employees of facilities registered as designated caregivers and acting within their scope of employment, shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for an action or conduct in accordance with this Part.

History

Added 1004.23 on 4/15/15; amended 1004.23(effective 10, 05, 17) on 10/25/17, expired 60 days after filing; amended 1004.23(effective 01, 03, 18) on 1/24/18, expired 60 days after filing; amended 1004.23(effective 03, 01, 18) on 3/21/18, expired 60 days after filing; amended 1004.23(effective 04, 30, 18) on 5/16/18, expired 60 days after filing; amended 1004.23 on 6/06/18.

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§ 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.

History

Added 1004.24 on 12/27/17.

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