

Pursuant to the authority vested in the Commissioner of Health by Section 3369-a of the Public Health Law (PHL), Sections 1004.3, 1004.4, 1004.22 and 1004.23 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (k) of section 1004.3 is amended to read as follows:

(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; an 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:

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(3) date of birth of the proposed designated caregiver(s), unless the proposed designated caregiver is not a natural person;

\* \* \*

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

(b) A facility or natural person selected by a certified patient as a designated caregiver [shall] 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 fifty (\$50) dollars, 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;

([6]vi) acknowledgement that a false statement in the application is punishable under section 210.45 of the penal law;

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

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

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

([8]viii) If the documentation submitted by the applicant in accordance with paragraph ([7]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 thirty (30) days prior to the date of the application. The photograph shall be submitted in a form and manner as directed by the department, including as a digital file (.jpeg).

([9]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;

(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.

Subdivision (e) of section 1004.22 is amended to read as follows:

(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.

Section 1004.23 is amended as follows:

§ 1004.23 Designated Caregiver Prohibitions and Protections

\* \* \*

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

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

The Commissioner is authorized pursuant to Section 3369-a of the Public Health Law (PHL) to promulgate rules and regulations necessary to effectuate the provisions of Title V-A of Article 33 of the Public Health Law.

### **Legislative Objectives:**

The legislative objective of Title V-A is to comprehensively regulate the manufacture, sale and use of medical marihuana, by striking a balance between potentially relieving the pain and suffering of those individuals with serious medical conditions, as defined in Section 3360(7) of the Public Health Law, and protecting the public against risks to its health and safety.

### **Needs and Benefits:**

The proposed regulations are necessary to allow certain defined facilities to seek Department of Health approval to become a designated caregiver for a certified patient in New York State's Medical Marihuana Program. A certified patient must have one of the severe debilitating or life-threatening conditions listed in Section 1004.2(8) of Title 10 Part 1004 in order to receive a certification and subsequently register with the Medical Marihuana Program. Patients with one of these conditions might not be able to visit the dispensing facilities operated by registered organizations to pick up their medical marihuana, or might not be able to administer medical marihuana to themselves properly, and therefore need to rely on designated caregivers.

Previously, the regulations only allowed for designated caregivers to be natural persons.

However, recognizing that certified patients may be located in certain facilities, the proposed

regulations would allow those certain facilities to be designated caregivers. Facilities designated as caregivers by certified patients would have the ability to register with the Department.

Further, each division, department, component, floor or other unit of a parent facility may be designated as a “facility” for purposes of being designated a caregiver. After registering, a designated caregiver facility would be authorized to possess, acquire, deliver, transfer, transport, and administer medical marijuana on behalf of a certified patient. This would help to prevent patients from experiencing adverse events associated with abrupt discontinuation of a treatment alternative that may be providing relief for the severe debilitating or life-threatening condition.

## **Costs**

### **Costs to the Regulated Entity:**

Facilities seeking to register as designated caregivers would incur nominal administrative costs in registering. Pursuant to PHL Section 3363(f), there is a \$50 application fee for designated caregivers to register with the department. However, the department is currently waiving the \$50 application fee for all designated caregivers, including facilities registering as designated caregivers.

### **Costs to Local Government:**

The proposed rule does not require the local government to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

### **Costs to the Department of Health:**

The Department anticipates an increased administrative cost to support facilities seeking to register as designated caregivers, however such increase would be minimal.

**Local Government Mandates:**

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

**Paperwork:**

No paperwork will be required to be maintained, as the registration process for designated caregivers is all done electronically. A registry identification card will be provided to the facility. The facility will be responsible for maintaining the registry identification card at all times when medical marihuana is present at the facility for the certified patient. The facility may have its own paperwork related to internal policies and procedures for possession of the registry identification card by staff members.

**Duplication:**

The proposed regulations do not duplicate any existing State or federal requirements.

**Alternatives:**

The Department could have chosen to keep the status quo and not allow patients to designate facilities as designated caregivers. The Department could have also allowed certified patients to designate an individual within the facility to be a caregiver. However, these options are not viable since patients in facilities may be cared for by multiple staff members in the course of a day. Certified patients have severe debilitating or life-threatening conditions and the regulatory amendments would help to prevent adverse events associated with abrupt discontinuation of a treatment alternative that may be providing relief for certified patients in these facilities.

**Federal Standards:**

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

**Compliance Schedule:**

There is no compliance schedule imposed by these amendments, which shall be effective upon publication of a Notice of Adoption in the New York State Register.

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## **Regulatory Flexibility Analysis for Small Businesses and Local Governments**

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

### **Cure Period:**

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement under the proposed regulation. The regulatory amendment authorizing the patients to designate facilities as designated caregivers does not mandate that a facility register with the medical marihuana program. Hence, no cure period is necessary.

### **Statement in Lieu of Rural Area Flexibility Analysis**

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

### **Statement in Lieu of Job Impact Statement**

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