

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;

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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 marijuana 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.

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

The Department of Health (“Department”) received comments from various stakeholders, including representatives of hospitals, nursing homes and assisted living providers. Comments were received regarding the storage and administration of medical marihuana products, the process for registering as a designated caregiver facility, the federal status of marihuana, and various other topics. Based on the comments received, no changes are being made to the proposed rulemaking.

ASSESSMENT OF PUBLIC COMMENT

The Department of Health (“Department”) received comments from various stakeholders, including representatives of hospitals, nursing homes and assisted living providers. Comments were received regarding the storage and administration of medical marihuana products, the process for registering as a designated caregiver facility, the federal status of marihuana, and various other topics. The comments are summarized below along with the Department’s responses.

COMMENT: Commenters stated that requiring facilities to register with the Department as designated caregivers after each certified patient designates the facility as a caregiver, would be burdensome and result in significant administrative costs. One commenter stated that this process will require facilities to return the facility registration identification card received for each patient when that patient is no longer a certified patient or resident and to de-register as a designated caregiver. The commenter also stated that although the Department is currently waiving the \$50 application fee for all designated caregivers, the waiver of the application fee may be eliminated or amended at any time, thus forcing facilities to pay a fee to register for each certified patient that selects the facility as a designated caregiver. Another commenter expressed concern with the timeframe for approvals, which could potentially exceed a patient’s length of stay in a facility.

Commenters proposed streamlining the registration process. One commenter suggested a notification to the Department that an already designated caregiver facility is assisting a new certified patient. Another commenter suggested that the regulation be modified to allow for eligible facilities to have a standing registration as a designated caregiver, which would make

patients aware of facilities that will serve as a designated caregiver, and make the Department aware of facilities electing to participate in the Medical Marijuana Program. Another commenter asked that the Department approve designated caregiver applications from hospitals in a streamlined manner, similar to the approval process for other hospital designations such as emergency Medicaid. The commenter asked that the Department allow hospitals to presume Department approval from the time the required designated caregiver paperwork is submitted.

RESPONSE: Sections 3362(2) and 3363(1) of the Public Health Law (PHL), require designated caregivers to register with the Department and receive a registry identification card before being authorized to possess or administer medical marijuana. Furthermore, Section 3360(5) of the PHL limits a certified patient to only two designated caregivers at any one time. As such, a facility caregiver cannot presume Department approval after submitting an application to register as a designated caregiver. The proposed rulemaking is consistent with these provisions of the Compassionate Care Act. As it relates to timeframe for approvals, this process will be expedited by allowing certified patients to designate a facility caregiver on the same form that the facility then uses to accept the designation and register with the Department. Once completed, registration forms can be e-mailed to the Department for processing and approval. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Comments were received regarding the limitation of five certified patients at any one time, for each designated caregiver facility. One commenter stated that this limitation may prevent hospitals from serving as designated caregivers for all certified patients. The commenter also stated that allowing each division, department, component, floor or other unit within a facility to be considered a unit, creates additional burdens for hospitals and causes undue delay for patients utilizing medical marijuana since hospitals would have to track and manage the

number of patients, applications, and approvals for each sub-facility. The commenter asked the Department to confirm that the cap on the number of certified patients would not apply to hospitals since hospitals, unlike individuals, address medication daily and are subject to the oversight of many entities, including the Department. Commenters also asked the Department to consider making changes to the PHL or regulations to remove the five-patient limit.

RESPONSE: The proposed rulemaking is consistent with Section 3363(5) of the PHL, which limits designated caregivers to no more than five certified patients at a time. To address this issue, the proposed rulemaking allows for each division, department, component, floor or other unit within a facility to be considered a separate designated caregiver. The Department will track registrations it receives to ensure that the number of certified patients per division, department, component, floor, or other unit, does not exceed the five patient limit. No changes to the proposed regulation were made as a result of these comments.

COMMENT: One commenter expressed concern that limiting certified patients to only two designated caregivers would require some patients to select among potential caregivers. The commenter provided an example of a pediatric patient being forced to choose between designating one or both parents, a school nurse, or a facility, as the child's caregiver. The commenter asked the Department to confirm that the cap on designated caregivers does not apply to hospitals. The commenter stated that unlike individuals or natural persons, hospitals address medications daily and are distinct because they are subject to oversight from many entities, including the Department.

RESPONSE: Section 3360(5) of the PHL limits certified patients to no more than two designated caregivers. The proposed rulemaking is consistent with this provision of the PHL.

The Department will review caregiver designations to ensure that certified patients do not exceed the number of designated caregivers authorized in statute. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Comments were received asking for the regulation to be amended to better define “reasonable costs” associated with the facility serving as a designated caregiver. One commenter stated that the regulation should be amended to indicate whether medical marijuana is considered a medication, and whether the designated caregiver facility can charge the resident an amount for assistance beyond the base fee. Another commenter asked whether costs incurred by a designated caregiver facility to transport and deliver approved medical marijuana products to a certified patient, could be charged as “reasonable costs.” This commenter also wanted to know who is responsible for remitting payment to the registered organization dispensing or delivering the medical marijuana.

RESPONSE: Reasonable costs associated with a facility serving as a designated caregiver include, but are not limited to: the actual costs associated with purchasing, transporting, and delivering approved medical marijuana products to certified patients at the facility; the exact amount paid by a designated caregiver facility to a registered organization for the patient’s medical marijuana product; as well as any costs associated with the storage or administration of approved medical marijuana products at the facility. A designated caregiver facility may assist its certified patient(s) with obtaining the product from the dispensing facility, if the facility’s policies and procedures allow for this level of service. A facility serving as a designated caregiver providing this level of service must determine terms of payment with the patient prior

to purchasing product from the registered organization. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Comments were received expressing concerns of federal enforcement of the Controlled Substances Act (CSA). One commenter stated that the Department should try to obtain clear written guidance from the federal government that it will not take legal action against designated caregiver facilities that comply with the provisions of this regulation. Another commenter stated that the regulations should be amended to clarify that facilities participating as designated caregivers shall be held harmless for their lawful activity under the Medical Marihuana Program. A commenter also stated that the Rohrabacher-Farr Amendment does not protect from actions against individuals or entities, even when acting in compliance with State law, and it is uncertain if and when the protection will end.

RESPONSE: These comments are outside the scope of the proposed regulations. However, the Department maintains a well-regulated Medical Marihuana Program and remains committed to ensuring that all New Yorkers who qualify are able to access this therapy. The Department will take these comments under advisement and will continue to look for ways to protect certified patients and their designated caregivers from federal intervention.

COMMENT: One commenter stated that Title V-A of New York's PHL does not authorize health care facilities to become designated caregivers. The commenter stated that while the term "individual" is not defined under PHL § 3302 or Title V-A, there are indications within Title V-A that a designated caregiver refers only to a natural person.

RESPONSE: PHL § 3360(5) defines "designated caregiver" as the individual designated by a certified patient in the patient's registry application. However, PHL § 3363 refers to a designated

caregiver as a “person.” PHL § 3302(25) defines “person” to mean “individual, institution, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.” Pursuant to Section 3308(2) of the PHL, the commissioner is authorized and empowered to make any rules, regulations and determinations necessary or proper to supplement the provisions of Article 33 to effectuate the purpose and intent thereof, or to clarify its provisions. Here, the proposed regulations are necessary and proper to clarify and supplement the definition of “designated caregiver” to include certain defined facilities. No changes to the proposed regulation were made as a result of these comments.

COMMENT: One commenter sought clarification regarding Class 3A (Institutional Dispenser, Limited) controlled substance licenses and whether medical marihuana is considered a controlled substance for purposes of Adult Care Facilities (ACF). The commenter further stated that if Medical Marihuana is considered a medication, the proposed regulation needs to clarify whether it should be handled like all other medications that ACF assist with (as defined in 18 NYCRR 487.7(f) and 488.11(e)) and if medical marihuana is not considered a medication, the regulation should include guidance for storage, including the Department’s expectation as to if/how assistance is documented, as well as other required documentation typical with medications. The commenter also sought clarification that the Department’s Bureau of Narcotic Enforcement supports this regulation and that ACF providers serving as a designated caregiver will not be out of compliance with their Class 3A (Institutional Dispenser, Limited) license obligations, nor their medication assistance regulations under 18 NYCRR Parts 487.7 (adult home) and 488.7

(enriched housing program). The commenter stated that without answers to these important questions, ACF providers may be hesitant to choose to serve as a designated caregiver.

RESPONSE: Medical marihuana is not dispensed pursuant to a prescription and does not fall under a facility's authority to possess controlled substances under any license issued pursuant to Title 10 Part 80. A facility that stores medical marihuana products on behalf of its certified patient(s), must do so under the authority to possess medical marihuana as a designated caregiver, in accordance with the requirements of the proposed rulemaking under 10 NYCRR § 1004.4, and per PHL § 3360(1) which authorizes designated caregivers to acquire, possess, deliver, transport or administer medical marihuana. A facility acting as a designated caregiver should develop and follow internal policies and procedures—in conjunction and compliance with any entities that may oversee and/or regulate the facility—that provide for storage of approved medical marihuana products in a secure manner to prevent diversion. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A commenter stated that the regulations should clearly state which facility staff or job titles are allowed to provide assistance with medical marihuana. Another commenter asked which facility staff member would be responsible for keeping track of certified prescribers on staff, which units are certified, and holding documentation for survey. The commenter also asked which staff members may accept a delivery of medical marihuana, whether the process of verification of receipt of medical marihuana should resemble the process of verifying narcotics and if the Bureau of Narcotic Enforcement will provide guidance for this.

RESPONSE: Any facility employee, deemed appropriate by the designated caregiver facility, can administer approved medical marihuana products to the patient. PHL § 3362(1) authorizes

designated caregivers to acquire, possess, deliver, transport or administer medical marihuana. Designated caregiver facilities should develop and follow internal policies and procedures—in conjunction and compliance with any entities that may oversee and/or regulate the facility—for inventory management and recordkeeping, including the acceptance of deliveries. No changes to the proposed regulation were made as a result of these comments.

COMMENT: A commenter stated that the regulation should be amended to include the allowable forms of medical marihuana that an ACF designated caregiver may assist with.

RESPONSE: Approved forms of medical marihuana that a designated caregiver facility, including an ACF, may assist with are all forms authorized by the Commissioner of Health in 10 NYCRR § 1004.11(g). However, facilities serving as designated caregivers should keep in mind that 10 NYCRR § 1004.18 restricts vaporization of approved medical marihuana products in certain places. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Commenters sought guidelines for safe transport, disposal or destruction, storage, documentation, and diversion reporting.

RESPONSE: Designated caregiver facilities should develop and follow internal policies and procedures—in conjunction and compliance with any entities that may oversee and/or regulate the facility—that provide for inventory management and recordkeeping so as to prevent diversion. When disposing of approved medical marihuana products, it must always be done in a manner that renders the product non-recoverable beyond reclamation. Approved medical marihuana products cannot be disposed of using medication drop boxes, DEA drug take-back events or via Bureau of Narcotic Enforcement drug destructions.

COMMENT: One commenter stated that the regulations should state that it is optional for facilities to serve as a designated caregiver.

RESPONSE: The proposed regulations do not require facilities to serve as designated caregivers. Instead, the proposed regulations state that a facility or natural person selected by a certified patient to serve as a designated caregiver *may* apply to the Department for a registry identification card. No changes to the proposed regulation were made as a result of these comments.

COMMENT: One commenter asked whether individual clinicians would be required to provide their information for the designated caregiver registry and if the information would be subject to the Freedom of Information Law (FOIL) and available to the public.

RESPONSE: The designated caregiver registration, completed by an authorized representative of the facility serving as a designated caregiver, does not include identification of individual clinicians. Any requests for public disclosure of information received by the Department will be reviewed by the Department's Records Access Office to determine whether or not the information requested can be released.

COMMENT: A commenter asked whether the designated caregiver registry identification card should be displayed somewhere in the facility or kept in a file for access during survey.

RESPONSE: The designated caregiver registry identification card provided by the Department is specific to each certified patient. This information must be maintained by the facility in a manner that protects patient confidentiality, but where it is readily retrievable.