

Medical Use of Marihuana

Effective date: 11/30/16

Pursuant to the authority vested in the Commissioner of Health by section 3369-a of the Public Health Law (PHL), subdivision 1004.1(a)(2) of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

§ 1004.1 Practitioner registration.

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

* * *

(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;

Regulatory Impact Statement

Statutory Authority:

The Commissioner is authorized pursuant to Section 3369-a of the Public Health Law to promulgate rules and regulations necessary to effectuate the provisions of Title V-A of Article 33 of the Public Health Law. Pursuant to Section 3360(12) of the Public Health Law, the Commissioner is specifically authorized to deem nurse practitioners as “practitioners” under Title V-A.

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 regulatory amendment is necessary in order for nurse practitioners registered with the Department to issue certifications for medical marihuana. Allowing nurse practitioners to issue certifications for medical marijuana will increase access to medical marihuana, benefiting patients suffering from one or more of the severe, debilitating or life threatening conditions enumerated in Section 3360(7) of the Public Health Law. This

regulatory amendment will particularly benefit those patients in rural counties where there are fewer physicians available to certify patients for medical marihuana.

Costs:

Costs to the Regulated Entity:

Nurse practitioners who are interested in registering with the Department to certify patients to use medical marihuana will first need to take a Department-approved medical use of marihuana course. Currently, the cost to take the required course is \$249.

Costs to Local Government:

This amendment to the regulation does not require local governments to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

Costs to the Department of Health:

With the authorization of nurse practitioners, additional practitioner registrations will need to be processed by the Department. In addition, the Department anticipates an increase in the number of patients certified to use medical marihuana. Depending upon the number of nurse practitioners who are interested in registering with the Department, this regulatory amendment may result in an increased cost to the Department for additional staffing to provide registration and certification support. However, any resulting cost of additional staffing is greatly outweighed by the benefit to public health in offering increased access to an alternative treatment option for patients suffering from one of the qualifying serious conditions.

Local Government Mandates:

This amendment does not impose any new programs, services, duties or responsibilities on local government.

Paperwork:

Nurse practitioners who register with the program and issue certifications to patients will be required to maintain a copy of the patient’s certification in the patient’s medical record.

Duplication:

No relevant rules or legal requirements of the Federal and State governments duplicate, overlap or conflict with this rule.

Alternatives:

The alternative would be to continue to limit the definition of “registered practitioner” solely to physicians.

Federal Standards:

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

Compliance Schedule:

There is no compliance schedule imposed by these amendments, which shall be effective upon publication of a notice of adoption.

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Regulatory Flexibility Analysis for Small Businesses and Local Governments

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 nurse practitioners is not a mandate imposed upon nurse practitioners.

Hence, no cure period is necessary.

Statement in Lieu of Rural Area Flexibility Analysis

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no other compliance costs imposed on public or private entities in rural areas as a result of the amendments.

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.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (“Department”) received comments from various stakeholders, including but not limited to professional associations, practitioners, legislators and the general public, in response to the proposed amendment to 10 NYCRR § 1004.1 that would allow nurse practitioners (“NPs”) to register with the Department to issue patient certifications for medical marijuana. The comments are summarized below with the Department’s responses. Overall, the majority of comments received were in support of the proposed amendment, with many commenters recommending the inclusion of physician assistants in addition to NPs. The Department reviewed and assessed each comment and determined that no revisions were necessary. However, the Department intends to proceed with a separate Notice of Proposed Rulemaking to allow physician assistants to register with the Department to issue patient certifications for medical marijuana.

COMMENT: One commenter recommended that NPs be allowed to certify medical marijuana only in suburban and rural areas of upstate New York. The commenter further stated that NPs should be prohibited from issuing patient certifications for medical marijuana in Long Island and New York City, where the majority of the registered physicians practice, and stated that a 50-mile restrictive covenant should be placed on NPs outside of all major cities within New York State. The commenter stated that an NP should be required to have a collaborative agreement with a registered physician.

RESPONSE: Although there are registered practitioners located in New York City and Long Island, data published in the Department’s Two-Year Report on the Medical Use of Marijuana demonstrates that there remains a need for additional practitioners who can issue patient certifications for medical marijuana. Pursuant to the New York State Education Law, an NP must have a collaborative agreement or relationship with a physician (depending on the circumstances). Within the scope of such arrangements, however, NPs are independently responsible for the care of their patients and do not require physician supervision or co-signature on their records or charts. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Several comments were received in support of adding physician assistants (PAs) as practitioners who may issue patient certifications for medical marijuana.

- Several commenters stated that PAs should be included as a means of increasing patient access and that failing to include PAs will disadvantage patients receiving medical care from PAs who would otherwise qualify for medical marijuana.
- Several commenters stated that it is within the scope of practice of PAs to issue patient certifications for medical marijuana, and that this would be consistent with the ability of PAs to prescribe controlled substances.
- One commenter stated that the reasons for allowing NPs to issue patient certifications also apply to PAs, and that the Department would be acting in an anticompetitive manner if it were to adopt this amendment without also including PAs. The commenter stated that PAs receive a broad, graduate-level education over approximately 27 months, which consists of a didactic and a clinical phase.

The commenter stated that by the time PA students complete their clinical rotations they have completed at least 2000 hours of supervised clinical practice in various settings. The commenter argued that this fully qualifies and equips PAs to diagnose, manage, and treat patients who present with conditions ranging from routine to complex. The commenter stated that it is vital to authorize PAs to certify patients for medical marijuana in order to ensure access for those patients throughout the State who receive their care from PAs, and to enable those patients to receive medical marijuana as part of their treatment without having to leave their practitioner.

RESPONSE: The Department will take these comments into consideration and intends to publish a Notice of Proposed Rulemaking that would enable PAs to issue patient certifications for medical marijuana. No changes to the proposed regulation were made as a result of these comments.

COMMENT: Several comments were received in support of adding NPs as practitioners.

- One commenter observed that NPs possess the skill, education and experience to diagnose patients as suffering from a “serious condition” and to determine whether a patient would benefit from medical marijuana.
- Several commenters observed that several other states already allow NPs to recommend medical marijuana.
- Several commenters observed that the addition of NPs will increase patient access to practitioners who can issue certifications.

- One commenter stated that the law already allows NPs to prescribe beneficial medications that can have risks if improperly used. The commenter also stated that New York passed the Nurse Practitioners Modernization Act in 2014 which allowed NPs to open their own practices, thereby demonstrating a degree of trust in NPs.
- One commenter expressed support for allowing NPs to issue certifications because, according to the commenter, it is increasingly difficult to secure an appointment with a pain management specialist. The commenter further stated that, because NPs can already prescribe pain medications, they should also have the ability to recommend medical marijuana.
- One commenter expressed support for allowing NPs to issue certifications because it would redress what, in the commenter's view, is inappropriate and unjustified discrimination against NPs in the current regulations.
- One commenter expressed support for allowing NPs to issue certifications because this will benefit patients in rural counties where fewer physicians are available.
- One commenter expressed support for allowing NPs to issue certifications and, in particular, the requirements that NPs must be in good standing and practicing within New York State, and that NPs must take a medical marijuana course approved by the Department. The commenter stated that the proposed regulation would increase access for patients living in rural areas and suffering from severe, debilitating, and life-threatening conditions, thereby reducing the disparity in availability throughout the state. The commenter further stated that the

amendment would stimulate a greater number of eligible patients to participate in the medical marijuana program, while also enlarging the number of qualified health care providers able to issue certifications. The commenter stated that the proposed amendment would increase the amount of excise taxes and fees collected by the State, thereby benefitting those areas where medical marijuana is manufactured and dispensed, and it would increase jobs and employment opportunities in New York.

RESPONSE: The Department acknowledges the comments in support of the regulatory amendment.