

Medical Use of Marihuana - Physician Assistants

Effective date: 3/15/17

Pursuant to the authority vested in the Commissioner of Health by Section 3701 of the Public Health Law (PHL), Section 94.2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, and in accordance with section 3369-a of the PHL, subdivision 1004.1(a)(2) of Title 10 is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

§ 94.2 Supervision and scope of duties.

(e) Prescriptions, certifications and medical orders may be issued by a licensed physician assistant as provided in this subdivision when assigned by the supervising physician:

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(6) A licensed physician assistant, in good faith and acting within his or her lawful scope of practice, and to the extent assigned by his or her supervising physician, may register as a practitioner under Part 1004 of this Title to issue patient certifications for medical marihuana, to those patients under the care of such supervising physician.

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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:

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(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;

Regulatory Impact Statement

Statutory Authority:

The Commissioner of Health 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 PHL. The Commissioner of Health is also authorized pursuant to section 3701 of the PHL to promulgate regulations defining and restricting the duties which may be assigned to physician assistants by their supervising physician, the degree of supervision required and the manner in which such duties may be performed.

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 amendments are necessary to allow physician assistants the ability to register with the Department to issue certifications for medical marihuana to patients under the care of such physician responsible for the physician assistant's supervision. Allowing physician assistants to certify patients to use medical marihuana 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:

Physician assistants who are interested in registering with the Department and whose supervising physician is already registered with the Department to certify patients to use medical marihuana, will 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 physician assistants, 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 physician assistants 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:

Physician assistants who certify patients to use medical marihuana 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 and nurse practitioners.

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 physician assistants is not a mandate imposed upon physician assistants. 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 healthcare providers and healthcare provider associations. The comments are summarized below with responses.

COMMENT: A commenter objected to the requirement that the physician supervising the physician assistant (PA) must be registered with the Department to certify patients, in order for the PA to certify patients for medical marijuana. The commenter stated that there is no such requirement for nurse practitioners (NPs) and that there is little difference between nurse practitioners and PAs. The commenter further stated that requiring the supervising physician to also register will thwart the intent to increase access to practitioners. The commenter suggested allowing a supervising physician, as well as a collaborating physician for nurse practitioners, to acknowledge his or her approval of a PA’s or nurse practitioner’s registration with the Department, instead of requiring the supervising physician to register.

RESPONSE: The requirement that a PA’s supervising physician be registered with the Medical Marijuana Program to certify patients is consistent with the scope of practice of PAs. Pursuant to New York State Education Law § 6542, a PA may perform medical services, but only under the supervision of a physician and only such acts and duties as are assigned and within the scope of practice of such supervising physician. The Commissioner is authorized pursuant to Public Health Law § 3701 to promulgate regulations defining and restricting the duties which may be assigned to PAs by their supervising physician, the degree of supervision required, and the manner in which such duties may be performed. Requiring a PA’s supervising physician to register with the Medical Marijuana Program ensures that the PA is practicing within the scope

of practice of the supervising physician. Pursuant to New York State Education Law § 6902, NPs work collaboratively with licensed physicians but are not required to practice under physician supervision. No changes to the proposed regulation were made as result of these comments.

COMMENT: A commenter stated that NPs with less than two years of experience must have a collaborative agreement or relationship with a physician and therefore do not work independently. The commenter further stated that many NPs are employed by hospitals, health practices, and community health centers, and are therefore subject to policies and protocols of the practice and not practicing independently. The commenter stated that the regulations proposed do not address how NPs who are employed within a practice setting should resolve differences of opinion concerning treatment, or whether they need to receive approval prior to registration.

RESPONSE: These comments are beyond the scope of the proposed regulation, which deals specifically with the authority for PAs to certify patients for the medical use of marijuana. No changes to the proposed regulation were made in response to this comment.

COMMENT: Comments were received in support of the proposed regulation:

- A commenter stated that PAs work in a wide variety of medical disciplines throughout New York State and are involved in all aspects of patient care. The commenter stated that the proposed rule will benefit patients receiving medical care from PAs throughout the state for treatment of serious conditions, as set forth in Public Health Law § 3360(7). This is particularly true in rural counties where fewer

physicians are available to treat such illnesses and ailments. The commenter further stated that authorizing PAs to certify patients suffering from these conditions is consistent with the authority given to PAs to prescribe controlled substances, including opioids.

- A commenter stated that the proposed regulation is consistent with PA education and training and that the Centers for Medicare and Medicaid Services recently attested to the quality of PA education and training. The commenter further stated that the proposed regulation is consistent with New York State Public Health Law § 3703.

RESPONSE: The Department acknowledges the comments in support of the regulatory amendment. No revisions to the regulation are necessary to address these comments.