

Medical Use of Marihuana

Effective date: 7/12/18

Pursuant to the authority vested in the Commissioner of Health by section 3369-a of the Public Health Law (PHL), Section 1004.2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, to be effective upon filing with the Secretary of State, to read as follows:

Section 1004.2 Practitioner issuance of certification.

(a) Requirements for Patient Certification. A practitioner who is registered pursuant to 1004.1 of this part may issue a certification for the use of an approved medical marihuana product by a qualifying patient. Such certification shall contain:

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(8) the patient's diagnosis, limited solely to the specific severe debilitating or life-threatening condition(s) listed below;

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(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]

(xii) post-traumatic stress disorder;

(xiii) any condition for which an opioid could be prescribed, provided that the precise underlying condition is expressly stated on the patient's certification; or

(~~xiii~~xiv) 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 thirty-three hundred sixty 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) post-traumatic stress disorder;

(vii) opioid use disorder, but only if enrolled in a treatment program certified pursuant to Article 32 of the Mental Hygiene Law; or

(~~vi~~viii) such other conditions, symptoms or complications as added by the commissioner.

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 3360(7) of the PHL to add serious conditions under which patients may qualify for the use of medical marihuana.

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 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 registered practitioners to issue certifications for the medical use of marihuana as an alternative to prescription opioids. This regulatory amendment will particularly benefit patients with conditions for which opioids could otherwise be prescribed, as medical marihuana will now be an available alternative to opioids. Permitting the medical use of marihuana as an alternative to opioids will offer an additional treatment option for registered practitioners. In addition, adding opioid use disorder as a clinically associated condition will allow individuals who are addicted to opioids to instead use medical marihuana. Requiring practitioners to expressly state the precise underlying condition will help the

Department to better understand how medical marihuana can be used as an alternative to prescription opioids.

The amendments are also necessary to conform the regulations to recent amendments to Section 3360(7) of the PHL that added post-traumatic stress disorder as a serious condition.

Costs:

Costs to the Regulated Entity:

Patients certified by their practitioner for the medical use of marihuana will have to pay a \$50 non-refundable application fee to obtain a registry identification card to register with the Medical Marihuana Program. However, the Department may waive or reduce this fee in cases of financial hardship. Patients will also have a cost associated with the fees charged by registered organizations for the purchase of medical marihuana products.

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 inclusion of these new serious conditions, additional patient registrations will need to be processed by the Department. In addition, there may be an increase in the number of practitioners who register with the program to certify patients who may benefit from the use of medical marihuana for these new serious conditions. This regulatory amendment may result in an increased cost to the Department for additional staffing to provide registration support for patients and practitioners as well as certification support for registered practitioners. However,

any resulting cost of additional staffing is greatly outweighed by the benefit of making another treatment option available to practitioners who are treating patients suffering from severe pain or opioid use disorder.

Local Government Mandates:

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

Paperwork:

Registered practitioners who certify patients for the program 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:

An alternative would be to not allow medical marihuana as a treatment for opioid use disorder or conditions for which an opioid could be prescribed. However, medical marihuana has been shown to be an effective treatment for pain, to reduce the chance of opioid dependence, and there is no risk of fatal overdose compared to opioid-based medications.

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 filing with the Secretary of State.

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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 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 regulation. The regulatory amendment authorizing the addition of this serious condition does not mandate that a practitioner register with the program. This amendment does not mandate that a registered practitioner issue a certification to a patient who qualifies for this new serious condition. 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 amendment, that it will not have an adverse impact on jobs and employment opportunities.

Emergency Justification

In New York State, the number of overdose deaths involving opioids has increased from over 1,000 deaths in 2010, to over 3,000 deaths in 2016. The opioid epidemic is an unprecedented crisis and practitioners should have as many treatment options available to them as possible.

Medical marihuana has been demonstrated to be an effective treatment option for pain, thereby reducing the chance of dependence and the risk of fatal overdose as compared to opioid-based medications. Studies of some states with medical marihuana programs have found notable associations of reductions in opioid deaths and opioid prescribing with the availability of cannabis products. States with medical marihuana programs have also been found to have less opioid overdose deaths than other states by as much as 25 percent. Studies of opioid prescribing in some states with medical marihuana programs have noted a 5.88 percent lower rate of opioid prescribing.

The regulations are necessary to immediately allow registered practitioners the option of certifying patients to use medical marihuana instead of prescribing opioids. In doing so, the regulations will help prevent patients from relying on prescription opioids for severe pain that is not expected to last more than three months. In addition, adding opioid use disorder as a clinically associated condition will allow individuals who are addicted to opioids, but who don't suffer from severe or chronic pain, to instead use medical marihuana. The amendments are also necessary to conform the regulations to recent amendments to Section 3360(7) of the PHL that added post-traumatic stress disorder as a serious condition.