

Medical Use of Marihuana - Chronic Pain

Effective date: 3/22/17

Pursuant to the authority vested in the Commissioner of Health by sections 3360 and 3369-a of the Public Health Law (PHL), sections 1004.1 and 1004.2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby 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 section 1004.2 unless the practitioner:

(1) is qualified to treat patients with one or more of the serious conditions set forth in [subdivision 7 of section 3360 of the Public Health Law or as added by the commissioner] subdivision 1004.2(a)(8) of this Part;

\* \* \*

**§ 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:

\* \* \*

(8) the patient's diagnosis, limited solely to the specific severe debilitating or life-threatening condition(s)[, as defined in subdivision seven of section thirty-three hundred sixty of the public health law and] listed below [as the following];

\* \* \*

(x) Huntington's disease; [or]

(xi) [any other condition added by the commissioner.] 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) any other condition 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 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 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 health and safety of the public.

### **Needs and Benefits:**

The regulatory amendments are necessary to allow registered practitioners to issue certifications for the medical use of marihuana to those patients suffering from severe debilitating pain. This amendment benefits patients with severe debilitating pain which 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 extending three months or more beyond onset, or the practitioner reasonably anticipates that the pain will last three months or more beyond onset.

Permitting the medical use of marihuana for patients suffering from chronic pain will offer an additional treatment option for those patients.

**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 register with the Medical Marijuana Program and obtain a registry identification card. However, the Department may waive or reduce this fee in cases of financial hardship. Patients will also have a cost associated with the purchase of approved medical marihuana products from registered organizations.

**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 this new serious condition, 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. 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. It is anticipated that these additional activities can be accommodated within the existing resources of the Department.

**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:**

The alternative would be to continue to limit serious conditions solely to those enumerated in Section 3360(7) of the Public Health Law.

**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 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 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 public comments in response to the proposed changes to Title 10 NYCRR sections 1004.1 and 1004.2, which would allow practitioners to certify patients for medical marijuana for any severe debilitating or life-threatening condition that the practitioner determines causes the patient chronic pain which degrades the health and functional capability of the patient. Comments were received from various stakeholders, including but not limited to professional associations, practitioners, registered organizations and the general public. These comments and the Department’s responses are summarized below:

**COMMENT:** A commenter noted that there is very little scientific literature on the use of medical marijuana for medical conditions, especially chronic pain. The commenter stated that the use of medical marijuana to treat chronic pain may be inconsistent with national treatment guidelines established by the Centers for Disease Control and Prevention (CDC) and reported by the Institute of Medicine (IOM). The commenter also stated that as the federal administration changes, the continuation of the United States Department of Justice’s position is questionable. Because enforcement actions are performed by both state and federal agencies, there is a desire to not expose healthcare providers to additional liability and prosecutorial actions without explicit federal protection.

**RESPONSE:** The Department conducted a thorough review of available scientific literature before determining that chronic pain should be included as a condition that may qualify a patient for the use of medical marijuana. Because the federal government classifies medical marijuana as a Schedule 1 Controlled Substance, neither the CDC nor the IOM has established guidelines for its medical use. Nevertheless, New York State has established a medical marijuana program

that provides a comprehensive regulatory framework that includes, but is not limited to, strict guidelines for manufacturing, quality control, security, reporting, and prevention of diversion of marijuana.

**COMMENT:** A number of comments were received seeking to expand the definition of chronic pain to allow for increased access to medical marijuana.

- Several commenters shared personal stories of illnesses that resulted in chronic pain and of the negative impact caused by long-term use of opioids. Numerous commenters urged that the provision requiring contraindications, intolerable side effects, or failure of other therapeutic options, as a requirement for medical marijuana certification, be eliminated because such options may involve use of prescription opioids. Many commenters stated that this might cause patients to try what they considered more dangerous treatment involving prescription opioids, and to fail or be harmed by them, before qualifying for the safer alternative of medical marijuana. Commenters stated that patients and their physicians should not be required to try other medications before qualifying for medical marijuana. Commenters stated that severe pain can wreak devastation on the lives of patients, and that having marijuana as an option when a physician first sees a patient would make patients' lives more manageable.
- Commenters claimed that chronic pain is a qualifying condition in other states that have legalized medical marijuana, that in nearly all of these states medical marijuana can be recommended in the first instance, and that there are no added requirements that patients suffer contraindications, intolerable side effects or failure of other therapeutic options causing a significant diminution in their quality of life for at least three months.

- Commenters suggested that the proposed regulation be revised to allow any patient with “severe pain” to access medical marijuana when their practitioner recommends it, without any other conditions. One commenter suggested that any amount of pain experienced on a daily basis should be able to be treated initially by medical marijuana.
- Several commenters referred to studies or data that they argued demonstrate that medical marijuana is a safer alternative to other medications, and that it may help people suffering from chronic pain to reduce opiate use.

**RESPONSE:** The proposed regulation does not steer practitioners or their patients toward any medication or type of treatment. The regulation acknowledges the many therapeutic treatment options available for severe, debilitating pain, while recognizing the absence of available guidance on the use of medical marijuana as a first option for treating pain. When reviewing the scientific literature on the potential benefits of the use of medical marijuana by patients suffering from chronic pain, the Department evaluated the availability of conventional treatments. Such treatments include, but are not limited to: physical or occupational therapy, massage therapy, acupuncture, the use of non-steroidal anti-inflammatory medications (NSAIDs), acetaminophen, topical creams or ointments and Transcutaneous Electro-Nerve Stimulator Units (TENS). The Department expects that the certifying practitioner will attempt one or more treatments appropriate for a patient, prior to recommending medical marijuana. However, there is no requirement that opioids, surgery or other specific treatments be attempted. Also, a practitioner with an established patient relationship may already have documentation related to the patient’s pain lasting three months or longer. Further, under the regulation, the practitioner may determine that, in their professional medical judgment, they “reasonably anticipate such pain to last three months or more beyond onset.” No revisions were made to address these comments.

**COMMENT:** Comments were received in support of the proposed regulation as follows:

- A commenter claimed that chronic pain has already been approved as a qualifying condition for medical marijuana treatment in a number of other states.
- A commenter suggested that the proposed amendment would have the effect of relieving long-term, debilitating pain and suffering of individuals with serious medical conditions while also reasonably protecting public health and safety.
- A commenter stated that the proposed change would likely stimulate a significant number of severe pain patients to participate in the medical marijuana program, oftentimes in lieu of opioid-based pain therapy. The commenter further speculated that this would result in an increased amount of taxes and fees collected by the State, a reduction in the harm caused by opioid addiction and diversion, and an increase in medical marijuana-related jobs and employment opportunities for New York residents.
- A commenter claimed that many medical marijuana patients have been able to reduce or eliminate the use of addictive and dangerous pharmaceuticals that have far more severe side effects than marijuana. The commenter further noted that the proposed rule retains strict standards for patients to qualify for medical marijuana, which are more stringent than those of many other states. The commenter predicted that the program would provide relief for thousands of patients suffering from pain and from the negative and harmful effects of opiates, anti-seizure medicines, anti-depressants and other potentially deadly drugs commonly prescribed for pain. The commenter stated that each day, more individuals begin using addictive prescription drugs for pain. Others become ill, suffer permanent damage, or die from their use. The commenter urged that the Department immediately enact this rule change.

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