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.