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 publication of a notice of adoption in the State Register, 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 subject to completion of subdivision (e) of this section. Such certification shall contain:

* * *

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

* * *

(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) pain that degrades health and functional capability where the use of medical marihuana is an alternative to opioid use, provided that the precise underlying condition is expressly stated on the patient's certification; or

(xiv) substance use disorder; or

([xii]xv) 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; or

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

(10) a statement that by training or experience, the practitioner is qualified to treat the serious condition, which encompasses the severe debilitating or life-threatening condition listed pursuant to paragraph (8) of this subdivision and the clinically associated condition, symptom or complication listed pursuant to paragraph (9) of this subdivision;

(i) for purposes of this subdivision, a practitioner must hold a federal Drug Addiction Treatment Act of 2000 (DATA 2000) waiver to be qualified to treat patients with substance use disorder or opioid use disorder.

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 PHL, and protecting the public against risks to its health and safety.

Needs and Benefits:

The regulatory amendments are necessary to conform the regulations to recent amendments to Section 3360(7) of the PHL that added post-traumatic stress disorder, pain that degrades health and functional capability where the use of medical marihuana is an alternative to opioid use, and substance use disorder, as serious conditions for which patients may be certified to use medical marihuana. This regulatory amendment will particularly benefit patients with these conditions as medical marihuana will now be an available treatment option. 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 or adjunctive therapy to prescription opioids.

In addition, adding substance use disorder as a severe debilitating or life-threatening condition and opioid use disorder as a clinically associated condition will allow individuals who are addicted to opioids to use medical marihuana as part of their treatment. The regulation requires practitioners certifying patients for substance use disorder and opioid use disorder to hold a federal Drug Addiction Treatment Act of 2000 (DATA 2000) waiver.

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, and is currently waiving this fee for all patients and caregivers. 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 amend the regulation to align with Section 3360(7) of the PHL. However, this was not considered a viable alternative, as it would create confusion for registered practitioners and patients seeking to be certified for the medical use of marihuana.

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 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 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.