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. This revised rulemaking removes the requirement that a patient be enrolled in a treatment program certified pursuant to Article 32 of the Mental Hygiene Law. The regulation would instead require 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.

Assessment of Public Comment

The Department of Health ("Department") received comments from various stakeholders, including practitioners, addiction treatment programs, and patients. Comments were received regarding the evidence surrounding marihuana as a treatment for opioid use disorder, the federal status of marihuana, and various other topics. These comments are summarized below along with the Department's responses.

COMMENT: Comments were received regarding the scientific evidence demonstrating the effectiveness of medical marihuana as an alternative treatment to opioid use disorder. Commenters noted the dangers associated with opioid use disorder and the need to ensure the safety of those patients recovering from opioid use disorder without the benefit of medication assisted treatment. Commenters were concerned that medical marihuana would be advertised as a first line of treatment or as a treatment for all patients with opioid use disorder, and asked the Department to conduct more public education around medical marihuana. Some commenters proposed conducting a pilot study before allowing medical marihuana to be added to the list of available treatments for opioid use disorder.

RESPONSE: The regulations conform to recent amendments to Section 3360 of the Public Health Law (PHL), which became effective on September 24, 2018, and that specifically included substance use disorder as a qualifying condition. Further, a practitioner must be registered with the Department and must be qualified by training or experience to treat the serious condition for which the patient's certification is being issued. When issuing the certification, the registered practitioner must comply with the requirements of certification, as provided in 10 NYCRR § 1004.2. In particular, practitioners must consult the prescription

monitoring program registry to review the patient's controlled substance history, review past treatments to determine if the patient is likely to receive therapeutic or palliative benefit from primary or adjunctive treatment with medical marihuana, explain the potential risks and benefits to the patient, and document in the patient's medical record that the explanation has been provided. These steps ensure that appropriate safeguards are in place so that only patients who would benefit from medical marihuana receive certification. Allowing medical marihuana for opioid use disorder provides another tool in the toolkit for practitioners to use, in their clinical discretion, for their patients. No changes to the proposed regulations were made as a result of these comments.

COMMENT: Comments were received stating that medical marihuana is not a treatment option approved by the U.S. Food and Drug Administration (FDA).

RESPONSE: Although medical marihuana is not an FDA-approved treatment option, Title V-A of the Public Health Law makes marihuana available to patients who are suffering from a serious condition, as defined in the statute. Medication assisted treatment with FDA-approved medications, such as methadone, buprenorphine or naltrexone, in combination with counseling and behavioral therapies, continues to be the standard of care for opioid use disorder and has been proven to be clinically effective. Registered practitioners must weigh the risks versus the benefits for each patient when determining whether certification for medical marihuana is appropriate. No changes to the proposed regulations were made as a result of these comments.

COMMENT: Comments were received regarding the interplay between federal law and the proposed regulation. Commenters noted that any inconsistency with federal law may make treatment providers that receive federal funding uncomfortable with changing their policies.

RESPONSE: The Medical Marihuana Program and the Compassionate Care Act are firmly established in state law, as are many other medical marihuana programs around the nation. Possible ramifications with respect to federal law are not within the Department's purview. No changes to the proposed regulations were made as a result of these comments.

COMMENT: Comments were received regarding the proposed regulations' impact on local government programs and treatment centers that have traditionally prohibited marihuana use. Commenters stated that significant changes to these entities' policies would need to occur to accommodate medical marihuana patients in these programs.

RESPONSE: OASAS has published guidelines for the use of medical marihuana in OASAS programs, which is available here: https://www.oasas.ny.gov/legal/documents/OASASFAQsMedicalMarihuana.pdf. No changes to the proposed regulations were made as a result of these comments.

COMMENT: Numerous commenters questioned the effectiveness of medical marihuana as a treatment option for opioid use disorder. Concern was expressed about side effects as well as the effect on brain development in adolescents.

RESPONSE: The regulations conform to recent amendments to Section 3360 of the PHL, which became effective on September 24, 2018, and that specifically included substance use disorder as a qualifying condition. Moreover, preclinical studies have demonstrated that

marihuana may help patients with opioid use disorder. As noted above, registered practitioners must weigh the risks versus the benefits for each patient when determining whether certification for medical marihuana is appropriate. When issuing the certification, the registered practitioner must comply with the requirements of certification, as provided in 10 NYCRR § 1004.2. Practitioners must consult the prescription monitoring program registry to review the patient's controlled substance history, review past treatments to determine if the patient is likely to receive therapeutic or palliative benefit from primary or adjunctive treatment with medical marihuana, explain the potential risks and benefits to the patient, and document in the patient's medical record that the explanation has been provided. These steps ensure that appropriate safeguards are in place so that only patients who would benefit from medical marihuana receive certification. Allowing medical marihuana for opioid use disorder provides another tool in the toolkit for practitioners to use, in their clinical discretion, for their patients. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter pointed out how there are now two serious conditions relating to pain, and how patients could be certified to use medical marihuana for both short-term pain management, as well as long-term pain management.

RESPONSE: As background, these regulations were amended in March 2017 to include chronic pain as a serious condition for which a practitioner could recommend medical marihuana. Those amendments defined chronic pain as "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." Additionally, chronic pain must also have lasted three months or be

anticipated to last more than three months. The proposed regulation would add, as a serious condition, pain that degrades health and functional capability where the use of medical marihuana is an alternative to opioid use and substance use disorder as qualifying conditions. As noted above, these amendments conform to the recent statutory amendments to Section 3360(7) of the PHL, which were signed into law on September 24, 2018. Accordingly, the proposed regulations would permit medical marihuana to be recommended for any condition for which an opioid could be prescribed including, but not limited to: acute pain, post-operative pain management, severe or persistent muscle spasms, and opioid use disorder. No changes were made to the proposed regulations as a result of this comment.

COMMENT: A commenter suggested limiting the scope of the proposed regulation by allowing for the use of medical marihuana for opioid use disorder only pursuant to a research study approved by an Institutional Review Board (IRB).

RESPONSE: The regulations conform to recent amendments to Section 3360 of the PHL that specifically include substance use disorder as a qualifying condition, and which became effective on September 24, 2018. These statutory amendments do not contemplate approval by an IRB as a required step to access medical marihuana. No changes were made to the proposed regulations as a result of this comment.

COMMENT: Commenters expressed concern that practitioners would recommend medical marihuana without adequate knowledge about how it works.

RESPONSE: Every practitioner must complete a two- to four-hour course on the medical use of marihuana in order to register with the Department to certify patients for the medical use of

marihuana. The practitioner must also be qualified by training or experience to treat the serious condition for which a patient's certification is being issued. Practitioners must explain the potential risks and benefits to the patient and document in the patient's medical record that the explanation has been provided. No changes to the proposed regulations were made as a result of these comments.

COMMENT: Commenters requested clarification on how practitioners should monitor Tetrahydrocannabinol (THC) levels and dosages in patients.

RESPONSE: These comments address issues beyond the scope of the regulatory amendment. However, the Department notes that appropriate dosing depends on various factors, such as the cannabinoid content of THC and cannabidiol (CBD) in the product, as well as the patient's condition and prior history of cannabis use. No changes to the regulations were made as a result of these comments.

COMMENT: A comment was received regarding the security of marihuana at treatment programs certified pursuant to Article 32 of the Mental Hygiene law.

RESPONSE: OASAS has published guidance that includes information regarding secure storage of marihuana at treatment programs, which is available here: https://www.oasas.ny.gov/legal/documents/OASASFAQsMedicalMarihuana.pdf. Patients may hold and self-administer their medication in accordance with OASAS Local Services Bulletin No. 2012-04: Medication Administration Policies for the Administration of Medications in OASAS Intensive Residential Programs. An inpatient or residential treatment program certified pursuant to Article 32 of the Mental Hygiene Law may seek designation as a caregiver with the

DOH Medical Marijuana Program, thereby permitting such facilities to hold and/or administer medical marihuana on behalf of a certified patient. No changes to the proposed regulations were made as a result of these comments.

COMMENT: Comments were received regarding the legalization of marihuana generally.

RESPONSE: These comments address issues beyond the intended scope of the regulation. No changes to the regulations were made as a result of these comments.