

Pursuant to the authority vested in the Commissioner of Health by section 3369-a of the Public Health Law (PHL), section 1004.11 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (n) of section 1004.11 is amended to read as follows:

\* \* \*

(n) No synthetic marihuana additives nor any cannabinoid preparation not produced by a registered organization in an approved manufacturing facility shall be used in the production of any medical marihuana product[.]; provided, however, that a registered organization may use hemp, or extracts derived from hemp, grown and processed under the authority of the New York State Department of Agriculture and Markets in the manufacturing of medical marihuana products.

## **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.

### **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:**

Regulatory amendments to subdivision (n) of section 1004.11 are necessary to allow registered organizations the ability to use extracts derived from hemp, such as cannabinoids and terpenes, as additives to the registered organization's approved medical marihuana products. This use is limited to hemp and extracts derived from hemp, and only when grown and produced under the authority of the New York State Department of Agriculture and Markets. Allowing registered organizations to use hemp and its derivatives will help to reduce registered organizations' manufacturing costs, thereby reducing costs to patients.

**Costs:**

**Costs to the Regulated Entity:**

The regulatory amendments do not impose additional costs to regulated entities. Registered organizations will likely benefit from a reduction in manufacturing costs as a result of the allowance of hemp and extracts derived from hemp.

**Costs to Local Government:**

The regulatory amendments do 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 availability of hemp and hemp extracts, additional effort will be required to review product proposals, test new medical marijuana products, and monitor compliance as the Department continues to balance the need to make medical marijuana products available at lower costs while protecting public health and safety. Any additional workload will be handled within existing resources.

**Local Government Mandates:**

These amendments do not impose any new programs, services, duties or responsibilities on local government.

**Paperwork:**

The regulatory amendments do not impose any new recordkeeping or paperwork requirements.

**Duplication:**

No relevant rules or legal requirements of the Federal and State governments duplicate, overlap or conflict with these regulations.

**Alternatives:**

An alternative to the regulatory amendments would be to not make any changes to the regulation. However, this alternative was not adopted since the regulatory amendments will help to lower registered organizations' manufacturing costs, ultimately resulting in lower-cost medical marihuana products for patients, without compromising patient safety.

**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 New York State Register.

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### **Statement in Lieu of Regulatory Flexibility Analysis**

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.

### **Statement in Lieu of Rural Area Flexibility Analysis**

A Rural Area Flexibility Analysis for these amendments is not being submitted because the 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.