

Pursuant to the authority vested in the Commissioner of Health by Section 3369-a of the Public Health Law (PHL), Section 1004.14 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended, and pursuant to Section 502 of the PHL, Subpart 55-2 of Title 10 is amended, to be effective upon publication of a notice of adoption in the State Register, to read as follows:

Section 1004.14 is amended to read as follows:

(a) Medical marihuana products produced by a registered organization shall be examined in a laboratory located in New York State that is licensed by the [Federal Drug Enforcement Administration (DEA)] department's Bureau of Narcotic Enforcement and approved for the analysis of medical marihuana by the department in accordance with article 5 of the Public Health Law and Subpart 55-2 of this Title.

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(g) Testing for contaminants in the final medical marihuana product shall include but shall not be limited to those analytes listed below. The department shall make available a list of required analytes and their acceptable limits as determined by the commissioner.

Analyte:

E. coli

Pseudomonas (for products to be vaporized)

Salmonella species

Enterococcus species

Bile tolerant gram negative bacteria, specifically including Klebsiella species

Clostridium botulinum

Aspergillus species

Mucor species

Penicillium species

Thermophilic Actinomycetes species

[Aflatoxins A1,] Aflatoxins B1, B2, G1, G2

Ochratoxin A

Antimony

Arsenic

Cadmium

Chromium

Copper

Lead

Nickel

Zinc

Mercury

Any pesticide used during production of the medical marihuana product

Any growth regulator used during production of the medical marihuana product

Any other analyte as required by the commissioner

(h) laboratories performing final product testing pursuant to this section must report all results to the department, in a manner and timeframe prescribed by the department.

([h]i) Stability testing shall be performed on each brand and form of medical marihuana product as follows:

(1) For testing of open products, stability testing shall be performed for each extract lot, at time zero when opened and then, at a minimum, at 60 days from the date of first analysis. This shall establish use of the product lot within a specified time once opened.

(2) For testing of unopened products, until stability studies have been completed, a registered organization may assign a tentative expiration date based on available stability information. The registered organization must concurrently have stability studies conducted by an approved laboratory to determine the actual expiration date of an unopened product.

(3) For stability testing of both opened and unopened products, each brand shall retain a total THC and total CBD concentration in milligrams per single dose that is consistent with section 1004.11(c)(3) of this Part. If stability testing demonstrates that a product no longer retains a consistent concentration of THC and CBD pursuant to section 1004.11(a)(2) of this Part, the product shall be deemed no longer suitable for dispensing or consumption. The department may request further stability testing of a brand to demonstrate the ongoing stability of the product produced over time.

(4) The department may waive any of the requirements of this subdivision upon good cause shown.

([i]j) The laboratory shall track and use an approved method to dispose of any quantity of medical marihuana product that is not consumed in samples used for testing. Disposal of medical marihuana shall mean that the medical marihuana has been rendered unrecoverable and beyond reclamation.

(l) Any submitted medical marijuana products that are deemed unsuitable for testing shall be returned to the registered organization under chain of custody.

Subdivision (b) of section 55-2.15 is amended to read as follows:

(b) (1) Prior to performing testing for any medical marijuana, medical marijuana product or final medical marijuana product, a laboratory physically located within New York State shall submit a request to the department, and receive an initial or revised certificate of approval that includes the specialty of medical marijuana testing and the approved method(s) the laboratory is authorized to employ as stipulated in sections 55-2.1 and 55-2.5 of this Subpart, in addition to a valid [and federally-recognized Drug Enforcement Administration registration] Class 8 Analytical Laboratory license, issued by the department's Bureau of Narcotic Enforcement. The certificate of approval shall also list the specific subcategories, analytes, and approved methods included in the approval. No laboratory shall examine a sample related to medical marijuana without certification of approval specific to this category and meeting all other provisions within this Subpart; and

(2) the department may withhold or limit its approval if the department is not satisfied that:

(i) the laboratory has in place adequate policies, procedures, and facility security (physical and cyber security) to ensure proper: collection; labeling; accessioning; preparation; analysis; result reporting for; and disposal of and storage of medical marijuana, medical marijuana product or final medical marijuana product as defined in section 55-2.15(a) of this Subpart; or

(ii) the laboratory is able to meet the requirements applicable to it as set forth in title V-A of article 33 of the Public Health Law, and section 1004.14 of this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The Commissioner 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. Pursuant to Section 502 of the PHL, the Commissioner is authorized to promulgate rules and regulations necessary to effectuate the provisions and purpose of Title I of Article 5 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 medical conditions, as defined in Section 3360(7) of the Public Health Law, and protecting the public against risks to its health and safety. The legislative objective of Section 502 of the PHL is to regulate the approval of environmental laboratories and the examination of samples or specimens that could contribute to pollution or be contaminated.

Needs and Benefits:

The proposed regulations are necessary to remove the requirement that laboratories seeking Environmental Laboratory Approval Program (ELAP) certification to test medical marihuana products in New York State be registered by the Drug Enforcement Administration (DEA). The DEA recently indicated that it is not registering commercial laboratories to perform testing in

state regulated medical marihuana programs. Therefore, the removal of this requirement is necessary in order for an independent commercial laboratory to obtain ELAP approval to perform medical marihuana testing in New York State. A failure to certify independent laboratories to perform such testing could result in delays in medical marihuana availability to patients suffering from serious conditions. The amended regulations also clarify that laboratories seeking to perform medical marihuana testing must first obtain a class 8 analytical laboratory license from the Department of Health's Bureau of Narcotics Enforcement (BNE), in addition to meeting all other ELAP standards. The amended regulations also fix the spelling of the word "Aflatoxins" and remove the requirement for testing of Aflatoxin A1. Finally, the amended regulations will require medical marihuana testing laboratories to report all results to the Department.

Costs

Costs to the Regulated Entity:

Laboratories seeking ELAP approval to test medical marihuana will benefit from the removal of the DEA registration requirement, as there are costs associated with obtaining such registration.

Costs to Local Government:

The proposed rule does not require the local government to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

Costs to the Department of Health:

The proposed rule does not require the Department of Health to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

Local Government Mandates:

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

Paperwork:

Laboratories performing final product testing will be required to report all test results to the department, in a manner and timeframe prescribed by the department. It is anticipated that this reporting will be performed electronically to the department so that no additional paperwork would be required.

Duplication:

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

Alternatives:

The Department's Wadsworth Center could continue to be the sole provider responsible for conducting all testing for medical marijuana. However, this option is not viable given that the Wadsworth Center's capacity to conduct all of the necessary testing on every medical marijuana

product is diminishing as the medical marihuana program expands with additional registered organizations and expanded product offerings.

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.

Contact Person:

Ms. Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (Fax)
regsqa@health.ny.gov

**STATEMENT IN LIEU 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 clarifying laboratory requirements does not mandate a laboratory to participate or register with the medical marihuana program. Hence, no cure period is necessary.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

No Rural Area Flexibility Analysis is required pursuant to Section 202-bb(4)(a) of the State Administration Procedure Act (SAPA). It is apparent from the nature of the proposed regulation that it will not impose any adverse impact on rural areas, and the rule does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

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.