Section 55-2.15 - Requirements for laboratories performing testing for medical marihuana

55-2.15 Requirements for laboratories performing testing for medical marihuana.

(a) For purposes of this subpart, the following terms shall have the following meanings:

(1) “medical marihuana” shall mean marihuana as defined in subdivision twenty-one of section thirty-three hundred two of the public health law, intended for a certified medical use, as determined by the commissioner in his or her sole discretion.

(2) “medical marihuana product” shall mean any material produced from medical marihuana prior to its final packaging, e.g, extracts.

(3) “final medical marihuana product” shall mean the final medical marihuana product as dispensed to the patient. Any form of medical marihuana not approved by the commissioner is expressly prohibited.

(4) “registered organization” shall mean a for-profit business entity or not-for-profit corporation organized for the purpose of acquiring, processing manufacturing, selling, delivering, transporting, distributing or dispensing medical marihuana in accordance with the requirements of title 5-A of article 33 of the public health law.

(b) (1) Prior to performing testing for any medical marihuana, medical marihuana product or final medical marihuana 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 marihuana 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. 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 marihuana 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 marihuana, medical marihuana product or final medical marihuana 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.

(c) In addition to application and attestation requirements found elsewhere in this subpart, a laboratory seeking approval to perform medical marihuana, medical marihuana product or final medical marihuana product testing shall submit:

(1) a standard operating procedure manual documenting laboratory policies, procedures, facilities, equipment, supplies, instrumentation and personnel for medical marihuana, medical marihuana product or final medical marihuana product testing, which are designed to ensure proper: collection; labeling; accessioning; preparation; analysis; result reporting or, disposal of and storage of medical marihuana, medical marihuana product or final medical marihuana product as defined in section 55-2.15(a) of this subpart including any validation summaries or data as requested; and

(2) an attestation signed by the owner(s) and director(s) that, in addition to meeting the preceding requirements of this subpart, a laboratory engaged in medical marihuana testing, through its owner(s) and director(s), shall:

(i) confirm that the laboratory shall accept only the type(s) of samples specified on the laboratory's certificate of approval;

(ii) confirm that the laboratory owner(s) and director(s) is independent of any owner and employee of a registered organization; and

(iii) confirm that the owner(s) and director(s) will ensure that all test results are reported in a manner and form consistent with the approved method and with requirements in title V-A of article thirty-three of the public health law, including but not limited to:

(a) reporting of results, as applicable, including regulated analytes as well as any contaminants listed in section 1004.14(g) of this title to the registered organization and the department using a department approved mechanism; and

(b) reporting of any improprieties regarding the medical marihuana product testing, including but not limited to, theft and the falsification of any data, documentation, or attestation related to the medical marihuana product testing to the department within two (2) business days from the date of learning of the impropriety.

(c) The approval of mobile laboratories is prohibited for the purposes of this section.

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