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From: Tim Schnupp <tschnupp@uscannalytics.com>
Sent: Monday, April 5, 2021 4:08 PM
To: DH, MMRegulations
Cc: Greg Gottheimer; Tara Pendergraft
Subject: [External] Public Comment - Proposed Rulemaking Medical Marijuana Proposed Regulations
Attachments: 210405 US Cannalytics Draft Comments_FINAL.pdf

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To Whom it May Concern,

Please find the attached public comments for US Cannalytics. Thank you and please feel free to reach out with any questions.

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US Cannalytics
Cannabis and Hemp Testing You Can Depend On

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John J. Collins, Director
Office of Medical Marijuana
Department of Health Room 628
Health and Welfare Building
625 Foster Street
Harrisburg, PA 17120

April 5, 2021

Via email: RA-DHMMregulations@pa.gov

Dear Director Collins:

US Cannalytics, headquartered in Bethlehem, utilizes the vast experience of its chemists, microbiologists, health care practitioners, and laboratory operators to ensure patients and customers receive the testing industry's most accurate results and unparalleled customer service.

Our core principles revolve around consistently producing high-quality results, creating and nourishing genuine relationships with stakeholders, and constantly innovating methods and processes to drive efficiency and add value to our clients throughout the Commonwealth.

1151a.39 Electronic Tracking System

Application-programming interface (known as "API") is a commonplace computing process that allows two different applications to communicate with each other and is the standard for business in other state level marijuana programs. This type of software integration is not only in secure applications such as banking software, health care, smartphones and other business software, but also is the standard for every medical marijuana state in the country, with the exception of Utah and Pennsylvania. In fact, when the Pennsylvania program started, API integration was "open" but it has inexplicably been closed.

Allowing for an API to link with the seed-to-sale inventory tracking software mandated by law and regulation (MJ Freeway) and an interfacing software, will prevent human error from uploading the incorrect test results, prevent duplicate record keeping, and allowing laboratory systems to communicate results using their business software that would link to the MJ system seamlessly. API integration will increase overall operational efficiency and enhance patient safety by eliminating manual entry of 65 fields per sample.

In a laboratory setting, implementing the ability for licensees to upload tracking data via .csv import into MJ Freeway would significantly streamline data inputs. At least fifteen states with medical programs utilize open API technology: Alaska, California, Colorado, Louisiana, Maine,

Maryland, Massachusetts, Michigan, Missouri, Montana, Nevada, Ohio, Oklahoma, Oregon, West Virginia, and the District of Columbia.

We recommend the following change:

§ 1151a.39. Electronic tracking system.

A grower/processor shall use the electronic tracking system prescribed by the Department containing the requirements in section 701 of the act (35 P.S. § 10231.701) and which shall allow two-way communication and application-programming interface of each medical marijuana organization's software with the software of the department or its contracted seed-to-sale vendor with regard to that medical marijuana organization.

1171a.29 Testing Requirements

Subsection (e) requires testing laboratories to collect a "statistically significant number and size of samples." Although current testing guidance suggests a gram-sized range for samples to be collected for harvest and process lots, we suggest that this amount be modified to a statistical *minimum* to be collected. This will eliminate compromising analytical reliability in lieu of relinquishing less product to the testing process.

Instead, we suggest requiring a scientifically derived minimum sample size. For example, testing laboratories cannot realistically perform all required testing (including two stability timepoints) with a total two-gram sample size of concentrates. Regarding flower, testing on less than seven grams from a ten-pound batch is not statistically significant. To obtain a statistically significant sample size, many states require at least 0.5% of a batch. For example, in a 10lb batch = 4540g x 0.005 = 22.7g sample size.

Regarding 1171.29(c), the regulatory analysis of the current subsection (c) appears inconsistent with the language of current subsection (c), implying that an approved laboratory must test *four* samples: two samples at harvest and two samples at the process stage. Whereas, the actual language of the current subsection (c) requires just two samples: one sample at the harvest stage and one sample at the process stage. We would like to point out this inconsistency to avoid confusion and recommend that the Department clarify its regulatory analysis to align with the language of the regulation.

1171a.31 Test results and report

Stringent testing requirements should be at the forefront of a regulatory scheme. However, it's also important to balance that policy objective against supply chain efficiencies. The proposed

rule explicitly prohibits harvest batches that fail testing to be transferred to a processor. Product remediation solves this supply chain logjam and is a concept we, as well as several other states support. Those states include Maryland, Ohio, Oregon, Washington, Michigan, California, Oklahoma, among others. Modern extraction procedures have proven to successfully remediate contaminated products, of which is ultimately tested again at the final process lot stage to ensure safety to consumers.

To solve this wasteful problem, we recommend permitting remediation through extraction processes. Ultimately, the processing and extraction of a harvest batch remediates most contamination issues and the batch will ultimately be re-tested again at the concentrate stage before being released for sale to medical patients. This additional re-test should be the mechanism to ensure a final product is free of microbials and contaminants. Furthermore, it is exceptionally rare to see any microbial growth on final concentrate products due to the antimicrobial nature of most extraction processes.

1171a.33 Transporting Samples

We strongly suggest that testing laboratories only be required to have one individual instead of two individuals for transportation of samples. This will drastically reduce costs. By way of example, each employee that chaperones the transport of testing samples is paid approximately $18/hour. By requiring two agents for sample and transport, it doubles the cost of sampling for laboratories. This unnecessary added cost is ultimately passed on to the patient. Requiring one individual for this task puts Pennsylvania in line with many other states as well as best-in-class requirements for laboratory transport. Indeed, Maryland permits one driver to facilitate transportation of lab samples due to lower quantity of material in transport as compared to transportations finished products to dispensaries.

Instead of requiring laboratories, grower/processors or third-party contractors to follow each transportation requirements of §§1151a.35 and a.36 respectively, we recommend the below language:

1171a.33 Transporting samples.

(a) An employee of an approved laboratory, grower/processor or third-party contractor shall follow the transportation requirements under 1151a.35 and 1151a.36 (relating to transportation of medical marijuana; and transport manifest) except for the requirement that:

(i) A transport vehicle must be staffed with a delivery team consisting of at least two individuals.

(b) When transporting a sample or test sample under this part, it shall be deemed acceptable for the vehicle to be staffed with at least one individual.

Thank you for the opportunity to comment on the proposed regulatory changes and we look forward to participating in the next stage of the process.

Sincerely,

Timothy Schnupp, PharmD
Laboratory Director | Partner
US Cannalytics, LLC