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Independent Regulatory Review Commission

DH, MMRegulations

From: bobm@actlabllc.com
Sent: Monday, April 5, 2021 1:53 PM
To: DH, MMRegulations
Cc: bobm@actlabllc.com; 'Jeff Nemeth'; 'Susan Campbell'
Subject: [External] Comments on New Legislation
Attachments: PA DOH.4.5.21 new regs.docx

John

On behalf of ACT labs, enclosed please find the comments that we have related to *Medical Marijuana Regulation #10-219 (IRRC #3290).* We look forward to work with you and the state in this very important piece of legislation within Pennsylvania. If you have any questions, please don't hesitate to call.

Bob

April 5, 2021

VIA Email to:

RA-DHMMregulations@pa.gov

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

Re: Medical Marijuana Regulation #10-219 (IRRC #3290); Proposed Permanent Medical Marijuana Regulations by the Pennsylvania Department of Health

Dear Director Collins:

ACT Laboratories has seven testing facilities throughout the continental United States including in the Commonwealth of Pennsylvania.

We have been operating in the cannabis space since 2010. Since then, we have expanded and grown into a multi-state operation with laboratories operating independently. Our labs are in full compliance with state law and we work closely with regulators as we elevate cannabis testing standards nation-wide.

Each location is accredited to the international standard ISO 17025:2017. For the purposes of cannabis testing, this ensures our methods are fully validated and independently reviewed.

1151a.35 Transportation of medical marijuana

Regarding subsection (b)(1), we ask the Department to clarify its requirement that vehicles permitted to transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products be capable of being "temperature controlled". To the extent the Department means temperature monitoring, we support this position and request the Department set forth specific criteria to meet these requirements.

Indeed, there is a significant difference between the vehicles equipped with temperature controlled technology and vehicles equipped with temperature monitoring technology. The former is technology whereby a change of temperature in the vehicle is measured and the passage of heat into our out of the space is subsequently adjusted to retain the desired temperature. Temperature monitoring technology on the other hand captures temperature data via a sensor and logs changes accordingly.

These different technologies achieve the same desired outcome but temperature monitoring technology is less expensive.

In the spirit of the 71 P.S. § 745.5b(3)(ii), this regulation should be reviewed for "clarity and lack of ambiguity."

1161a.35 Transportation of medical marijuana products

While we understand the underlying intent behind the proposed change to subsection (b)(1), lockbox storage is unnecessary for product transportation. More importantly, it jeopardizes the integrity and quality of the products inside the lockbox because it is difficult to maintain temperature and humidity of the product due to poor ventilation. Accordingly, this proposed change is antithetical to product safety and has the potential to negatively impact the safety of patients.

Maintaining the status quo and permitting medical marijuana products to be transported in a vehicle with a locking cargo area is the preferred method of transportation because it allows for ventilation and better temperature monitoring. It also does not create an additional fiscal burden on companies.

1171a.22 Laboratories generally

We request that the Department clarify the specific requirements it would like to see in a written contract between a grower/processor and a laboratory. The term "contract" implies the existence of a defined business relationship. However, that does not currently align with the practical relationships between growers/processors and laboratories. On some occasions a grower/processor might not have a formal contract, but rather bill for goods and services on a case by case basis.

Mandating contractual relationships or even requiring them, conflicts with the Pennsylvania Regulatory Review Act 71 P.S. § 745.5b standard that regulation should be reviewed for, "Whether a less costly or less intrusive alternative method of achieving the goal of the regulation has been considered for regulations impacting small business." In this case, the ability to simply invoice clients on an invoice for services arrangement is less costly and less intrusive.

1171a.23 Approval of laboratories

The proposed section 1171a.23(c) grants the Department discretion to approve a laboratory based on the applicant's financial suitability and professional suitability to conduct the requisite testing. Given the wide latitude the Department has, we recommend clearly defining what the Department means by "professionally suitable" to provide clarity to testing laboratory applicants.

1171a.26 Stability testing and retention of samples

The current requirements of subsection (c) mandating a laboratory to retain stability testing samples from *each* harvest batch for one year is excessive and even more stringent than standards for the pharmaceutical industry. There, once the expiration date is developed, only one single representative sample is put on stability each year. Here, the Department requires one sample per each harvest batch.

We suggest that the Department apply the standard within the pharmaceutical industry and require laboratories to retain just one sample from the entire harvest to store for stability each year.

As the Pennsylvania Regulatory Review Act 71 P.S. § 745.5b stipulates, this regulation should be reviewed on the basis of "whether the regulation is supported by acceptable data."

Our suggested language follows:

§ 1171a.26:

(c) An approved laboratory shall retain a sample from *one harvest batch each year* sufficient to provide for stability testing and properly store the sample for one year.

1171a.29 Testing requirements

Currently, subsection (c) requires cannabis to be double tested; once at time of harvest, and again after manufacturing. This creates not only a large financial impact on both the public and private sector, but there is also a less costly method for achieving this policy objective.

We suggest that the Department remove duplicative stability testing all together because the state's testing requirement is an outlier compared to other state regulations. Moreover, it places an unnecessary burden on testing laboratories and unnecessary cost on cannabis businesses, inevitably carrying over to the medical patients who bear the brunt of added cost. Other states that require a single laboratory quality assurance test at the end of the manufacturing process shows that the streamlined single-test protocol is sufficient to ensure a high quality and safe cannabis product for consumers.

Subsection (e) requires testing laboratories to collect a "statistically significant number and size of samples." Although current testing guidance suggests gram-sized samples to be collected for harvest and process lots, we suggest that the regulation be flexible to collect a

larger sample. This will eliminate compromising analytical reliability in order to sacrifice 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 stability testing) with a 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 of flower product, many states require at least 0.5% of a batch.

1171a.31 Test results and reporting

Proposed changes to subsection (b) clarify that only testing performed on harvest lots and process lots are required to be entered into the electronic tracking system. This means that "R&D" products do not need to be entered. While we understand the intent behind this proposed change, the implementation of this regulation could create the following unintended situation if not properly accounted for: a growers/processor unsure if a product would pass initial testing could submit a batch for "R&D" testing. Then, if the batch does pass, simply designate to a routine batch for release. Conversely, if a batch fails, a grower/processor could designate it as an "R&D" product without the need to report an initial failure.

Accordingly, we recommend that the Department maintain the current regulation that all test results must be entered into the system.

1171a.33 Transporting samples

The regulatory analysis expresses the Department's intent behind this rule change to subsection (b)(3) by explaining samples should be transported from a grower/processor to an approved laboratory in a manner that adequately protects the integrity and composition of the samples from outside interference. The proposed rule attempts to further clarify what is meant by "outside interference" like "time, temperature and other environmental factors."

We would like additional clarity on what is meant by "other environmental factors" to ensure compliant transportation of samples.

Our proposed changes follow:

§ 1171a.33:

(b)(3) Protect the sample against factors that interfere with the validity of testing results, including the factors of time, temperature and other environmental factors that may work to jeopardize the integrity of the sample.

(i) For purposes of this section, environmental factors include factors such as temperature, humidity, moisture and light.

We thank the committee for its consideration of the above comments and recommendations.

Sincerely,

Robert T. Miller, Ph.D.

COO ACT Labs