DH, MMRegulations

From: Aaron Lopez <Aaron.Lopez@trulieve.com>
Sent: Monday, April 5, 2021 1:39 PM
To: DH, MMRegulations
Subject: [External] Comments on Proposed Regs #10-219
Attachments: Trulieve Comments on Proposed Regs #10-219.docx

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Thank you for the opportunity to submit comments to the commission. Please find the attached set of comments for your review.

If you have any questions please feel free to reach out,

Aaron

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Trulieve grows one patient at a time!

Via Email

April 5, 2021

John J. Collins, Director
Office of Medical Marijuana, Department of Health
Room 628, Health and Welfare Building
625 Foster St, Harrisburg, PA 17120
RA-DHMMregulations@pa.gov

RE: Comments on Proposed Rulemaking - Medical Marijuana Proposed Regulations #10-219

Dear Director Collins,

Thank you for the opportunity to submit comments regarding the proposed regulations for the Pennsylvania Medical Marijuana Program. We have recently acquired licenses in Pennsylvania and look forward to engaging patients and providing them with help and relief.

We have reviewed the regulations and feel there are some areas that would need to be changed to allow us better flexibility in serving our patients. Please see the following recommendations to the proposed rules:

1. **Grower/Processors**

1151a.26. Security and Surveillance (b)(3)
The burden placed on the grower/processors to keep all records for 4 years can become a great burden if we need to keep physical records. We are requesting the allowance of electronic storage for all records to minimize the storage space and allow for safer keeping of the records.

1151a.29. Limit on Medical Marijuana Processing
When listing the requested profiles of the cannabinoids in section (a)(5), (6), (7), (8), (9), (10), or (11), we request we do not have to add it to the label if the profile is 0.0. Adding it to the label can confuse and detract from other information that needs to be on the packaging to better inform the patient such as Terpenes and other cannabinoids.

1151a.34. Packaging and Labeling of Medical Marijuana Products
We want to produce a label that is clear and understandable with the information that is pertinent to the patient. In 1151.a.34 (d)(6) the words “where applicable” should be added at the end of the first sentence to clarify that such results should only be listed if they are shown on a COA, not if they are 0.0%. Further review should be done of this section, as it lends itself to be vague when speaking of individual terpenes and their corresponding percentages.

We also think that the extra label requirements in (d)(11) are too burdensome. This should be eliminated as a dispensary is already required to place an exit label on the product before it

leaves, requiring double work. If the dispensary already is required to do this, the grower/processor should not be required to do this as well.

1151a.35. Transportation of Medical Marijuana
We would like to see removal of the requirement to always have 2 drivers during the transportation of medical marijuana. 1151a.35(c) causes excessive economic burden on the grower/processor. We would like to see the requirement for 2 drivers only be applied when the drive is scheduled to be longer than 5 hours.

1151a.36 Transport Manifest
In section 1151a.36(c) the use of the term "shipping container" is confusing and may be interpreted as needing another vehicle in which to transport product. We suggest the phrase "shall be packaged in shipping containers" be changed to "shall be packaged for shipment" to remove the ambiguity. It should be made clear here that the intent of a shipping container is packaging, not a large metal shipping apparatus.

1151a.37 Transportation of Seeds, Immature Medical Marijuana Plants and Medical Marijuana Plants
To be clear and inclusive, the title of this section should also include "and Medical Marijuana Products). In subsection (a) "and medical marijuana products" should be added, to make it clear that grower/processors can sell biomass to other grower/processors, so they might be able to process those materials into their own products.

2. **Chapter 1171 – Testing**

1171a.26 Stability Testing and Retention of Samples.
Subsection (a) requires stability testing at 6 and 12 months. These tests are unnecessary and can become cost prohibitive, having to pass on the extra charge to the patient. Most grower/processors place a 12-month expiration date on their products. Eliminating this requirement would go a long way to making products more affordable.

1171a.29 Testing Requirements
The changes in subsection (c)(2) while well intended do not offer the safeguards intended. First, the change in process disrupts the current workflow and agreements already in place, and adds layers of complication for transport increasing risk, not decreasing it.

The mandate to use two different laboratories does not have any basis in science and forces grower/processors to use labs that might not have the same level of expertise as the laboratory that they first would choose to send samples to. This requirement should be removed and returned to allowing for a grower/processor to use only one laboratory of their choosing.

3. **Chapter 1211 Clinical Registrants**

1211a.36 Sale or Exchange
The purpose of Chapter 20 licensees is to conduct clinical research, not to compete in the commercial market. Subsections (c)&(d) may cause undue hardship to the commercial grower/processors. These two subsections should be removed.

Thank you for the opportunity to comment on the proposed regulations. Should you need to reach out to us to discuss any parts of these sections for further explanation, please do not hesitate. We feel it would be better to fix these now before these are in place and disrupt patient access.

If you have any questions, please feel free to contact me directly at aaron.lopez@trulieve.com.

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