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DH, MMRegulations

From: Gabe Perlow <Gabe@purepenn.com>
Sent: Monday, April 5, 2021 2:45 PM
To: DH, MMRegulations
Subject: [External] Comments to Proposed Rulemaking Medical Marijuana
Attachments: Comments to Final Regulations - PurePenn LLC GP 5016-17.pdf

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To Whom it may concern,

Please find attached comments to the proposed final regulations for the Pennsylvania Medical Marijuana program on behalf of PurePenn LLC.

Best regards,

Gabe Perlow

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Via FedEx and Email
John J. Collins
Office of Medical Marijuana
Department of Health
Room 628, Health and Welfare Building
625 Forster Street, Harrisburg, PA 17120
RA-DHMedMarijuana@pa.com

Re: PurePenn LLC Comments on Proposed Final Regulations #10-219

Dear Commission Members,

Thank you for the opportunity to provide public comment in response to the proposed permanent regulations for Pennsylvania's Medical Marijuana Program, filed by the Department of Health under 28 Pa. Code §1131 et. seq. On behalf of PurePenn LLC ("PurePenn"), GP-5016-17, we are providing a series of comments in regard to these proposed regulations for your review and consideration.

PurePenn was one of the first 12 Grower/Processor ("GP") to receive a license under Pennsylvania's Act 16 and was the 4th producer of medical marijuana products to market in 2018. PurePenn has operated under the temporary regulations since it received its license in June 2017 and is intimately familiar with the regulations. PurePenn is adequately situated to opine on both the outstanding nature of the temporary regulations, as well as their shortcomings; and, it is our hope that these comments are incorporated and memorialized into the final regulations so that Pennsylvania's medical marijuana program can remain the gold standard throughout the United States.

Please find our comments regarding the proposed permanent medical marijuana regulations below and attached.

Thank you in advance for your consideration,

Gabriel Perlow

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1151a.26. Security and Surveillance

(b)(3) – allow for electronic storage. – Rationale, 4 years is excessive and will require significant file storage space. 90 days is reasonable time to discover an issue and alert the department.

1151a.29. Limit on medical marijuana processing

(a) Remove (5)(6)(7)(8)(9)(10)(11) - Rationale – in an effort to reduce packaging size and waste it would make sense to make these cannabinoids optional as they are often listed as 0.0% and take up room on labels that would include information much more valuable to patients, such as Terpenes and other cannabinoids.

11.51.a.34. packaging and labeling of medical marijuana products

(d)(6) add "where applicable" at the end of the first sentence as it is makes clear that such results should only be listed if they are shown on a COA not if they are 0.0%. This section is also too vague and could strike altogether the words "and the individual terpenes and corresponding percentages." As that alone could cause an issue, because labs often show 30+ terpenes on their COAs.

(d)(11) ELIMINATE – this is a redundant process for a Grower/Processor, as it requires an additional label with each of the up to 200 dispensaries we sell to. All dispensaries also place an exit label on their products so the patients are aware where they purchased the product from that label and therefore the Grower/Processor should not have the burden created by this section.

1151a.35. transportation of medical marijuana

(c) REMOVE requirement of having 2 drivers. This causes excessive economic burden on the GP. Only drives over 5 hours should require 2 drivers. With the precautions taken, there should not be a time that the single driver is ever exposed outside of a secure location in a drive under 5 hours.

1151a.36. transport manifest

(c) REMOVE the words "shipping container" and replace with "for shipment". Rationale- a shipping container is an actual thing and is not necessary for transporting cannabis. What they mean is a box, so by saying packaged for shipment, then the vagueness of a shipping container is eliminated.

1151a.37. transportation of seeds, immature medical marijuana plants and medical marijuana plants (ADD TO THE TITLE ", and medical marijuana products")

(a) ADD ", and medical marijuana products" – rationale, this makes clear that Grower/Processors can sell biomass and plant material to other GPs for them to process into their own products.

1151.a.40. Management and disposal of medical marijuana waste.

- I would like to see this section add language that allows for the reprocessing of any unopened returned medical marijuana products. Since the product has tamper evident labels we can reprocess it without fear of it being contaminated so long as the tamper seal is intact.

(b)(1) ADD "opened," prior to the first word and remove the word "Unused"

Chapter 1171 – Laboratories

1171a.26. Stability testing and retention of samples.

(a) ELIMINATE 6 and 12 month stability testing. Most Grower/Processors place a 12 month expiration date on their products. Have two additional stability tests on all products is a major expense that gets passed on to the patient. Eliminating this would go a long way to making products more affordable for patients by eliminating undue expenses.

1171a.29. Testing Requirements

(c)(2) This is a big change to the current system. I understand they think it is a check and balance, but in reality it causes massive problems to force us to use 2 different labs. They are not all created equal, they do not all use the same equipment, ect. This will create significant inconsistency for GPs and will create a logistical nightmare having to manage 2 different labs, one for Harvest tests and one for final product tests. It is merely a ploy by the labs that are not performing well to try to use regulations to force GPs to use them. We, for example, only have one lab that we trust and the others have proven woefully incompetent.

Additional Rationale:

• **Disruption and Uncertainty.**
Process testing should occur immediately after harvest testing to minimize product time to market.
The proposed changes to §1171a.29(c)(2) would require our business to:
- Manage relationships and schedules across multiple testing laboratories.

- Make it significantly harder to maintain inventory control and scheduling workflows
- Productivity losses will increase overhead costs and reduce your product availability and revenues.

• More State Control Over Product Inventories.
DOH has acted slow and irresponsibly in its handling of the "re-testing process" failing to provide a functional pathway for qualified material.
This proposed change would give them another opportunity to gridlock your inventory with unnecessary regulation.

The state further proposes new "checks and balances" without any explanation or objective mechanism when a review process already exists in §1171.24 which should be used instead. No other state in the country has even identified or discussed the need for additional testing regulation such as this.

• Loss of Data Continuity.
The imposition of a forced testing decision disadvantages your testing team here in PA, as well as our lab teams in other states, in product data tracking and bulk pricing incentives. Other laboratories may not use the same technology or methods resulting in differences in the way our sample data is generated and reported. *The decentralization of our testing program will lead to a direct loss of our data integrity*, and will increase your uncertainty in making important business and product decisions.

• Loss of Your Right to Free Choice.
The proposed change levers a forced reduction in testing opportunities for laboratories in a free market and limits our right to free choice with whom you do business. The right to operate in a free market economy is sacrosanct and must preserved.

Section 1171a.35(b)(1)
The regulations now propose in §1171a.35(b)(1) that we immediately send them all of our R&D Results to the DOH, which we believe is a loss of privacy in our own internal development processes. The right to operate in privacy within our own businesses is the very foundation of the free market economy and is implicit from our constitutional rights, even within our highly regulated program. These samples are for our own internal business purposes and are not meant to determine the compliance of our products. We ask that this requirement be eliminated from the final regulations.

Chapter 1211

1211a.36.

(c)&(d) ELIINATE these sections. Chapter 20 licensees have 6 dispensaries and a GP, they are established to conduct clinical research, not compete in the commercial market. This could cause undue hardship to the commercial Grower Processors.