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House of Representatives
Commonwealth of Pennsylvania
Harrisburg

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September 27, 2022

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Pennsylvania Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Via Electronic Mail to irrc@irrc.state.pa.us
Via Electronic Mail to RA-DHMMregulations@pa.gov

Dear Members of the Independent Regulatory Review Commission:

Re: Rulemaking #10-219: Medical Marijuana
Permanent Regulation 28 Pa. Code § 1171a.29(c)

In our capacity as members of the House of Representatives, we have reviewed the above section of the final regulations as submitted by the Department of Health (Department) concerning testing requirements for medical marijuana at the harvest and processing stages.

Under the proposed and final regulations, despite numerous comments and concerns from the public, members of the legislature, and as reiterated by the Commission, the Department has kept the requirement that different laboratories must perform the harvest lot and process lot tests. We are concerned that this creates an undue burden on a nascent industry that goes against the plain language of the statute as enacted by the General Assembly. Further, as we will explain below, the Department has not provided sufficient reasons why it has changed the testing requirements from the temporary regulations that do not require separate laboratories to test harvest and processing stage lots.

While we are commenting on these regulations in our individual capacity as members of the House of Representatives and we are not speaking on behalf of the House Health Committee, which oversees these regulations and for which we serve, we must note that we have received no reports of high rates of unacceptable medical marijuana that necessitates having two different laboratories test medical marijuana. Further, we have received no evidence from the Department justifying this added expense to the business community.

In the final regulations, the Commission asked the Department to explain three separate issues (see page 65):

1. Why the Department believes the language of Section 704 of the Act allows for testing of harvest batches and final product by two different approved laboratories.
2. Provide a more detailed explanation of the specific problems it has encountered with the existing testing protocols and how testing by two different approved laboratories solves those problems.
3. Quantify the costs for growers/processors associated with entering into a contract with a second approved laboratory.

We will offer our comments and concerns on each issue separately.

1. Why the Department believes the language of Section 704 of the Act allows for testing of harvest batches and final product by two different approved laboratories.

The Department responded to this inquiry by stating that Act 44 of 2021 revised section 704 to require a grower/processor to contract with "one or more independent laboratories" to test medical marijuana. This was the Department's only justification for inclusion of this requirement. The Department has failed to explain how this provision in the Act authorizes the Department to require growers/processors to use separate laboratories at the harvest and processing stage lots.

The plain language of this provision allows growers/processors to use multiple laboratories if they so desire. It does not mandate such a requirement. The General Assembly could have easily written this provision of Act 44 to state that growers/processors must use separate laboratories when testing lots at the harvest and processing stages. By using the word "or," we assert that the General Assembly made it clear that use of multiple laboratories was not a requirement but rather an option.

The Department's requirement undermines the criteria that growers/processors must use to select the most appropriate laboratories to test their products. Further, in speaking to this community, it

is apparent that using two separate laboratories to test two completely different products at two different phases of the process does not create any sort of check or balance. We are also concerned by the fact that the Department approves these laboratories for the medical marijuana program. If the Department approves these laboratories, it stands to reason that each laboratory should be able to test lots at both the harvest and processing stages. If they cannot, they should not be an approved laboratory. Further, if there are issues with a laboratory, the Department already has the authority under Act 16 to conduct proficiency testing on laboratories to determine whether they meet the requirements to be an approved laboratory.

While patient safety is paramount, one factor that must also be mentioned is that this will be a greater financial burden on the regulated community because this requirement will eliminate volume discounts that a grower/processor may obtain from using a single laboratory. Further, as it is likely that growers/processors have existing contracts with laboratories to conduct tests, this new requirement will place growers/processors in a quandary: abide by their existing contracts and risk discipline by the Department, or cancel existing contracts and risk being sued by laboratories for breach of contract. We are concerned that as a government agency, the Department is impairing private contracts that were legal under the temporary regulations but will immediately become illegal once these new regulations are approved.

2. **Provide a more detailed explanation of the specific problems it has encountered with the existing testing protocols and how testing by two different approved laboratories solves those problems.**

Regarding this issue, the Department stated that it "frequently hears allegations from patients that lab results are inflated to reflect higher THC percentages than the product actually contains." (See pg. 66). Further, the Department admits that Pennsylvania's medical marijuana program has not seen widespread corruption in the testing of medical marijuana, but other states have experienced these issues. This concern is one reason the Department is requiring separate laboratories to test these samples.

This explanation is wholly inadequate to justify the expense of two separate laboratory testing requirements. First, the Department has heard "allegations." The Department does not state that it has investigated these allegations and found merit to them. The Department could have easily provided concrete information if it does exist to justify this requirement. Second, the Department has the authority to impose discipline against entities in the medical marijuana program for violations. An onerous requirement should not be placed on this community merely from allegations.

3. **Quantify the costs for growers/processors associated with entering into a contract with a second approved laboratory.**

The Department's explanation for this issue is two-fold. First, it states that there should be no increase in operating costs because all permittees are currently required to conduct two laboratory tests. Second, since all permittees will be required to comply with this new requirement, laboratories will adjust their prices accordingly.

We assert that this response does not answer the question that the Commission put forth. There was no attempt to quantify the costs for growers/processors (also see pg. 17, section 23 of the Regulatory Analysis Form, which only details permit fees), nor does the fact that all permittees must comply with this requirement justify its placement. This requirement does not consider bulk/discount pricing, nor does it consider having to deliver lots to different laboratories in two different locations. While the Department may not have the ability to determine an exact cost, its answer shows that it did not address the Commission's concerns fully.

In conclusion, in determining whether a proposed, final-form, final-omitted or existing regulation is in the public interest, the commission shall, first and foremost, determine whether the agency has the statutory authority to promulgate the regulation and whether the regulation conforms to the intention of the General Assembly in the enactment of the statute upon which the regulation is based. In making its determination, the commission shall consider written comments submitted by the committees and current members of the General Assembly, pertinent opinions of Pennsylvania's courts and formal opinions of the Attorney General. 71 P.S. § 745.5b(a).

If the Commission finds that the regulation is consistent with the statutory authority, it then must look at several factors, including economic/fiscal impacts, protection of public health, the clarity/feasibility of the regulation, and other factors. 71 P.S. 745.5b(b).

In summary, the Department's justification for this requirement:

1. Goes against the plain language of the Act.
2. Does not consider pricing structures such as bulk/discount pricing.
3. Does not attempt to quantify what the costs will be to the regulated community.
4. Does not cite specific problems that this regulation is intended to address.

While we understand that the Department has a difficult task in regulating medical marijuana in this Commonwealth, it must do so under the authority provided to it by the General Assembly and under the requirements of the Regulatory Review Act.

Thank you for taking the time to consider our comments. Please do not hesitate to reach out to us if you have any questions.

Sincerely,

The Honorable Kathy L. Rapp
65th Legislative District

The Honorable Aaron Bernstine
10th Legislative District

The Honorable Timothy R. Bonner
8th Legislative District

The Honorable Jim Cox
129th Legislative District

The Honorable Kate A. Klunk
169th Legislative District

The Honorable Brad Roae
6th Legislative District

The Honorable Tim Twardzik
123rd Legislative District

The Honorable David H. Zimmerman
99th Legislative District

cc: The Honorable Dan Frankel, Minority Chair, House Health Committee
The Honorable Michele Brooks, Majority Chair, Senate Health & Human Services Committee
The Honorable Art Haywood, Minority Chair , Senate Health & Human Services Committee