#3290

Madison Brame

From: IRRC
Sent: Tuesday, October 18, 2022 9:58 AM
To: Michelle Elliott; Scott Schalles; Fiona Cormack
Cc: Madison Brame; Stephen Hoffman
Subject: FW: Pennsylvania Cannabis Coalition Comments on Regulation #10-219 Medical Marijuana
Attachments: PCC Comments Regulation #10-219 Medical Marijuana IRRC #3290.pdf

Comment on #3290

From: Meredith Buettner <meredith@pcanna.org>
Sent: Tuesday, October 18, 2022 9:05 AM
To: IRRC <irrc@irrc.state.pa.us>; RA-DHMedMarijuana@pa.gov
Subject: Pennsylvania Cannabis Coalition Comments on Regulation #10-219 Medical Marijuana

Chairman Bedwick & Director Mentch -

Please find attached comments related to Regulation # 10-219 Medical Marijuana submitted by the Pennsylvania Cannabis Coalition.

On behalf of the 75% of the regulated industry represented by PCC, thank you for the opportunity to comment. We look forward to continuing to work with PA DOH and IRRC to improve the industry for the benefit of Pennsylvania medical marijuana patients.

Thank you,

Meredith Buettner
Executive Director, PCC

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Via Email

Chairman George Bedwick
Independent Regulatory Review Commission
333 Market St, 14th Floor, Harrisburg PA 17101
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Director Laura Mentch, Office of Medical Marijuana
Department of Health
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625 Forster Street, Harrisburg, PA 17120
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Re: Pennsylvania Cannabis Coalition Comments on Final Form Regulations #10-219

October 18, 2022

Dear Commission Members,

Thank you for the opportunity to provide public comment in response to the Final Form Regulations for Pennsylvania's Medical Marijuana Program, filed by the Department of Health under 28 Pa. Code §1131 *et. seq*. On behalf of the members of the Pennsylvania Cannabis Coalition ("PCC"), we are providing a series of comments regarding these regulations for your review and consideration.

The Pennsylvania Cannabis Coalition represents more than 75% of the current permit holders in Pennsylvania's Medical Marijuana Program. Our membership represents grower/processor, dispensary, clinical research, and laboratory permittees throughout the Commonwealth. Over the six-year life of the Program, our members have delivered medicine safely and securely to qualifying patients in a highly regulated environment.

Notwithstanding that the Medical Marijuana Office ("Office") operated without senior leadership for much of 2022, we appreciate that the leadership at the Department of Health – notably Executive Deputy Secretary Pete Blank, Deputy Secretary Kate Roberts, Department of Health Director of Legislative Affairs David Toth, and Department of Health Director of Intergovernmental Affairs Faith Haeussler – have shown a renewed interest in the program and are engaging with our membership to address program-wide issues. Additionally, we are enthusiastic about leadership and approach the program's new director - Laura Mentch has demonstrated during her short, but meaningful tenure with the department.

Though not apparent in the Final Form Regulations, we are encouraged by this recent engagement and commit to the renewed partnership between regulator and the regulated industry in Pennsylvania. We thank Independent Regulatory Review Commission Chairman George Bedwick for his persistence helping facilitate the refreshed relationship.

While much of the Final Form Regulations continue to be overly burdensome for operators, patients, and practitioners alike, and are still not reflective of industry best-practice standards, there are areas of improvement from the proposed final regulations. The Department's use of the preamble to provide

clarity regarding issues such as "visitor access" and that a patient identification card is sufficient to enter a dispensary are helpful and represent an attention to comments submitted during the regulatory review process. Our hope is that the Department will continue to issue sub-regulatory guidance when clarity is broadly sought. There are many regulations where the regulated community has already indicated the necessity of sub-regulatory guidance including those related to labeling and medical professionals.

Additionally, revisions made to the regulations related to product transportation, onboarding employees prior to affiliation, and elimination of the prohibition on advertising discounts are welcomed amendments. These small fixes aid in bringing the program in-line with operational protocol from other jurisdictions.

In acknowledgement of the statutory requirements reflected in the regulations, PCC will reserve comments where satisfactory statutory explanation has been offered and seek continued partnership with the Department to address items that can only be rectified via the legislative process. PCC will focus our comments on areas where IRRC has jurisdiction in evaluating reviewing regulations.

We aim to address these areas by laying the important groundwork to improve the final regulations over the life of the Program much like the Department proposes periodic regulations related to hospitals or long-term care. Through the proactive use of the regulatory process, we will collectively continue to improve the Commonwealth's already robust medical marijuana program.

Thank you in advance for your consideration,

Meredith V. Buettner

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Pennsylvania Cannabis Coalition Comments on Final Form Regulations #10-219

1. 1141a.21 Definitions

Proposed definition: "Medical marijuana unit" – an amount of medical marijuana equivalent to 3.5 grams of dry leaf, 1 gram of concentrate, or 100 milligrams of THC infused into a pill, capsule, oil, liquid, tincture, or topical form.

Areas of Concern: 1) There is a concern that this measure will be unable to fully capture the existing market – for example there are dosages of less than 1 gram of concentrate approved for sale. 2) There is also a concern that the tracking software may not be adapted to this measurement system.

Proposed solution: Adopt a definition that does conversions based on weight/volume and equivalencies. The following equivalency charts are suggested for inclusion in defining medical marijuana units. Suggested conversion charts for development of more workable definition:

Quantity	Formula
Ounce to Gram	Mass in ounces x 28.35
Ounce to Milligram	Mass in ounces x 28,349.5
Grams to Milligrams	Mass in grams x 1,000
Grams to Ounces	Mass in grams ÷ 28,350
Milligrams to Grams	Mass in Milligrams ÷ 1,000
Milligrams to Ounces	Mass in Milligrams ÷ 28,350

Flower	Infused Products	Concentrates
1 ounce	0.018 ounces	0.176 ounces
28.35 grams	0.5 grams	5 grams
28,350 milligrams	500 milligrams	5,000 milligrams

2. 1141a.47. General Penalties and Sanctions

Proposed Regulation: The DOH proposes to hold accountable medical marijuana organizations for "failure to follow through on commitments made in the Community Impact section of the permit application."

Areas of Concern: As written this section subjects operators to potential permit revocation or suspension based on permit applications that are now in many instances five or more years old. This proposed regulation does not consider the necessity of community impact statements to evolve over the life of the program and puts operators at risk of facing permit revocation if they do not comply with financial commitments that are no longer sustainable as a result of outdated community impact statements.

Proposed Solution: Specifically allow medical marijuana organizations to update their community impact statements annually during permit renewal to reflect current economics, business operations, and community needs. PCC Members are proud of the work they have done as active members of communities across the Commonwealth. By allowing operators to adjust their community impact statements annually the industry can continue to positively impact the communities in which they operate.

3. 1151a.26(a) Security and Surveillance; 1161a.31 Security and Surveillance

Proposed regulation: The DOH proposes to maintain overlapping third-party security and surveillance monitoring requirements that will unnecessarily drive-up overhead costs for medical marijuana operators. In its security requirements for medical marijuana facilities, DOH intends to require (1) a security alarm system that is ***professionally-monitored 24 hours per day***, (2) a security and surveillance system that is ***professionally-monitored 24 hours per day***; and (3) **continuous *on-site monitoring*** of security cameras by designated employees.

> *§ 1151.26. Security and surveillance.*
>
> *(5) The grower/processor shall designate an employee to continuously monitor the security and surveillance systems at the facility.*
>
> *§ 1161.31. Security and surveillance.*
>
> *(5) The grower/processor shall designate an employee to continuously monitor the security and surveillance systems at the facility.*

The Department further clarifies in its interpretation of "continuously" on-site monitoring of surveillance equipment, that motion-activated cameras are not permitted. Medical marijuana permittees must then record and store irrelevant, dead air throughout the 180-day duration, as opposed to pertinent images of movement aligned with the intended purpose of the surveillance and data retention systems.

Areas of concern: PCC's concerns are three-fold, and primarily that the proposed security framework imposes duplicative cost-drivers that do not enhance safety or security but do pass unnecessary costs onto patients. These costs are passed onto product pricing hurting the overall health of the medical marijuana program.

(1) Requiring overlapping offsite and onsite security and surveillance monitoring does not improve facility safety or security. It does ultimately contribute to substantial increased overhead costs

that are carried over to final product pricing for patients. On-site surveillance camera monitoring should not be required, in addition to offsite professional monitoring.

However, besides being redundant and unnecessary, the Department's current interpretation of these sections is incorrect and in violation of the Last Antecedent rule of statutory construction. According to the Last Antecedent rule of statutory construction, which has been adopted by the PA Supreme Court, a limiting clause or phrase (at the facility) should be read as modifying only the noun or phrase that it immediately follows (security and surveillance systems). Therefore, the regulation as written indicates that the security and surveillance systems are at the facility, not that the monitoring needs to take place there. The regulation should not be enforced as such to require both an onsite and offsite security monitoring, but rather that an employee to monitor the security and surveillance systems. If the Department would agree to the correct interpretation of the regulation, this would provide significant financial relief to operators.

(2) Requiring the utilization of third-party contractual services to fulfill the "professional" surveillance monitoring requirement is another unnecessary cost-driver as well. Many medical marijuana businesses may be capable of utilizing internal security resources to monitor their facility cameras at a reduced overhead cost. As such, and in consideration of the Last Antecedent rule, medical marijuana licensees should be permitted to utilize *either* third-party or internal security resources to conduct remote monitoring of surveillance systems 24 hours per day. Finally, from a response and coordination standpoint, many licensees may find that utilizing remote internal security resources to monitor cameras are in fact superior, as professionally trained security personnel within the cannabis industry will know precisely what to look for and how to respond where an attempted security breach may occur.

(3) Storing irrelevant video when there is no motion detected does not improve safety but does increase data retention costs ***by an estimated 20%***. A motion-activated camera will record any human interaction on the facility premises, including any actual or attempted security breach, safety issue, or other meaningful activity for purposes of inspection. The data stored and retained will only be relevant images to the facility security and the Department, thus increasing the value of the retained camera storage within the 180-day time frame.

Proposed solutions:

1. The Department should begin to interpret the monitoring requirement in the regulations as written by 1) ending its interpretation that the regulations require both on-site and offsite monitoring of the security and surveillance system, and 2) ending its interpretation that professionally-monitored automatically means a third-party service.

   Estimated Cost: The combination of an internal security monitor and a third-party monitoring service after the facility's business operational hours can increase overhead security costs by an estimated ***$555,000 to $900,000*** per year.

2. Allow for motion-activated cameras to continuously monitor grower/processor and dispensary facilities.

Estimated Cost: PCC estimates that the current data storage and retention cost is $50,000 per year for dispensaries, and $500,000 per year for grower/processors. Moving to motion-activated cameras increase data storage and retention savings of 20%, or ***an additional cost increase of $10,000 per year for a dispensary and $100,000 per year for a grower/processor.***

Reducing these duplicative costs while not only maintaining but enhancing medical marijuana facility security and cybersecurity for operators is a shared interest for both PCC and DOH. These simple changes have the potential to save millions in overhead, carrying over reduced costs for patients that will ensure pricing continues to fall, and bringing more patients into the Commonwealth's safely regulated medical program.

4. 1151a.34. Packaging and labeling of medical marijuana products.

Proposed Regulations:

1151a.34. Packaging and labeling of medical marijuana products.

(a) A grower/processor shall package and label at its facility each form of medical marijuana products prepared for sale....

. . .

(d) . . . Each label must meet the following requirements:

. . .

(17) Be firmly affixed to the container directly holding medical marijuana except when the product is being used for a blinded research program and be firmly affixed to the outer packaging if used.

Areas of concern:

Within the Final Form regulations, the Department seeks to add relevant and comprehensive information to product labels, such as additional cannabinoids and terpenes present in the product. While the PCC strongly supports full product transparency made readily available on labels for the benefit of medical patients, there are many cannabis products that simply do not have enough space on the packaging for more than a dozen categories of information, every cannabinoid and terpene profile, and all requisite disclaimers and warnings.

As the DOH points out, some operators are already using accordion labels, but this is not evidence that the additional info requirements are cost-effective or without fiscal impact on the cost of MM to patients. Requiring that all the additional information be placed on "the container holding" the MM is certainly not the way best designed to inform the patient.

Proposed solution:

While such basic information as THC, CBD, and D8 levels should remain on the label, the use of an electronic link or QR code to all other required information will make it more likely the patients will access the information and be able to read it. Law enforcement has expressed concern that unlabeled containers such as vape cartridges, once removed from outer packaging, can't be distinguished from non-marijuana products. While such separation would be a violation of the patient requirement to return their medicine to the original packaging when not in use, perhaps the DOH should consider the alternative of requiring the universal marijuana symbol on otherwise unlabeled containers. The following qualifier added to 1151a.34 (17)(a) would alleviate concerns about the required labeling on small containers used specifically for the administration and/or dosing on medical marijuana:

1151a.34. Packaging and labeling of medical marijuana products.

(a) A grower/processor shall package and label at its facility each form of medical marijuana products prepared for sale....

. . .

(d) . . . Each label must meet the following requirements:

. . .

(17) Be firmly affixed to the container directly holding medical marijuana except when the product is being used for a blinded research program [and] or be firmly affixed to the outer packaging if used.

This language is reflective of the language used in 1161a.28 (c) (15) which governs the obligations of dispensaries to inspect labels and resolves the conflict between the two regulations which as written would result in the requirement for dispensaries to break the seal on medical marijuana packages to confirm labels are directly affixed to the container holding medical marijuana.

5. Testing Requirements

Proposed Regulations:

1171a.29. (c)Testing Requirements.

(b) Testing shall be performed as follows:

(1) An approved laboratory shall test samples from a harvest batch or a harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product.

(2) An approved laboratory other than the other that tested the harvest batch or harvest lot shall test samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.

Area of concern: As proposed, 1171a.29(c) requires that one approved lab test harvest samples and a DIFFERENT approved lab test process lot samples. We have long maintained the second testing of a lot that passed the first testing should not be required as it is overly burdensome, out of line with industry standards, provides no additional patient safety and adds to patient cost. If the second testing in these cases continues as a requirement, requiring the use of a different approved lab for the second test

should be eliminated because it is contrary to legislative intent, is without basis in the law, is without rational basis, and is contrary to the goals and aims of Act 16 & Act 44.

Proposed solution: Delete from 1171a.29(c)(2) the requirement that an approved lab "OTHER THAN THE ONE THAT TESTED THE HARVEST BATCH" do the testing on each process lot. The following chart demonstrates how the cost of duplicative testing directly impacts patient pricing:

	Massachusetts	Pennsylvania
State Test Package Flower (Useable Cannabis)	$510	
State Test Package Flower (Useable Cannabis) - Harvest		$584.25
State Test Package Flower (Useable Cannabis) - Final Product		$584.25
Total testing required for flower sold as flower	$510	$1,168.50
Price for 3.5G of Flower	$30	$40