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DH, MMRegulations

From: Shemariah Waggoner <Shemariah.Waggoner@trulieve.com>
Sent: Monday, October 17, 2022 3:07 PM
To: DH, MMRegulations
Cc: Gabe Perlow; Lauren Niehaus; Mentch, Laura; Blank, Peter; Nicole Stanton; Sarah Oglesby
Subject: [External] Trulieve Cannabis Corp Comments to the Proposed Final Regulations-For Submission
Attachments: Trulieve Inc. PA_Final Regulations Comments Submission_10.17.2022.pdf

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Good Afternoon-

On behalf of Trulieve Cannabis Corp., an operator of permitted Pennsylvania medical marijuana grower/ processor and dispensary facilities, please accept the attached document containing comments and commentary regarding the proposed final regulations for submission to the Independent Regulatory Review Commission ("IRRC") for consideration at the commission's October 20, 2022 meeting.

If you have any questions or require any additional information, please feel free to contact me.

Thank you. Shemariah

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OCT 17 2022

Independent Regulatory Review Commission

Shemariah Waggoner | Director of State Operations-Pennsylvania
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Trulieve

October 14, 2022

VIA E-MAIL (RA-DHMMREGULATIONS@PA.GOV)
Laura Mentch, Rph, MBA
Director, Office of Medical Marijuana Office of Medical Marijuana
Health and Welfare Building
625 Forster Street Harrisburg, PA 17120

Re: Regulation #10-219: Medical Marijuana
PROPOSED RULEMAKING Medical Marijuana – Trulieve Cannabis Corp.
Public Comments and Suggestions

Dear Director Mentch,

My name is Shemariah Waggoner, and I am the State Director of Operations-Pennsylvania for Trulieve Cannabis Corp., an operator of permitted Pennsylvania medical marijuana grower/ processor and dispensary facilities. I am writing today to provide comments and commentary regarding the proposed final regulations as submitted to the Independent Regulatory Review Commission ("IRRC") for consideration at the commission's October 20, 2022 meeting.

As you know, Act 16 of 2016 and its subsequent amendments established the Pennsylvania medical marijuana program and charged the Department of Health and the Office of Medical Marijuana ("OMM") with the promulgation of regulations for the program. As we near the seventh anniversary of the signing of Act 16 in April 2023, there are a plethora of lessons learned to properly guide the program into its future by both regulators and the regulated community of operators and patients.

While Trulieve advocates for the IRRC to accept these regulations as drafted, it is the Company's hope that the OMM will take heed of the comments submitted by Trulieve and others to keep the Pennsylvania medical marijuana program the gold standard for state regulated medical marijuana programs in the United States. Attached to this letter, and made a part hereof are fifteen (15) specific instances where the final regulations as written could pose problematic for operators and patients should the OMM chose to interpret the way the regulations are worded verbatim. Such hardships could lead to lack of access for patients, increased costs to operators and patients, and vagueness and uncertainty which could present issues as further represented below.

Thank you for your consideration, and if Trulieve can serve as a resource to address any questions please feel free to contact me.

Sincerely,

S. Waggoner

Shemariah Waggoner
State Director of Operations-Pennsylvania
Trulieve Cannabis Corp.

Trulieve Cannabis Corporation's Comments to Proposed Final Regulations for the Pennsylvania Medical Marijuana Program as Promulgated by the Pennsylvania Department of Health for Approval by the Independent Regulatory Review Commission on October 20, 2022

1. 1141a.21 Definitions

Proposed definition: *"Added Substance* – Any additional ingredient added to medical marijuana during or after processing that is present in the final product or any substance used to change the viscosity or consistency of a cannabinoid product."

Area of concern: Under this definition in making determinations, the Department may be relying on authority derived from jurisdictions that do not permit legal medical marijuana or that have no experience regulating the same.

Proposed solution: The Department identify the "multiple sources" of authority upon which it will rely and will limit those sources of authority to jurisdictions and agencies that allow or regulate medical marijuana.

2. 1141a.21 Definitions

Proposed definition: "*De-Identified Data* – a record retrieved from the electronic tracking system by a clinical registrant and transmitted to an ACRC for medical marijuana research purposes after the clinical registrant has removed all the personal information that could identify a patient."

Area of concern: This definition would have patient identifying data being transmitted to a third party, creating an increased risk of patient information being breached.

Proposed solution: The Department should de-identify the data sets prior to any release to any ACRC. Additionally, the information, once de-identified by the Department could be more broadly shared to the benefit of the program and patient community.

3. 1141a.21 Definitions

Proposed definition: *"Harvested Hemp"* – unfinished plant material, certified as hemp by a Department of Agriculture approved laboratory, obtained directly from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under the 3 Pa.C.S Ch. 15 (relating to controlled plants and noxious weeds) by a grower/processor holding a permit under the act. Unfinished plant material does not include extracted by product, such as oils and concentrates.

Area of Concern: The proposed definition of harvested hemp is in conflict with the scope of existing Pennsylvania Hemp Grower Permits.

Proposed Solution: Substitute the following definition:

"Harvested hemp" - unfinished plant material certified as hemp by a Department of Agriculture approved laboratory, obtained directly from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under the 3 Pa.C.S. Ch. 15 (relating to controlled plants and noxious weeds) by a grower/processor holding a permit under the act.

4. 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. There are also dosages greater than 3.5 grams 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.

5. 1141a.21 Definitions

Proposed definition: "Terpenes" Naturally occurring hydrocarbons found in essential oil secreted from the marijuana plant.

Area of concern: The definition's limited scope makes it scientifically inaccurate and limits the Departments ability to help contain costs through the approval of the use of non-marijuana terpenes that are chemically indistinguishable from those derived from marijuana.

Proposed solution: Include all terpenes within the definition to give the Department its statutory scope and discretion:

"Terpenes" Terpenes, terpenoids, flavonoids, polyphenols, and other naturally occurring phytochemicals and secondary metabolites.

6. 1151a.26(a) Security and Surveillance; 1161a.31 Security and Surveillance

Proposed regulation: Extension of the requirement to have a 24/7 on site monitoring in addition to the same surveillance being monitored by a third party and in addition to being record and stored. Additionally the 24/7 surveillance will be continuously recorded and stored, not limited to the storage of video when motion is detected.

Areas of concern: 1) the additional monitoring does not improve safety but does ultimately contribute to an increased cost to the patient; and 2) storing video when there is no motion detected does not improve safety but does increase costs.

Proposed solution: Allow for the elimination from the required retained videos those in which no motion is captured and allow for remote 24/7 monitoring of location cameras. Limit the on-site monitoring of facility security cameras to hours when the facility is in actual operation.

7. 1151a.27 Requirements for growing and processing medical marijuana; 1171a.30 Standards for testing.

Proposed Regulations:

(h)(3) Do not contain a level of mold, rot of other fungus or bacterial diseases higher than the minimum levels established in Appendix A (relating to Guidance for Quality Testing and Sampling Approved Laboratories). The Department will periodically publish a notice in the Pennsylvania Bulletin updating Appendix A.

An approved laboratory shall follow the methodologies, ranges and parameters consistent with Appendix A and the scope of the certificate of accreditation issued to the laboratory.

Areas of concern:

Simply stated, the regs overlook the latest industry standards and aren't built on a solid footing informed by the best scientific evidence. Besides the duplicative, wasteful double-testing scheme and lack of remediation process, PA ignores the recognized national product purity standard of the American Herbal Pharmacopoeia. The PA standard in most cases allows only 10% of the elements permitted by the AHP standard, which is followed by MA, MD, MI, and IL, among others. As to permitted pesticides, despite the statutorily-mandated update of the approved pesticide list and significant advances in the science, the list has not been updated since its initial publication 4 years ago.

On remediation specifically, with the scientific evidence convinced Gov. Wolf and the legislature supported the inclusion in act 44 of a research initiative on the efficacy of remediation. DOH received the results of the study in March, 2022 yet no determination has been announced. The lack of remediation might be the single greatest factor frustrating the universal goal of efficiently delivering affordable, safe medicine to patients in PA.

Proposed solution:

Utilize the work done by PCOM studying remediation to develop a remediation plan implemented in new proposed regulations. Update and maintain currency of the Appendix A quality standards and permitted pesticides, all based on the latest scientific evidence and recognized national standards.

8. **1151a.27. Requirements for growing and processing medical marijuana.**

Proposed Regulation:

(f) A grower/processor may not use any added substance that alters the dosage level, color, appearance, smell, taste, effect or weight of the medical marijuana unless the grower/processor has first obtained the prior written approval of the Department. Excipients must be pharmaceutical grade, unless otherwise approved by the Department. In determining whether to approve an added substance, the Department will consider:

(i) Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under Federal guidelines.

(ii) Whether the added substance constitutes a known hazard such as, but not limited to, diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.

(iii) Whether the added substance is permitted by the United States Food and Drug Administration for the applicable route of administration and dose

(iv) Where the added substance has known drug interactions.

Areas of concern:

In a process of regulation by email, on a topic it had no rulemaking authority over, DOH ordered that the medicines (previously approved by DOH) used by thousands of Pennsylvanians be withdrawn from the market almost overnight. And if that wasn't bad enough, the stated basis was lack of FDA approval of certain ingredients for such use. Of course, because MM remains illegal under federal law the FDA has no authority and has never evaluated the ingredients for use in MM.

Proposed solution:

The DOH acted on a topic it has no statutory authority on so the two new subsections should be deleted. Delete from the proposed regs 1151a.27(f)(iii) because the FDA does not evaluate such substances for use in a product that is illegal as a Schedule I drug under federal law. Also delete 1151a.27(f)(iv) because the standard of "known drug interactions" is overbroad and will deny patients needed medicines that they may tolerate with some interactions.

9. 1151a.34. Packaging and labelling of medical marijuana products.

Proposed Regulations:

(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 we strongly support full product transparency made readily available on labels for the benefit of medical patients, there are many marijuana 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.

10. Testing Requirements. 1171a.26. Stability testing and retention of samples.

Proposed Regulations:

Area of Concern:

Laboratories will no longer store stability samples, posing a potential problem for facilities facing storage issues around where to store these samples and how to track when they must be tested at 6 and 12 month intervals.

Proposed Solution:

Require laboratories to continue to collect and store samples for stability testing at 6 and 12 month intervals.

11. 1171a.29. (c)Testing Requirements.

Proposed Regulation:

(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. As discussed above, we maintain the second testing of a lot that passed the first testing should not be required. 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 the MMA.

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.

12. 1161.a.23. Licensed Medical Professionals at Facility

Proposed Regulation:

(b) Prior to dispensing medical marijuana products to a patient or caregiver, the [dispensary] dispensary's medical professional shall:

(1) Verify the validity of the patient or caregiver identification card using the electronic tracking system.
(2) Review the information on the patient's most recent certification by using the electronic tracking system to access the Department's database.

Area of Concern: Checking a patient's credentials is a purely administrative function that should be carried out by a badged dispensary associate, not a pharmacist or other medical professional. There are substantive checks and balances with the electronic tracking system that should allow for a badged, but not medical, professional to process patient check ins.

Proposed Solution: Modify (b) to state: *(b) Prior to dispensing medical marijuana products to a patient or caregiver, the [dispensary] dispensary's badged dispensary associate shall:*

13. 1161a.25. Licensed Medical Professionals at Facility.

Proposed Regulation:

(a) Except as provided in subsection (b), a dispensary shall ensure that a physician or a pharmacist is [present at the facility] available, either in person or by synchronous interaction, to verify patient certifications and to consult with patients and caregivers at all times during the hours the facility is open to dispense or to offer to dispense medical marijuana products to patients and caregivers.

(b) If a dispensary is authorized to operate more than one facility under its permit, a physician assistant or a certified registered nurse practitioner may be [present onsite] available, either in person or by synchronous interaction, to verify patient certifications and to consult with patients and caregivers at each of the other locations instead of a physician or pharmacist. The physician, pharmacist, physician assistant or certified registered nurse practitioner may rotate coverage of the facilities, provided that a physician or pharmacist is always [present] available, either in person or by synchronous interaction, at one of the facilities. Furthermore, no less than one dedicated medical professional must be present either, physically or by synchronous interaction, for each distinct dispensary facility location and shall not cover more than one dispensary facility location regardless of whether in-person coverage or synchronous interaction is used.

Area of Concern: Portions of Section (b) contradict one another. First, the rule states that if a dispensary is authorized to operate more than one facility under its permit, a physician assistant or Nurse Practitioner .... May rotate coverage. Later in this subsection, however, it states that a medical professional... shall not cover more than one dispensary facility location. The latter is problematic, in that current employment shortages in the nursing industry have impacted the medical marijuana industry, making it improbable to hire a sufficient number of medical professionals to cover all dispensary locations simultaneously. The desired approach is to allow one medical professional to be available in person or via synchronous interaction across various facilities under one permit.

Proposed Solution: Insert the following language at the end of part (b): *Furthermore, no less than one dedicated medical professional must be present either, physically or by synchronous interaction, for each distinct permit.*

14. 1161a.30 Access to dispensary facilities

Area of concern: Not consistent with security provisions governing other types of licensed facilities. Final Regulation Section 1151A.25 "Access to grower/processor facilities" clarifies potential investors and potential employees may access a facility.

Proposed solution: Insert into 1161a.30 "*potential investment or employment*" as reasons authorized for access so dispensaries parallel grower/processor facilities.

15. 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. Operators 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.