DH, MMRegulations

From: Teddy Scott <teddy.scott@EthosCannabis.com>
Sent: Monday, April 5, 2021 3:14 PM
To: DH, MMRegulations
Cc: David Clapper
Subject: [External] Ethos Comments on Proposed Medical Marijuana Regulations
Attachments: PA Regs-Comments - Ethos.pdf

Please find attached comments from Ethos on the proposed regulations set forth by the Department of Health for the Medical Marijuana Program. We appreciate the opportunity to submit these comments for your review.

Please let us know if we can be of assistance,

Best regards,
Teddy Scott

Ethos
530 Walnut Street, Suite 1160
Philadelphia, PA 19106

April 5, 2021

John J. Collins, Director
Office of Medical Marijuana
Department of Health
Health & Welfare Building, Room 628
625 Forster Street
Harrisburg, PA 17120

Re: PROPOSED RULEMAKING Medical Marijuana Proposed Regulations

Dear Director Collins:

Ethos Cannabis ("Ethos") respectfully submits these comments in response to the proposed medical marijuana regulations set forth by the Department of Health. Ethos is an innovative, research, and knowledge-based cannabis company active in in the cultivation, processing and dispensing of cannabis in Pennsylvania, Massachusetts and Maryland. We have a clear and compelling data-driven vision focused on helping individuals feel and live better through their experiences with medical marijuana.

We appreciate the opportunity to provide these comments based on the experience of Ethos and others in the Commonwealth and, importantly, from other States with highly regulated medical marijuana programs. We believe that the proposed medical marijuana regulations along with our suggested changes will help to position the Commonwealth's medical marijuana programs at the forefront of patient safety and access.

Please do not hesitate to contact me directly if you have any questions regarding our comments on the proposed rules below or would like to discuss our input further. We appreciate your time and the opportunity to submit these comments.

Respectfully Submitted,

David Clapper
Chief Executive Officer

Section Number	Language in Proposed Regulations	Comment on Language	Proposed Language Revision
1151.27 (Requirements for growing and processing medical marijuana)	(h) A grower/processor may only process the parts of the medical marijuana plant that: (1) Are free of seeds and stems. (2) Are free of dirt, sand, debris or other foreign matter. (3) Do not contain a level of mold, rot or other fungus or bacterial diseases higher than the minimum levels acceptable to the Department.	The levels of mold, rot or other fungus or bacterial diseases are a substantial risk only in final forms of medical marijuana – i.e., products with raw plant material or finished products after extraction. There should not be a requirement for passing a minimum level threshold prior to processing plant material because the extraction process typically removes any mold, rot or other fungus or bacterial diseases. We propose that all plant material should be allowed to be processed while still requiring the final processed products to pass independent testing pursuant to 1171.29. It is important to note that the initial test under 1171.29 would still be required, thus alerting for potential scrutiny of the second test of the final finished products. As further evidence that these comments and suggested changes to the language are appropriate, the processing of plant material without passing a laboratory test is allowed under other highly regulated medical marijuana regulatory frameworks, such as in New York, Massachusetts, New Jersey, Ohio, Maryland, Illinois, Virginia and Florida.	(h) A grower/processor may only process the parts of the medical marijuana plant that: (1) Are free of seeds and stems. (2) Are free of dirt, sand, debris or other foreign matter. ~~(3) Do not contain a level of mold, rot or other fungus or bacterial diseases higher than the minimum levels acceptable to the Department.~~

1151.34(d)(17) (Packaging and labeling of medical marijuana products)	(d) A grower/processor shall obtain the prior written approval of the Department of all packaging and the content of any label to be affixed to a medical marijuana product package. Each label must meet the following requirements: … (17) Be firmly affixed to the container directly holding medical marijuana and be firmly affixed to outer packaging if used. …	Certain products are too small to contain a label – e.g., a vaporizer cartridge. We propose that the language should provide the Department discretion to approve alternative labeling that takes into account other factors on a case by case basis for each individual product form. Furthermore, the suggesdted language would allow the Department to approve research studies where it is necessary to blind the product, such as a double-blind placebo trial.	(d) A grower/processor shall obtain the prior written approval of the Department of all packaging and the content of any label to be affixed to a medical marijuana product package. Each label must meet the following requirements, unless otherwise approved by the Department: … (17) Be firmly affixed to the container directly holding medical marijuana and be firmly affixed to outer packaging if used. …
1151.35(e) (Transportation of medical marijuana)	(e) Except as provided in subsection (h), a delivery team shall proceed in a transport vehicle from a grower/processor facility, where the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are loaded, directly to a medical marijuana organization facility or approved laboratory, where the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple medical marijuana organization facilities or approved laboratories, as appropriate, to deliver	We suggest that the language allow for multiple pickups by a transportation vehicle in addition to making multiple deliveries. Incorporation of such a change addresses the potential for disproportionate impact on underserved areas.	(e) Except as provided in subsection (h), a delivery team shall proceed in a transport vehicle from a grower/processor facility, where the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are loaded, directly to a medical marijuana organization facility or approved laboratory, where the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple medical marijuana organization facilities or approved laboratories, as

	seeds, immature medical marijuana plants, medical marijuana plants. medical marijuana and medical marijuana products.		appropriate, to deliver and/or pick up seeds, immature medical marijuana plants, medical marijuana plants. medical marijuana and medical marijuana products.
1151.39 (Electronic Tracking System)	A grower/processor shall use the electronic tracking system prescribed by the Department containing the requirements in section 701 of the act (35 P.S. § 10231.701).	There is only a single commercial electronic tracking system that is currently available for use by the Department and medical marijuana organizations, and there have been numerous issues with this commercial entity that have been endured over the past few years. We suggest that the language permit the Department to allow additional commercial electronic tracking systems that are compliant with section 701 of the act.	A grower/processor shall use ~~the~~ an electronic tracking system prescribed by the Department containing the requirements in section 701 of the act (35 P.S. § 10231.701).
1161 Security and Surveillance.	(c) A dispensary shall install commercial-grade, nonresidential steel doors and door locks on each room where medical marijuana products are stored and shall install commercial grade, nonresidential doors and door locks on each external door of the facility. Keys or key codes for all doors shall remain in the possession of designated authorized individuals. (d) At all times, all entrances to and exits from the facility must be securely locked.	We believe that the suggested changes to the language will better serve patients, especially during inclement weather where a patient would otherwise be subject to potential delays in entering the dispensary. Any concerns with security can be addressed by requiring interior locked door(s) separating the waiting area from other areas of the dispensary.	(c) A dispensary shall install commercial-grade, nonresidential steel doors and door locks on each room where medical marijuana products are stored and dispensed, and shall install commercial grade, nonresidential doors and door locks on each external door of the facility. Keys or key codes for all doors shall remain in the possession of designated authorized individuals. (d) At all times, all doors on each room where medical marijuana products are stored and dispensed and entrances to and exits from the facility must be securely locked. Notwithstanding

			the foregoing, an entrance to the waiting area of a dispensary used by patients may remain unlocked during business hours, so long as there is a commercial-grade, nonresidential steel door and door lock that remains locked separating the waiting area from any room where medical marijuana products are stored or dispensed.
1171.29(c) (Testing requirements)	(c) At a minimum, testing, as prescribed by the Department, shall be performed as follows: (1) An approved laboratory shall test samples from a harvest batch or harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product. (2) An approved laboratory other than the one 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.	Requiring different testing laboratories introduces unnecessary administrative burdens on a grower/processor. A grower/processor should be able to contract with and rely on a Pennsylvani-licensed independent laboratory of its choice. In the event there is concern with the accuracy and/or compliance of independent testing laboratories, this should instead be addressed in the licensing and standards for independent laboratories.	(c) At a minimum, testing, as prescribed by the Department, shall be performed as follows: (1) An approved laboratory shall test samples from a harvest batch or harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product. (2) An approved laboratory ~~other than the one 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.