DH, MMRegulations

From: Sonya Weigle <sweigle@paofw.com>
Sent: Saturday, April 3, 2021 12:19 PM
To: DH, MMRegulations
Cc: Thomas Trite
Subject: [External] Responses to Proposed Rulemaking Changes
Attachments: PA Options for Wellness Response to Proposed Rulemaking Changes.pdf

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Good afternoon Mr. Collins,

Attached are the responses to the proposed rulemaking changes from PA Options for Wellness.

Please let me know if you have any questions or need anything else.

Thank you,

Sonya

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April 2, 2021

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

Dear John:

Thank you for this opportunity to respond to the Proposed Rulemaking Changes for Medical Marijuana. As a compliance focused company that is driven by our focus on patient safety and patient outcomes, these proposed regulations will have a tremendous impact on our business. Captured in the boxes below are our thoughts, recommendations and requests as it relates to the proposed regulation changes and their potential impact on the PA MMJ industry's ability to improve efficiency and ensure low cost to our patients.

Laboratories
§ 1171a.29. Testing requirements
Subsection (c).

PA's Medical Marijuana program currently has the most stringent quality control requirements in the Country and is in fact better than many international programs, which ensures that we exceed the requirements of Federal Government research programs.

However, the proposed requirement that different labs test different phases of production creates several significant and costly challenges. Currently, it is PAOFW practice, that if a sample should fail either test, we reserve the opportunity to contract with a different lab to confirm sample tests. As such, if the proposed testing requirements are implemented, are we then obligated to find a third laboratory to confirm any testing failures from either of the first two?

Requiring different labs to test different phases of production also creates several logistical issues in terms of transportation and product security. Inconsistencies already exist in the regulations for the transport of products and for security during transport as required during different phases of distribution (reference, § 1161a.35. Transportation of medical marijuana products) versus § 1171a.33. Transporting samples). Adding the need to transport product to different labs during different phases of production creates an added cost in logistics and the prospect of further inconsistent reporting and tracking.
In an already expensive industry, adding the requirement for different labs at different phases of production, the possibility of needing a third lab for results confirmation, and all of the additional logistics required for varied transport, creates substantial added costs for DOH partners to incur and inevitably pass through to patients in product pricing.

For these reasons, PAOFW opposes the proposed requirement for different labs testing different phases of production. Instead, we would recommend that the DOH provide duplicate samples to multiple labs for proficiency testing to ensure that the laboratory results are in agreement with acceptable deviations.

Labeling and Packaging

§ 1151a.29. Limit on medical marijuana processing

- Labeling on outside packaging and container directly touching MMJ product

The Number and cannabinoids and terpenes to be listed on the labels is in excess of 10 items. This will be very difficult and will provide patients will labels that are very hard to read and utilize.

Additionally, the size of cartridges and RSO syringes will present labeling challenges if this is the final package being referred to in the new regulations. Clarification is needed on the location of labeling required by the new regulations.

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

Subsection (b).

This proposed subsection lists the general requirements for medical marijuana product packaging. The current subsection (b)(3) provides that packaging must be ''light resistant or opaque, or both.'' **This proposed subsection revises that provision and requires that packaging be opaque and removes the option to be ''light resistant.''** This revision effectuates the Department's intent that packaging not be transparent.

We like to continue to use our current lotion dispenser which has UV block plastic but is slightly transparent. This allows the patient to see the amount of remaining lotion or cream so that they know when to reorder. All of this, in addition to the fact that our packaging provides an improved method of administration, is designed with the intention of providing our patients with a positive and user-friendly patient experience.

Subsection (d).

This proposed subsection requires that all packaging and labeling be approved by the Department and sets out the information that must be included on each label. The Department proposes to expand upon the requirements in the current subsection (d) by: (1) requiring that all packaging receive prior written approval of the Department; (2) **requiring labels to list the species and percentages of all cannabinoids and individual terpenes**; (3) requiring that labels be firmly affixed to the container directly holding medical marijuana as well as outer packaging; and (4) requiring that THC be the first number in a THC:CBD ratio, when the labeling includes a ratio. These revisions minimize patient confusion caused by medical marijuana packaging, and also ensure that individuals and law enforcement officials can readily determine if a medical marijuana product was purchased at a dispensary. This proposed subsection otherwise mirrors the current subsection (d), except for technical revision to subsection (d)(2) to correct syntax.

- Please define the term, species, as it relates to medical marijuana products.
- Requiring that labels “firmly affixed to the container directly holding medical marijuana as well as outer packaging” contain a full list of individual terpenes creates multiple significant challenges. Such a requirement could mean as many as 30 terpenes are listed on a label. Products that may be administered in a syringe would be prohibitively small to list all that is required.
- We suggest DOH require a percentage threshold to list terpenes that make up a significant presence in the product.
- Also, the terpene profile that shows in MJ Freeway is just a small snapshot of the terpene profile that would show in a true COA. What is the DOH’s direction for which profile should be used?

Industrial Hemp

PAOFW would like to propose an additional consideration related to patient treatment and products available. In PA, the Industrial Hemp industry is equally as young and burgeoning as the medical marijuana program. Together, these programs address several needs of PA's citizens. PAOFW proposes that any Industrial Hemp product that passes the testing requirements spelled out in the Medical Marijuana program be made available for sale in dispensaries. Allowing dispensaries to dispense Industrial Hemp products that pass this stringent testing would give dispensaries additional products with which to treat patients and conduct research on product effectiveness.

Security

§ 1161a.35. Transportation of medical marijuana products) versus § 1171a.33. Transporting samples

Proposed transportation regulations are not consistent for dispensaries and grower/processors. Proposed dispensary regulations would require a transport vehicle to "Be equipped with a secure lockbox located within a locking cargo area", while the proposed grower/processor regulations do not. If accepting the proposed change to the dispensary regulations, the G/P regulations should mirror the dispensaries.

§ 1161a.31. Security and surveillance

PAOFW proposes that data and video storage requirements mirror other high security industries such as gaming industry, pharmaceutical and banking. Long time periods in data storage requirements are prohibitively expensive, therefore we recommend the reduction of video storage from the current DOH standard of to a minimum of 90 days but not more than a year – this would be much greater than the current surveillance data and video requirements of PA's Gaming code 465a.9 (see below).

§ 465a.9. Surveillance system; surveillance department control; surveillance department restrictions.

(j) The surveillance recordings required under subsection (e)(1), (8), (9), (10) and (11) shall be retained for a minimum of 30 days. All other surveillance recordings shall be retained for a minimum of 7 days. Surveillance recordings shall be made available for review upon request by the Board or the Pennsylvania State Police.

§ 1141a.31. Background checks
Subsection (c)

On occasion we may have a prospective employee that has a prior charge or conviction but has since reformed and/or has not been convicted of a subsequent or related additional offense. The proposed standards regarding a financial backer, principal or employee's past convictions, limit our ability to find the best individuals with whom to associate. Some of the most experienced people in the industry have a mark on their record. PAOFW proposes that, instead of a lifetime ban and depending on the severity of the conviction, the DOH consider convictions recorded within 10 years prior to the application. This consideration would happen only after DOH review and approval. This approach to prior convictions would also be consistent with the requirements set forth in the Clean Slate legislation.

§ 1141a.48. Training

PAOFW recommends that this training be updated more frequently to reflect any updates, such as added conditions, updated requirements, etc.

§ 1211a.33. Dispensing and tracking medical marijuana products

PAOFW currently records the relevant patient information in a separate database. The proposed regulations imply that information is to be entered into the electronic tracking system as required by the Department. Where, specifically, is this data to be entered?

Product Importation

§ 1151a.24. Start-up inventory

Subsection (a).

PAOFW appreciates the current proposed regulations allowing grower/processors the ability to potentially import additional genetic material. This proposed opportunity allows GPs to access newly developed genetics that are present in the marketplace elsewhere. While the initial 30-day window provides a good opportunity for initial acquisition, the amount of genetic development in the industry multiplies on an exponential scale annually; with continued development towards varied goals.

The proposed regulation reduces the forms in which material can be imported into the state. The proposed language reduces the form to only seeds; which limits the ability to import cuttings and/or live plants. This reduction will severely hamper the ability of organizations to access the most beneficial strains for patients within the Commonwealth. As intellectual property firms within the industry continue to develop highly specialized varieties of medical marijuana, the protection of that development increases as well. This protection is specifically focused on limiting the production of seed and other available genetic material; which includes both legal and biological protections. As it stands now, almost all of horticultural production is done through the use of germplasm or tissue culture; which is the most stable form for storing plant material. By limiting material importation to seeds only, we are potentially limiting our ability to bring life-changing medicine to the patients of the Commonwealth of Pennsylvania.

Therefore, based on the above-mentioned concerns, we recommend that the allowable forms of medical marijuana for importation be allowed to remain with the current language in the temporary regulations.

Emergency Regulations Not Addressed

The temporary rules established in the Governor's executive order during the COVID-19 pandemic are not addressed in the proposed regulations. Practices like, dispensing 90-day supplies and the definitions of "Caregiver", remote working, and health professional coverage at a dispensary are not addressed in the proposed regulations, but are currently being practiced under the executive order.

Are these practices to be continued upon the execution/approval of the proposed regulations?

Thank you for your time and consideration,

Tom

Thomas A. Trite

Founder and CEO
PA Options for Wellness