DH, MMRegulations

From: Joy Strand <joy@gleaf.com>
Sent: Monday, April 5, 2021 4:32 PM
To: DH, MMRegulations
Subject: [External] Comments to proposed regulatory changes
Attachments: gLeaf IRRC Comments 4.2021.pdf

Good Afternoon,

Please see the attached comments from Green Leaf Medicals, LLC on the proposed regulatory changes as published in the 51 Pa.B. 1141 on March 6, 2021.

Please contact me with any questions.

Sincerely,

Joy A. Strand, MHA
Executive Vice President
Green Leaf Medical

gLeaf Medical Cannabis

www.gleaf.com

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

April 5, 2021

Via email: RA-DHMMregulations@pa.gov

Dear Director Collins,

Thank you for the opportunity to provide public comment to the Pennsylvania Office of Medical Marijuana regarding proposed regulatory changes as published in the 51 Pa.B. 1141 on March 6, 2021.

I write to you in my capacity as the Executive Vice President at Green Leaf Medicals, LLC (gLeaf). Previously, I served as the executive director of Maryland's Medical Cannabis Commission and was the lead regulator for the Maryland program. gLeaf is happy to provide comments as outlined in this letter. Please note, *italicized text is proposed or current state language,* while proposed changes that are agreeable or not applicable to gLeaf are not mentioned here.

Regulatory Analysis - Question 22a/22b
Exhibit C1: "Reporting Individuals Affiliated with a Medical Marijuana Organization"

gLeaf presently operates a 100 SF grower/processor facility in Saxton, PA (Bedford County) with approximately 130 employees. We are embarking on an expansion project to add another 180 SF and will employ over 500 employees when at full production. Currently, the Department processes affiliations over a 7-to-8-week period. The length of time to affiliate an employee is untenable for a rapidly expanding business. Delays in affiliations result in inability to get employees working. We have lost good hires due to unreasonable delays, and these delays cause staffing and production issues as well. An employee should be affiliated within a two-week period.

As such, we request that this form include language requiring the Department to affiliate within a two-week maximum timeframe.

1141.39 Application for approval of a change in ownership of a medical marijuana organization

'The Department proposes to clarify that it only determines the suitability of the individuals affiliated with medical marijuana organizations and does not approve a medical marijuana organization's equity transaction.'

gLeaf asks for further clarification of if the Department does not approve a medical marijuana organization's equity transaction, who is the approving authority? Licensees need a defined and timely process to have equity transactions processed and approved.

1141a.50. Advertising by a medical marijuana organization.

This proposed section mirrors the current § 1141a.50 (relating to advertising by a medical marijuana organization). This proposed section provides that medical marijuana organizations must be consistent with applicable Federal regulations when advertising or marketing medical marijuana products, and before use, these materials must first be approved by the Department. This proposed section further provides that it does not apply to information provided by a grower/processor to a dispensary listing various medical marijuana products, instruments, and devices that the grower/processor is offering for sale to the dispensary.

gLeaf believes that this regulation should have the word "promotional" omitted from the following regulation:

(b) ~~Promotional,~~ Advertising and marketing materials shall be approved by the Department prior to their use.

gLeaf has noticed that promotional material such as branded hats, shirts, pens, bags, and other such items are currently being distributed in Pennsylvania. The Department has in some cases taken the position that this type of material will not be approved. gLeaf believes the word "promotional" should be omitted to make promotional material permissible and requests the Department implement consistent enforcement across all licensees.

1151a.23 Grower/processor facilities and 1151a.25 Visitor access to grower/processor facilities

This proposed subsection revises subsection (b)(3) with respect to signage for limited access areas. Current subsection (b)(3) requires that limited access areas have a sign that states "Do Not Enter—Limited Access Area—Access Limited to Authorized Personnel and Escorted Visitors." This proposed subsection replaces the word "visitors" with "individuals." The Department proposes replacement of the term "visitor" to accentuate the fact that grower/processor facilities are not open to the public and are not permitted to have non-essential visitors.

If this proposed regulation is adopted, it will require gLeaf to have new signs made and replace current signs. The proposed change is unnecessary, adding incremental cost for materials and labor to an issue where a problem does not exist.

While visitor access is adequately addressed in the current regulation, the Department has the most restrictive 'visitor prohibitions' practice of any state where gLeaf operates. While cannabis facilities are not public facilities there are many non-employee individuals that need to come into the facility to provide necessary services or would benefit from the education the facility could provide. gLeaf request the Department adopt the standard practice of allowing visitors to the grower/processor facilities as specified in the current regulation.

1151.24 Start-up inventory

The Department proposes removing references to 'immature medical marijuana plants' and only permit the importation of seeds from outside the Commonwealth. Additionally, the Department proposes an additional 30-day window to allow grower/processors more flexibility in acquiring seeds <u>if the Department determines that importation of additional seeds is necessary.</u>

gLeaf request that the references to 'immature medical marijuana plants' remain. The dependence on seeds for inventory start-up and rejuvenation of genetics is unpredictable and restrictive. To assure pure female genetics of high quality, live plants are required. Seeds may be sterilized and unable to germinate, contain male genetics which are unsuitable and a potential hazard within the growing facility, and contain unknown strain genetics or be of low quality. For these and other reasons, total reliance on seeds for genetics is undesirable and dangerous.

Additionally, allowing new genetics to be added only 'if the Department determines that importation of additional seeds is necessary' does not specify a certainty that this would ever be allowed, or under what criteria or conditions this would be allowed. gLeaf requests a reliable and scheduled 30-day window every 6 months to allow processors to refresh genetics with immature medical marijuana plants or seeds. Ideally, all growers would be on the same schedule, to reduce the administrative burden within the department for the scheduling and tracking different timeframes for different growers.

1151.27 Requirements for growing and processing medical marijuana.

This proposed section provides that a grower/processor may only use pesticides, fungicides and herbicides approved by the Department of Agriculture and that the Department will periodically publish the list of approved pesticides, fungicides and herbicides in the Pennsylvania Bulletin.

gLeaf's comment: The approved pesticide list has not been updated since the inception of the program and it would be beneficial if this regulation were opened to have the Department of Agriculture have regulatory authority over pesticide use for medical marijuana approval.

This proposed section amends two subsections in the current § 1151.27. First, the phrase "additional active ingredients or materials" in current subsection (f) is replaced with the newly defined term "added substance" for the purposes of clarity. Further, proposed subsection (f) adds subparagraphs (i) and (ii) to provide guidance on what the Department will consider when determining whether to approve an added substance. Second, the current subsection (h)(3) provides that growers/processors only process parts of the medical marijuana plant that "[c]ontain a level of mold, rot or other fungus or bacterial diseases acceptable to the Department." The proposed subsection changes that language to more clearly read that a grower/processor may only process parts of the medical marijuana plant that "[d]o not contain levels of mold, rot or other fungus or bacterial diseases above the minimum levels acceptable to the Department."

gLeaf comment: Current regulation require excipients to be 'pharmaceutical grade', unless otherwise approved by the Department. gLeaf requests that 'food grade' additives also be allowed, if considered to be Generally Recognized as Safe ("GRAS") by the USFDA.

Regarding subsection (h)(3), it is imperative that the Pennsylvania regulations be changed to allow the remediation of flower that fails testing for microbials. This is one of the primary hindrances to a plentiful and robust product market for patients. Every other state that gLeaf operates in recognizes that cannabis is a plant with a high moisture content, grown in warm conditions and the presence of mold and mildew is not an anomaly. Remediation can safely process out the mold and mildew and the resulting oil-based product retested to demonstration and assure purity and safety.

Since beginning operations, gLeaf has had approximately 1200 lbs. of flower product wasted due to the inability to remediate flower into processed product. The translates to almost $ 5 MM. We are just one grower; it is likely that other grower/processors have similar circumstances. Regulations that increase the expense of operations result in higher prices for products for patients. We should all work together to have appropriate regulations that assure high quality product safety and prevent diversion, and do not add additional cost to the process. To help patient obtain medication at the lowest possible cost, operational costs need to be as low as possible.

1151a.29 Limit on medical marijuana processing

This proposed section differs from the current § 1151.29 in two ways. First, proposed subsection (a) is revised to replace the full name of each cannabinoid on the product label with the abbreviation—as each is a defined term—in addition to requiring that the amount of Delta-8 THC be disclosed on the product label. These revisions are aimed at providing transparency with respect to the cannabinoids in medical marijuana products.

First, gLeaf congratulates the department on taking an early lead in addressing the emerging prevalence of Delta 8 THC in the public arena and in requiring this cannabinoid be included in labeling requirements. Please clarify if the content of Delta 8 THC needs to be included if the tested amount is zero.

Next, in response to the proposal to include the full name of each cannabinoid on the product label, rather than just the abbreviation, gLeaf believes this change to be unnecessary and difficult to implement. The current require label information is already voluminous, so much so that the font on the labels is small and can be hard to read for some. The abbreviations are well-known, commonly used, and meaningful within the industry and with patients. Including long chemical names that no one uses is totally unnecessary.

1151.34 Packaging and labeling of medical marijuana products

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 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.

gLeaf suggests changes to (2) requiring labels to list the ~~species and~~ percentages of all cannabinoids and individual terpenes *present*; *and remove* (3) ~~requiring that labels be firmly affixed to the container directly holding medical marijuana as well as outer packaging;~~ *entirely.* In (2) the term species used here is confusing and open to interpretation. Requiring only those cannabinoids and terpenes present on the label the information is accurate and relevant, without consuming precious label space. In (3) requiring the same information on a label on the container holding the medical marijuana is unnecessary and difficult at best. Many product containers are too small to hold a label with this amount of information affixed to them.

Based on our current volume of production it would cost gLeaf more than $30,000 per year in materials to implement the second product sticker, in addition to the packaging sticker. That cost will increase exponentially as we expect to more than double our production when our expansion project is complete.

Additionally, gLeaf requests the removal of the current regulations:

~~(9) State the employee identification number of the employee preparing the package and packaging the medical marijuana product.~~

~~(10) State the employee identification number of the employee shipping the package, if different than the employee described in paragraph (9).~~

~~(11) Contain the name and address of the dispensary to which the package is to be sold.~~

gLeaf's comments: These requirements create additional burdens and obstacles in labeling and preparation of shipments that increase costs for materials and labor, reduces flexibility, creates rework and additional costs for last minute order or shipping changes, and do not add additional safeguards for quality or safety. Dispensaries label each product sold with the dispensary information; for the grower to also prepare and affix a label for the receiving dispensary is redundant and unnecessary.

Labeling and packaging of a batch of products is accomplished by a team of employees. The requirement to print the identification number of individual employees involved in packaging and shipping is unclear and not relevant information for patients.

1151.40 Management of disposal of medical marijuana waste

(b)(1) Unused, surplus, ~~returned,~~ recalled, contaminated or expired medical marijuana.

gLeaf comments: gLeaf proposes removing the term 'returned' from this regulation. Returned products is a broad category. Many returned products are safe for resale or reshipment. If a product is opened or defective that obviously would need to be destroyed, however if a product or large shipment of product is returned due to a clerical or record-keeping error that can be corrected, that should not require destruction and resale and reshipment allowed.

1171a.26 Stability testing and retention of samples

This proposed section mirrors the current § 1171.26 (relating to stability testing and retention of samples). This proposed section provides that an approved laboratory must conduct required stability testing of samples collected from growers/processors to ensure product potency and purity and accurate expiration dating, and that the laboratory must properly store those tested samples for 1 year.

OFFICE OF MEDICAL MARIJUANA
GUIDANCE FOR QUALITY TESTING AND SAMPLING
BY APPROVED LABORATORIES
Issued: January 16, 2018
Updated: August 10, 2018

Stability Testing.

In accordance with 28 Pa. Code § 1171.26 (relating to stability testing and retention of samples), a grower/processor shall provide samples from each process lot (final sample) to an approved laboratory for testing at 6-month and 1-year intervals for extraction-based products. The sample shall

be taken from the reserved sample portion provided to the approved laboratory that is collected from each process lot being tested. Any reserve samples remaining after testing at the end of the 1-year period shall be destroyed in accordance with the approved laboratory's disposal process.

A grower/processor shall provide samples from each process lot (final sample) to an approved laboratory for testing at 1-month and 3-month intervals for finished flower products.

gLeaf requests changes to the stability testing requirements to perform stability testing at 1 year, and then only if there is product remaining in inventory. Rarely do gLeaf products remain in inventory for more than 6 months.

The requirement for finished flower product to be tested at harvest, final product and at 1 month for stability means that a particular batch is tested three times in less than a 6-week period.

Required stability testing at the current 1- and 3-month interval for flower products, and 6 and 12 months for processed products, is wasteful if there is no product left to sell. Stability testing should be required at 1 year, only if there is product left in inventory. The request for stability testing should come from the grower/processor, only as needed, when product remains in inventory.

As most gLeaf products move out of inventory very quickly there would be a substantial cost savings of approximately $ 225,000 if revision to a more reasonable stability testing schedule was implemented. Rationally reducing the requirement for stability testing to only when needed will reduce operational costs which in turn will reduce the cost of medication to patients.

1171a.29 Testing requirements

Subsection (c).

The current subsection (c) specifies that an approved laboratory must minimally test two samples at harvest and at process stages. This proposed subsection (c) amends the current subsection (c) by providing that one approved laboratory must conduct testing on the harvest sample and a different approved laboratory must conduct testing on the processed sample. This revision creates checks and balances in the testing process.

gLeaf requests language changes:

(c) At a minimum, an approved laboratory shall perform tests as prescribed by the Department on the following items:

(1~~ Samples from a harvest batch or harvest lot prior to being used to produce a medical marijuana product.~~)

~~(2)~~ (1) Samples from each ~~process~~ finished product lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.

Flower that is going to processing into different medical marijuana forms and products should not require testing. This is redundant and doubles the testing cost and time to market for products. gLeaf currently has an annual expense of approximately $ 235,000 for only harvest testing of flower going to processing. If a final product passes testing it demonstrates safety to public health prior to sale.

Additionally, the requirement that one laboratory conduct testing at harvest while another laboratory conduct testing on the processed sample is unreasonable and confusing. Laboratories are required to be accredited and pass proficiency testing. As laboratories are licensees of the Department, the Department should implement a standardization program for laboratory testing to have PA labs perform round robin testing on blind samples and the Department compare these results to a known standard and evaluate variances. Requiring the use of two different laboratories places additional administration and cost burdens on grower/processors.

1171a.31 Test results and reporting

Subsection (c).

This proposed subsection (c) mirrors the current subsection (c), except as detailed as follows. This proposed subsection (c) provides the procedure for a sample that fails testing. This proposed subsection allows a failed sample to be re-tested by the same laboratory. If the initially failed sample were then to pass re-testing, proposed subsection (c)(2) requires a different laboratory to confirm that passing test. Proposed subsection (c)(3) allows the Department to opt to reject the confirming result from the approved laboratory. The term "confirming" was added to subsection (c)(3) as a grammatical clarification. If the Department rejects the confirming result, or if the sample were to fail again, under proposed paragraph (3), the lot is required to be disposed of in accordance with proposed § 1151a.40 (relating to management and disposal of medical marijuana waste). Proposed paragraph (4) had been added to clarify the expectation that a re-tested sample that fails is required to be disposed of in accordance with proposed 1151a.40. Finally, citations have been amended to refer to this proposed chapter and proposed Chapter 1151a.

gLeaf requested changes:

(c) If a sample fails any test required under § 1171.29, the following apply to the sample:

(1) The approved laboratory that performed the initial test, or another approved laboratory, may re-test the sample upon a request from the grower/processor in accordance with subsection (d).

(2) If the sample passes the re-test, a second confirmatory test by an approved laboratory shall sample the same harvest batch, harvest lot or process lot to confirm the passing test result.

~~(3) If the Department does not agree to accept the results from the approved laboratory, the sample shall be disposed of by the approved laboratory under § 1151.40 (relating to management and disposal of medical marijuana waste).~~

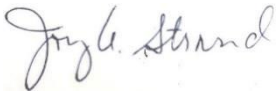
The grower/processor should be able to select the laboratory to perform the initial test and any re-tests. Despite best efforts testing and resulting errors do happen and grower/processors should be able to utilize laboratory options to demonstrate product safety and purity. There are no defined criteria as to how or why the Department would not accept the results from an approved laboratory, or the full intention of (c)(3).

Please note there are specific situations where the electronic tracking system (MJ Freeway) cannot accept all the test results performed on a lot. There are three fields for results in the system, and gLeaf has had a couple of situations where there are four test results. None of the test results can be removed and the fourth test result cannot be entered, resulting in incomplete information.

Thank you again for the opportunity to provide comments on the proposed regulatory changes. Please note that while it is helpful to have a narrative explanation of purpose, intent, and reasoning, it is most helpful to present proposed regulatory changes in a 'red-lined' version indicating the exact regulatory language being proposed. That format provides the most clarity and specificity.

Please contact me with any questions or if I can provide further information.

Sincerely,



Joy A. Strand, MHA
Executive Vice President
Green Leaf Medicals, LLC