#3290

Madison Brame

From: IRRC
Sent: Friday, October 14, 2022 12:22 PM
To: Michelle Elliott; Scott Schalles; Fiona Cormack
Cc: Madison Brame; Stephen Hoffman
Subject: FW: Organic Remedies' Comments - Proposed Final Regulations
Attachments: Proposed Final Regulations - OR comments IRRC # 3290.docx

Comment on #3290

From: Tammy Royer <T.Royer@OrganicRemediesPA.com>
Sent: Friday, October 14, 2022 12:18 PM
To: IRRC <irrc@irrc.state.pa.us>
Cc: Eric Hauser <E.Hauser@OrganicRemediesPA.com>; Mark Toigo <M.Toigo@OrganicRemediesPA.com>; Ryan Simpson <R.Simpson@OrganicRemediesPA.com>; Tammy Royer <T.Royer@OrganicRemediesPA.com>
Subject: Organic Remedies' Comments - Proposed Final Regulations

Dear IRRC members and analysts,

Please accept the attached document as public comments on behalf of Organic Remedies, Inc. in respect to the Regulation #10-219: Medical Marijuana - proposed final regulations. IRRC number 3290.

Please feel free to reach out to me if you have any questions or need clarity on any items.

Thank you,
Tammy Royer

Tammy Royer, RPh.
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Statute	Relevant Section/Info	Comments
Definitions	Harvested Hemp	Does not include extracted hemp. Is this by 3 Pa.C.S.Ch. 15 regulation? Extracted hemp has much less potential for contamination or concern. Defined as plant material specifically
Definitions	Medical Marijuana Limit	Is an oil intended for vaporization considered a concentrate?
1151a.23 (3)	Grower/Processor Facilities	All limited access signs must be changed to say "Do Not Enter- Limited Access Area - Access Limited to Authorized Personnel and Escorted Individuals. Several commentors have already indicated this creates added cost for little gain. Access to the facility is defined by the permitee SOPs and the required security at every facility. Changing signage to say Individual instead of Visitor is not going to fundamentally change the perception of the public or create a greater level of security. Instead, the department simply needs to provide clear guidance on the definition of Escorted Individuals permitted for business purposes and allow open communication if permittees have a question related to this. Additionally, the department dismissed concerns related to cost incurred by this revision indicating the sign choice by the permittee dictates cost and denies the need for a grace period to convert as paper could be used. While the signage choice is the permittees to make, these signs must be sturdy and durable and, in many cases, withstand the elements as the department has defined the exterior of the permittee location, even if medical marijuana product is not present upon entry, to be limited access areas. Paper is not a viable option for outside signage nor is it durable enough for longevity in any part of facility to ensure compliance.

1151a.24 (g)	Harvested hemp may be added	We agree with the ability to obtain harvested hemp from appropriately permitted individuals as per the regulation, however simply stating that does not provide the guidance as to how this may be done in the seed to sale system. Permittees should receive a guidance document outlining exact procedures for how this may be accomplished, or the addition of this revision is moot. Additionally, harvested hemp has much greater potential for contamination. Extracted help should be permitted and is prohibited by 1151a.24 (f).
1151a.27 (f) (iv)	Requirements for growing and processing	Prohibits additives that may have known drug interactions. This is very broad. Most anything can have drug interactions. OTC products available to the general public have drug interactions. What specific level of interaction will be reviewed, and a product denied?
1151a.34 (d) (17)	Packaging and Labeling of Medical Marijuana Products	Requires the label affixed to the container physically holding the marijuana to contain all cannabinoids and terpenes greater than 0.0%. Commenters expressed concern at the capability and feasibility of affixing a label with the newly required level of information directly to the container directly holding the medical marijuana product. The department dismissed these concerns and cited that accordion style labels have been used in some cases. However, what is not contemplated by that statement is the overall cost of utilizing

		those labels exclusively and that they have not been used on all forms or by all permittees. It is not feasible or reasonable to place even an accordion label on a 510 thread vape cartridge, for example, which is in large enough font to be read by the naked eye. Certainly, the concern of making legal products more easily discernable for law enforcement is understood, however, the regulation requires patients to keep products in the original packaging which should satisfy this concern.
1151a.34 (d) (6)	Packaging and Labeling of Medical Marijuana Products	Requires the species, which is cannabis sativa, cannabis indica, or a hybrid of the two, according to the definition, however not all products would be appropriately labeled for patients in this fashion as patients generally utilize these terms to equate to effects and non-species specific products such as some tinctures, capsules, and topicals may be created utilizing THC or CBD only extracts from multiple species. It would not be feasible or correct to add species to the label in this instance.
1161a.23 (b)	Dispensing medical marijuana products	Commentors previously asked if the requirement for the dispensary's medical professional to review the most recent certification could be removed. We understand the need to ensure a patient has an active certification, however, in order to properly utilize the medical knowledge of the medical professional, we suggest that the state tracking systems transmit that information and provide hard stops systematically to satisfy the safety of patients and the requirements of the act. The value of the pharmacist in the medical marijuana program is their direct contact and consultation with patients. The verification of information that can easily be hard stopped systematically (which is the precise value of a seed to sale tracking system) is unnecessary administrative work that the department is requiring rather than build a system that puts patient care first. At a minimum, if these arguments are again dismissed, the Department should see the value of creating a more efficient means for the dispensary medical professional to review the information so that they may spend their valuable time on patient consultations. The current process is not efficient, requires unnecessary clicks, and could be streamlined by providing better search capabilities and a view specific to dispensary medical professionals to remove wasted time clicking through unnecessary screens. In the most recent final regulation submission by DOH, the word dispensary was replaced by "dispensary medical professional" when describing the duties to verify patient eligibility. By making this change, the department not only requires the pharmacist to complete the solely administrative role of checking certifications but also: 1161a.23(b)(1) (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. We are concerned that this change will be interpreted as a requirement to have the medical professional physically check in patients to the state tracking system and view their card to satisfy this requirement. This is unnecessary as the state tracking system verifies this for the dispensary and if a pharmacist is required to do this, their time again will be relegated to non-patient care activities which is the exact opposite of what we believe the Department wishes to accomplish.
1161a.24 (b)	Limitations on dispensing	While we applaud the concept of creating a patient purchasing limit, a plan for implementation must be associated with that requirement. How will this be monitored and enforced? How will patients be notified of the limit being instated, their current purchase amounts, and if they have reached the limit? Will there be systemic flags to notify the dispensary personnel as they do not have access to purchases at other dispensaries? Currently, dispensaries cannot see purchases or purchase amounts from other dispensaries for a patient so it would be impossible for the dispensary to monitor a monthly limit for patients. If there is a plan for implementation it should be shared with impacted parties prior to taking effect and potential concerns addressed. If there is not a plan and systematic controls, which there is not today, this should be removed.

1161a.30	Access to dispensary facilities	The Department did change the final forms regulation to allow dispensaries to admit escorted individuals for the purposes of potential investment or employment as is permitted for GPS however, dispensaries are limited to these activities being outside of business hours. We do not believe this exclusion is necessary. Dispensaries are open extended hours to meet the needs of patients. Escorted individuals are permitted for individuals within the regulations if required to maintain operations for patients and ensuring proper funds for operations and adequate staffing are critical to maintaining a high level of patient care and operations.
1161a.26 c 1	Dispensary Facilities	All limited access signs must be changed to say "Do Not Enter- Limited Access Area - Access Limited to Authorized Personnel and Escorted Individuals. Several commentors have already indicated this creates added cost for little gain. Access to the facility is defined by the permitee SOPs and the required security at every facility. Changing signage to say Individual instead of Visitor is not going to fundamentally change the perception of the public or create a greater level of security. Instead, the department simply needs to provide clear guidance on the definition of Escorted Individuals permitted for business purposes and allow open communication if permittees have a question related to this. Additionally, the department dismissed concerns related to cost incurred by this revision indicating the sign choice by the permittee dictates cost and denies the need for a grace period to convert as paper could be used. While the signage choice is the permittees to make, these signs must be sturdy and durable and, in many cases, withstand the elements as the department has defined the exterior of the permittee location, even if medical marijuana product is not present upon entry, to be limited access areas. Paper is not a viable option for outside signage nor is it durable enough for longevity in any part of facility to ensure compliance.

1161a.31 b 5	Security and Surveillance	We ask that the department consider allowing the individual monitoring the security equipment to make hourly rounds and be present for deliveries. The individual could utilize an iPad to view the cameras while completing these duties. The requested functions provide a much greater presence to patients and the public, especially during deliveries which are likely the greatest risk for diversion. We do not believe this creates greater security risk.
1161a.23 (a)	Dispensing medical marijuana products	The Department received comments asking for the electronic tracking system to provide better clarity of the reason for a rejected card or to indicate the date of application fees due to help support patients and also dispensaries in serving patients. The Department opted to take no action because a dispensary is not able to dispense on a rejected card. This is true, however, the process developed by the Department makes the card issue and expiration dates ineffective in discerning a valid card and the reason for rejection may be any number of things. Depending on the nature of the rejection, the dispensaries instruction to the patient on how to resolve the rejection may be different. For example, if the patient simply needs to pay their fee, they may complete this transaction from their phone and immediately be able to purchase versus if they must obtain a new certification. Providing this information to dispensaries, who are the first line of communication, would alleviate unnecessary calls to the department by patients and dispensaries to ascertain the issue and help the patient resolve it. By the response from the DOH, it would seem that the Department would prefer to turn the patient away always when the solution might be as simple as providing information that will ascertain if a patient could correct on the spot or not. This creates significant frustration and wastes money and time for patients. This request is made to improve patient care/experience and relieve unnecessary calls and frustration for patients.
1171a.29 c (2)	Testing Requirements	The Department received comments indicating the requirement to have two different laboratories test the harvest and process lot would cause concern for volume discounts and inherently add costs. The Department dismissed this concern indicating that the same volume would be tested so therefore the costs should not increase. However, volume discounts only apply if there is higher volume that is not spread out. If the Department has approved the labs and their processes and holds them to a standard, why would it be necessary to require tests from different labs? Is there any defined evidence of incorrect data or testing? If not, there is no reason or benefit for this revision. And if so, the action should be to address the infractions seen.