DH, MMRegulations

From: Samantha Kramer <Samantha.Kramer@gtigrows.com>
Sent: Monday, April 5, 2021 12:27 PM
To: DH, MMRegulations
Subject: [External] GTI Public Comment - Regulation #10-219
Attachments: PA Green Thumb Public Comment 4.5.2021.pdf

Please see the attached public comment letter regarding Medical Marijuana Regulation #10-219 (IRRC #3290).

Thank you,

Samantha Kramer
Government Affairs Associate
c | 312.599.9785

325 W Huron St.
No. 412 | Chicago, IL 60654
Facebook | Instagram | Twitter | LinkedIn

Green Thumb

325 W. Huron Street
No. 700
Chicago, IL 60654
312.471.6720
gtigrows.com

April 2, 2021

Via email:
Independent Regulatory Review Commission
Commonwealth of Pennsylvania
irrc@irrc.state.pa.us

Re: Medical Marijuana Regulation #10-219 (IRRC #3290); Proposed Permanent Medical Marijuana Regulations by the Pennsylvania Department of Health

Members of the Independent Regulation Review Commission and Department of Health:

I am submitting public comment in response to proposed Regulation #10-219: Medical Marijuana. Green Thumb Industries ("Green Thumb") operates 55 dispensaries and 13 manufacturing facilities in 11 highly regulated cannabis markets. Based on lessons learned from our experience in a variety of regulatory structures, our team offers the input below with the goal of optimizing Pennsylvania's cannabis industry to meet patient needs, minimize environmental impacts, and to ensure Pennsylvania cannabis companies are positioned to generate valuable jobs and revenue for the Commonwealth. Thank you for your consideration.

I. Comment Regarding § 1141a.25, § 1141a.28 and § 1141a.40 As Related to the Relocation of Preoperational Facilities

As drafted § 1141a.25, § 1141a.28 and § 1141a.40 do not include a path for preoperational facilities to select a new location. These regulations should be amended to allow preoperational and operational facilities to relocate within the Department's originally approved region (as defined in § 1141a.24). We recommend that § 1141a.25 and § 1141a.40 be amended to allow grower/processors and dispensaries to relocate their facility to a new location of within the same region identified in the medical marijuana organization's original license application prior to becoming operational or once operational.

To our knowledge, at least three medical marijuana organizations have encountered circumstances beyond their control, such as zoning prohibitions, unwelcoming neighbors, or environmental risks that would make it unreasonable and/or impossible to site a facility in the location listed in the original application. Current regulations do not provide a process for seeking and obtaining approval for preoperational relocation. As a result, a medical marijuana organization is placed in the illogical position of having to operationalize a facility prior to being allowed to relocate it.

Medical marijuana organizations should have the flexibility to relocate prior to commencing construction or buildout of a facility. This will not only be economically efficient and allow for much faster benefit to patients, it will also prevent the Department from engaging in duplicative regulatory efforts with the original facility and then the relocated facility, thereby reducing Department costs and preserving resource while enabling the Department to take into account patient access and to reduce the proximity of one dispensary to another.

Green Thumb

325 W. Huron Street
No. 700
Chicago, IL 60654
312.471.6720
gtigrows.com

Thus, we believe that preoperational relocation will mutually benefit the Department, Pennsylvania's medical cannabis patients, and operators across the state. We therefore recommend that § 1141a.25 and § 1141a.40 be amended to allow operators to select a new location of equal or superior quality within the same defined region, as follows:

§ 1141 a.25. General requirements for permits.

(a) ~~The Department may issue a permit to an applicant only for the specific location identified in the applicant's application, by name and address.~~ A permit will specify that the applicant is authorized to begin the process necessary to become operational. A permit is only valid for the person named in the permit and only for the location specified in the permit.

§ 1141 a.40. Application for approval of a change in location of a~~n operational~~ facility.

(a) A medical marijuana organization wishing to change the location of a~~n operational~~ facility shall submit an application for approval of a change in location to the Department together with the fee required under § 1141a.28 (relating to fees).

(b) A change in location of a~~n operational~~ facility may not occur until the Department approves the change, in writing, under this section.

(c) The medical marijuana organization shall submit an application for approval of a change in location on a form prescribed by the Department.

(d) An application for approval of a change in location must include the reason for requesting the change and other information about the new location as the Department may require.

(e) The Department will issue a new permit to ~~the~~ an operational medical marijuana organization for the new location if the request is approved. The Department will issue a letter of relocation approval to a medical marijuana organization that has applied to relocation prior to receiving a permit.

(f) Within 180 days of the issuance by the Department of a new permit under subsection (e), ~~the~~ an operational medical marijuana organization shall change the location of operation to the new location designated in the new permit. Simultaneously with the completion of the move, the medical marijuana organization shall cease to operate at the former location and surrender its existing permit to the Department. The following apply:

(1) At no time may a medical marijuana organization operate or exercise any of the privileges granted under the permit in both locations.

Green Thumb

325 W. Huron Street
No. 700
Chicago, IL 60654
312.471.6720
gtigrows.com

(2) At the discretion of the Department, the Department may extend the 180-day deadline for relocation for up to an additional 90 days.
(3) Once the new facility is determined to be operational by the Department, the medical marijuana organization may resume operations under the new permit at the new location.

(g) The Department will not approve a change of location that is outside the boundaries of the region ~~for which the initial permit was~~ issued listed in the medical marijuana organization's permit application.

§ 1141a.28. Fees.

(c) A medical marijuana organization shall pay a fee of $250 by certified or cashier's check or money order to the Department with the submission of the following:

(1) An application for change in ownership of a medical marijuana organization.
(2) An application for approval of a change of location of a~~n operational~~ facility.
(3) An application for approval of alteration of a facility.

II. Comment Regarding § 1151a.29(a) and § 1151a.34 Packaging and Labeling Requirements

Transparency in our products and patient education are of the utmost importance to our business. It is critical to the relationships we build with patients that they understand what goes into their products so they have the knowledge to maximize the benefits of medical cannabis treatment. That said, evolving packaging and labeling regulations substantially increase our cost of business and environmental impact.

For each evolution of packaging and labeling requirements, operators must discard existing packaging and labeling inventory and execute a full redesign of the products patients have grown familiar with. Our goal is to find a way to require fewer physical changes in packaging, not only to save labor and expense, but also to prevent packaging from becoming obsolete and filling up landfills. It is further worth noting that most operators source packaging and labeling materials from China, which means it is a prolonged process to adopt changes to packaging and labels that is presently further delayed due to COVID-19. The packaging and labeling requirements are unreasonable to change due to the significant additional cost it would impose on companies such as Green Thumb—resources that could instead go toward community reinvestment and hiring new employees.

As a proposed solution to increase the amount of information available to patients while reducing the environmental impact of changed packaging and labeling requirements, we recommend that the Department provide a 12-month runway to use up existing packaging and labeling inventory and introduce a digital link on each label that easily leads patients, regulators, and law enforcement to the expanded list of disclosures proposed without increasing packaging waste.

Green Thumb

325 W. Huron Street
No. 700
Chicago, IL 60654
312.471.6720
gtigrows.com

In addition, we propose that the Department continue to permit packaging with greater light transparency, rather than requiring containers to be opaque. To our knowledge, the existence of transparent packaging has had zero impact on the State, patients, or public safety. Many of our patients prefer transparent packaging, as compared to opaque, for better visibility at the point of sale which increases confidence in the purchase they are making and reduces the number of product returns to be processed. We believe this change would create unnecessary environmental waste and financial expense in packaging redesign for no public gain and would disadvantage purchasers who prefer transparent packaging.

Thus, Green Thumb recommends a digital solution to labeling disclosures be required following an adequate amount of time to utilize existing packaging and labeling inventory, and that the Department continue to permit packaging with a degree of transparency, rather than an opaque standard, which adds no public safety benefit.

III. Comment Regarding § 1151a.35(b) Transportation Lockbox Requirements

Green Thumb has experienced zero transportation security incidents since launching our Pennsylvania business. We therefore request clarity as to the expectations proposed in § 1151a.35(b)(1) which would require transportation vehicles to be "equipped with a secure lockbox or locking cargo area." We do not support the addition of costly new and unnecessary security requirements as our currently compliant and highly secure transport vehicles have proven to be sufficient.

In the unfortunate event of a robbery, a criminal holding a driver at gunpoint or other physical threat would simply force the driver to use his key to unlock a lockbox or locked cargo area. While we support enhanced security in all aspects of our business, we feel an additional locking mechanism will be a significant and unnecessary expense that will not, in practice, have the desired impact.

IV. Comment Regarding § 1161a.31(c) Dispensary Door Requirements

Green Thumb respectfully requests clarity as to the meaning of "commercial-grade" as proposed in "commercial-grade, nonresidential steel doors."

V. Comment Regarding § 1151a.43 Pesticides

We request that the following list of Active Ingredients ("AIs") be added to Appendix A:

Green Thumb

325 W. Huron Street
No. 700
Chicago, IL 60654
312.471.6720
gtigrows.com

Active Ingredient	Use
Peroxyacetic acid (all plant parts)	fungicide
Hydrogen Peroxide (all plant parts)	fungicide
Trichoderma harzianum (all plant parts)	fungicide
T . viride	fungicide
T. virens	fungicide
Streptomyces lydicus	fungicide
BLAD (beta conglutin) proteins of Lupine	fungicide
Reynoutria spp. extract	Fungicide
Beauveria bassiana	insecticide
Chromobacterium subtsugae (all plant parts)	insecticide
Burkholderia spp	insecticide
Isaria fumosorosea	insecticide
Bacillus thurgensis var israelensis	insecticide
Harpin Proteins	immune elicitor

Each of the above AIs meets or exceeds the standards of those listed in the current Appendix A list. All proposed Active Ingredients (AI's) are Residual Tolerance Exempt under Title 40, Chapter I, Subpart E, part 180 subpart D. This means: "An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to the public health." *Id*. Labeling for these products is designed in such a way to maintain this exemption for requirements of a tolerance when used as directed. Since it is a violation of federal law to use these products in a way that contradicts the label, all labels will be followed, so that no dangerous residuals are possible for these products. Such AIs would not be used on flowering parts of the plant or on finished product. All products selected for use will be currently registered with the State of Pennsylvania as a pesticide, and the final medical cannabis product will be required to meet the Commonwealth's high laboratory testing standards for consumer safety.

We further request the Department eliminate the "comments" section of Appendix A or amend the existing list to reflect the specific label instructions when used in compliance with 3 P.S. §§ 111.21—112. For example, this would allow hydrogen peroxide/peroxyacetic to be used on above ground portions of the cannabis plant provided that the specific tradename product(s) utilized have this as a listed acceptable use on their label for greenhouse vegetable or herb crops. This would also allow the AI Chromobacterium substage PRAA4-1 cells to be applied above ground (provided this is a labeled usage for the specific tradename).

* * *

Thank you for the opportunity to comment on these important and substantive rules. We would welcome the opportunity to provide any additional information.

Green Thumb

325 W. Huron Street
No. 700
Chicago, IL 60654
312.471.6720
gtigrows.com

Sincerely,

Samantha Kramer

Samantha Kramer

Government Affairs Associate

Green Thumb Industries, Inc.