DH, MMRegulations

From: Luke Shultz <kimlukes@gmail.com>
Sent: Sunday, April 4, 2021 11:00 PM
To: DH, MMRegulations
Subject: [External] Final Regulations Suggestions

Director John Collins,

I would like to submit for consideration the following changes and additions to the Medical Marijuana Program final regulations.

§ 1161.21. Definitions.

Add to the definition of Devices: Patients and caregivers may purchase devices from a dispensary or other source.

This would add clarification that devices not purchased in a dispensary by a patient or caregiver are legal for patients to use with medical marijuana and medical marijuana products. Currently there is confusion by patients, caregivers, law enforcement and others as to what is or isn't legal to use within the Pa program. Obviously, if the device can only be used for combustion then it would not be legal to use.

§1151.25. Visitor access to grower/processor facilities.

(g) Add to this section a statement to allow for prospective principals, financial backers, operators or employees of the organization, local first responders, lawmakers and others to enter grower/processor facilities for the purpose of information gathering, training or orientation with the prior written approval of the Department.

Currently, certain officials and others, including those listed above cannot enter the facilities even though they may have a legitimate reason to do so. Former Secretary of Health Dr. Levine even publicly stated that she could not enter a grower/processor facility due to regulatory restrictions. Protocols and controls are in place in the regulations to assure that anyone entering a facility is properly identified, escorted and monitored during their visit.

§1151.28

Add "(vii) Edible forms, including marijuana-infused food and drink products".

On February 1, 2019, the Advisory Board passed a recommendation to allow for edible forms of medical marijuana. The need for edible forms of medical marijuana was presented to the Board upon the requests of patients, caregivers and medical professionals for the reasons that edible forms of marijuana allow for easier administration than other forms and to limit patients and caregivers from going outside of the program to source edible products or trying to make them themselves without the proper knowledge or equipment. Sourcing medical marijuana from outside of the program or making edible products without the proper knowledge or equipment can lead to unsafe and adverse events for patients.

§ 1151.34. Packaging and labeling of medical marijuana products

Subsection d (6) Remove the requirement to list the number of individual doses.
(The would also apply to § 1161.28. Labels and safety inserts c (6))

Medical marijuana dosing standards have not generally been established and to attempt to do so without that knowledge base can cause confusion to patients and caregivers and even result in undesired or adverse events.

Also in this section:
Require that all known ingredients, including cannabinoids, terpenes, additives, fillers, excipients, etc be identified on the product label.
Some patients have adverse effects to alcohol, dyes or other ingredients that might be present in products and they should be able to identify what is in a product before they use it.

§ 1151.42. Complaints about or recall of medical marijuana products.
(also apply to § 1161.38)

Establish a means for other complaints, such as mold or contaminants or similar issues which do not cause an adverse event, but certainly could.

If a patient chooses not to use a contaminated product and thus does not incur an adverse event it doesn't mean that the product is fine and a complaint should not be taken as seriously as if the patient proceeds to use the product and exposes themselves to an adverse event.

§ 1151.45. Effective date and applicability.

Appendix A. Acceptable Pesticide Active Ingredients for Use

Add that the list of acceptable pesticide active ingredients shall be reviewed by both the Department of Health and the Department of Agriculture at least annually and updated as deemed appropriate.

This would help to insure that the list is current and appropriate for use in the program.

§ 1161.26. Dispensary facilities.

Add that patients may be assisted into dispensaries and with transactions by an individual who cares for the patient but is not in possession of a caregiver card.

This would allow for family member and others who care for patients but do not have a caregiver card to assist a patient in lei of a cardholding caregiver. This could be of benefit to someone from out of state or who is temporarily filling in for the caregiver to assist as needed. This would not allow someone without a caregiver card to purchase products on behalf of patients.

§ 1161.27. Items and services provided at a dispensary.

Add that dispensaries may purchase medical marijuana or medical marijuana products from a Pa authorized hemp producer with an appropriate permit, provided the hemp permittee products can pass all lab testing required for other medical marijuana products and has a THC concentration of 0.3% or less.

This would allow Pa hemp farmers to enter into the Pa medical marijuana program to supply low THC content products and allow permitted grower/processors to focus more on higher THC content products. The additional volume of available products would benefit patients with a greater product selection and potentially lower overall pricing due to added competition.

§ 1161.30. Access to dispensary facilities

a. This proposed section seems to be in conflict with § 1161.26.
Dispensary facilities d., which does allow for individuals under the age of 18 who are not patients but accompanied by a parent or guardian to enter a dispensary, which I do support.

Not allowing non-patient minors to enter a dispensary accompanied by a parent or guardian can create a substantial burden to those parents who must take their minor children with them when visiting a dispensary for a patient. At the very least, allow this policy decision to be made by individual dispensaries.

Additionally:

1. Establish regulations related to the Medical Marijuana Program Fund, and in particular, the "program to assist patients with the cost of providing medical marijuana to patients who demonstrate financial hardship or need under this act, and the department shall develop guidelines and procedures to ensure maximum availability to individuals with financial need." From Act 16, Section 902 c. (1) (i)

2. Allow for final product lab analyses reports to be available to patients.

3. Allow for flower that has failed initial lab testing for biocontanimants to be remediated for use in concentrated products.

Thank You,

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