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prime
Wellness of Pennsylvania

April 2, 2021

Via FedEx and Email
John J. Collins
Office of Medical Marijuana
Department of Health
Room 628, Health and Welfare Building
625 Forster Street, Harrisburg, PA 17120
RA-DHMedMarijuana@pa.gov

Re: PWPA Comments to Proposed Final Regulations

Dear Mr. Collins,

Please allow this letter to serve as Prime Wellness of Pennsylvania, LLC's ("PWPA") official comments to the final proposed regulations. Below you will find a breakdown of the specific regulations' section and our commentary thereto.

§1141a.50: Advertising by a Medical Marijuana Organization

Comments: The current and proposed regulations do not state that pictures of products inside the facility for advertising and marketing purposes are not allowed. However, it is a current policy of the Department's that G/Ps cannot take photographs of products inside the facility for advertising and marketing purposes. If this policy is to continue, it needs to be clarified within the regulations, otherwise G/Ps will consider this policy void.

§1151a.22: Plans of Operation and §1151a.23(b)(3): Grower/Processor Facilities

Comments: Regarding revising the language to reflect "individuals" versus "visitors", this affects the signage for the entire facility, including the limited access areas. To be compliant with this change, we would need to remove and buy new signage for several locations of the facility. This change would cost the facility **$2,000.00+** dollars to be compliant with the proposed final regulations. If this change is still required, the Department needs to give G/Ps adequate time to order and hang the proposed, revised signage within the facility.

§1151a.24(a)(2): Start-up Inventory

Comments: Regarding the proposed change to reflect "any 30-day window established by the Department", is there a process to allow a G/P to formally request an additional 30-day window to bring in additional seed? If there is a process, is there a specified turnaround time that the Department must respond/approve by so a G/P can plan accordingly? How does the Department make the determination and how does the G/P place a formal request due to patient demand/other factors? Importantly, this has caused competitive disadvantages amongst the G/Ps. PWPA was only allowed to bring in seed prior to the Department allowing dry leaf as an allowable form. Since 2018, newer strains, which are desirable to patients, have been created and are available. Therefore, newer competitors/G/Ps have an unfair advantage, since they could bring in more desirable dry leaf and newer strains due to being deemed operational later.

§1151a.24(b): Start-up Inventory

Comments: Regarding the removal of "immature medica marijuana plants", the inability to bring in clones is a competitive disadvantage to any new G/Ps compared to those who could. This is a huge disservice to the patients and caregivers in the Commonwealth, who may benefit from varieties that are already proven. Many of the CR applicants should also be able to utilize strains of which some previous research has been done, so that they may build upon and make further advancements faster.

§1151a.29(b): Limit on Medical Marijuana Processing

Comments: The Department needs to clarify what the exact timeframe is to notify the Department of a potential increase or decrease in production.

§1151a.35(f): Transportation of Medical Marijuana

Comments: There are not any details outlined in this section that defines the nature of diversion or protocol in the case of an accidental delivery of product to the wrong dispensary. Additionally, the Department directed PWPA to destroy all product that was wrongfully delivery by a third-party delivery company to a dispensary that was not on the planned route. Instead of allowing us to provide proof that the products were not tampered with and deliver to the correct dispensary, the Department stated that we had to pick up the products in question and destroy. This is an **extreme** hinderance to the patient/caregiver community that is relying on medicine. It seems that the Department does not have the patient/caregiver communities' best interest in mind with this decision. This decision only adds to and exacerbates the overarching issue of product shortages statewide. Additionally, overall, the final proposed regulations do not outline a G/P's ability to prove any product has not been tampered with, which needs to be defined. Because of the decision stated above, PWPA had to destroy over **$9,000.00** worth of products.

§1151a.42(h): Complaints about or recall of Medical Marijuana products

Comments: Regarding "receipt of information that a condition…" This statement is vague. What would the "conditions" be that are the basis for this comment? The Department needs to clarify.

§1161a.36(c): Transport Manifest

Comments: Regarding the requirements "secure locked box located within a locked cargo van", will this relate to G/Ps for regular deliveries or returns? Please provide clarification on how final products must be packaged prior to delivery to a dispensary.

§1171a.29(c)(1) and §1171a.29(c)(2): Testing Requirements

Comments: The proposed regulation creates a significant cost issue for the G/P. PWPA would spend an additional **$225,000.00** annually to meet this requirement, which is an enormous burden on PWPA Also, PWPA utilizes percentages in cost factor, when being sold to the dispensary. Using the two laboratories could cost the facility **$3 to $5 million dollars** annually due to inconsistent test results. Utilizing two laboratories will cause inconsistency issues with our data, which will cripple our ability to utilize the data to improve our processes and ultimately cost the business significant incremental funds. Additionally, we have created a great relationship with the laboratory we utilize and now that we will be forced to do business with another laboratory, other G/Ps will likely get preferential treatment. The proposed change levers a forced reduction in testing opportunities for laboratories in a free market and limits our right to free choice with whom we do business.

The mandated testing changes proposed will increase complexity in our testing process and market dynamics, it will create chaotic inventory control and scheduling workflows, and will ultimately decrease productivity, while increasing overhead and our ability to move products to market for patient use. Net, it will lead to increased patient costs and decreased product access at the dispensaries.

§1171a.31(c)(3): Test Results and Reporting

Comments: Regarding "If the Department does not agree to accept the confirming results from the approved laboratory, the sample shall be disposed," this appears to give the Department full control whether to accept the **confirming passed** results. The department needs to define the qualifying basis for disagreeing with the certified laboratories results. This does not detail the current "process" that is being used for initial failed products. The Department has made an additional process, which is not detailed in the current or the proposed regulations to get products to market after the subsequent pass results from two separate laboratories. If the process is not defined in the regulations, G/Ps should not have to follow the guidance the Department is currently requiring G/Ps to do. Additionally, there needs to be a defined turnaround time that the Department has to adhere to in order to discuss the confirmed results with the G/P to get the products to market. PWPA has over **$150,000.00** worth of product that has been submitted to the Department with the RCA process and the Department has done nothing about it and has refused to follow the regulations and continues to make up rules, as they go. No other states have identified the need for additional regulation in testing. Implementing more "checks and balances" without objective explanation or process creates profound product and operations concerns in light of the problematic handling of the retesting or transitory RCA process.

§1171a.31(c)(4): Test Results and Reporting

Comments: Regarding "If the re-tested same fails, the lot shall be disposed of…," There is not a single marijuana market in the world regulated with such stringent standards. Thousands of pounds of biomass with amounts of microbials higher than the Commonwealth threshold are processed into millions of doses of perfectly safe product in almost every single marijuana market besides Pennsylvania. Since a single failure has shown to completely freeze the plant material, G/Ps are forced to excessive methods of mitigation, which causes elevated costs to the G/Ps in producing the products and only grow varieties that are more resistant microbes.

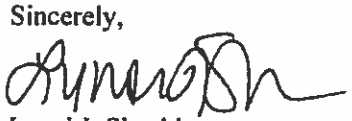
§1171a.31(e)(2)(iv) Test Results and Reporting

Comments: Regarding "Whether the harvest batch, harvest lot, or process lot is within specification for the strain for the characteristics of: (a) odor (b) appearance…," Different environments, fertilizers, harvest timing and other factors can manipulate the perceived smell of any given marijuana strain. It cannot be assumed that any person in the laboratory is qualified to determine what every single marijuana strain grown in the program should look or smell like. This is unrealistic, especially given the proposed regulation that everyone must use seed instead of clones, this would also be very conflicting knowing that each seen has potential to give a unique genetic expression based on the genetics of the two parent strains and it would be impossible for a person to say what each plant is supposed to smell like.

In closing, PWPA has expressed key concerns with the final proposed regulations. The Department needs to be held accountable, as they have held all operating entities accountable in the Commonwealth. The end goal should always be to serve the patient and caregiver communities to the best of our ability.

Should you have any questions or comments, please do not hesitate to reach out to me directly at l.sheckler@acreageholdings.com.

Sincerely,



Lynsi J. Sheckler
Director, Compliance
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