April 18, 2013

William M. Rubenstein, Commissioner
Connecticut Department of Consumer Protection
Medical Marijuana Program
165 Capitol Ave, Room 147
Hartford, CT 06106

Re: Comment on the Proposed Regulation Concerning Palliative Use of Marijuana

Thank you for the opportunity to provide comments on the Proposed Regulation Concerning Palliative Use of Marijuana. We appreciate the great task the Department undertook to craft these regulations. While we recognize the Draft Regulations are well thought out and carefully drafted, we would like to submit limited comments on the following sections for your consideration.

Sec. 21a-408-20. Producer selection.
(h) What is meant by the term commenced operations is not clear. Assuming commenced operations means that a crop has been planted and not yet been harvested, the requirement that facilities be operational within 180 days of registration may be problematic. Local permitting and approval may be delayed given certain circumstances which would prevent a reasonable time period to design, permit and construct a production facility.

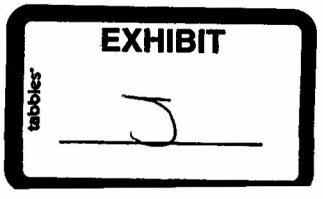
We would suggest the Department consider a process for granting an extension to a producer who has made and continues to make good faith efforts toward commencing operations.

Sec. 21a-408-33. Confidentiality of information.
(b) Prohibition from data intermediaries having access to data will prohibit a facility from utilizing many of the commonly used POS systems in the medical marijuana industry such as MJ Freeway and Biotrack. These providers often need access to a dispensary or producer system for set-up and troubleshooting.

We suggest the Department consider amending this regulation to require HIPAA compliance by these providers rather than a prohibition from them accessing a system.

Sec. 21a-408-53. Minimum requirements for the storage and handling of marijuana by producers.
(g) The requirement to receive written authorization from the commissioner prior to a visitor entering the premises seems burdensome to the Department. Production facilities often require equipment deliveries and repairs. Additionally, in the event of an emergency, a producer needs to allow a technician on-site as soon as possible to prevent crop damage (i.e. a power outage or HVAC failure).

We suggest the Department consider regulation to authorize certain classes of visitors without prior permission including repair personnel, equipment delivery personnel, consultants and other service providers. A process of issuing visitor IDs and documenting entry by the producer would provide information to the Department or law enforcement if necessary.



Sec. 21a-408-55. Manufacturing of marijuana products.
(b)(3) The prohibition from utilizing pesticide chemicals or organic solvents is detrimental to the production of quality products for patients. Organic solvents can be safely utilized to make extremely beneficial extracts that are allowed by (a)(3). The prohibition of many safe synthetic pesticides prevents producers from controlling pest damage to product. USDA organic standards do allow for the use of pesticides.

We suggest the Department consider regulation allowing the use of organic solvents utilizing current good manufacturing practice. Please also consider allowing production utilizing pesticides in accordance with USDA organic standards as the recent Massachusetts proposal allows.

Sec. 21a-408-56. Packaging and labeling by producer.
(c)(7) It is our understanding that CBDA is not a readily available standard without a DEA license. Laboratories testing marijuana are not able to obtain DEA licensing. Also, the requirement to profile any other ingredient is unattainable due to the lack of testing standards available to labs without DEA registration. This regulation is not required for other botanical medicine and is not necessary for a safe product.

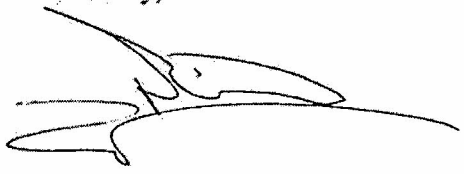
We suggest the Department consider revising these requirements to mandate any available cannabinoid profile test available from laboratories licensed to test medical marijuana products.

Sec. 21a-408-59. Brand name.
(b) As a plant medicine, medical marijuana presents large variations in potency in each plant itself, often ranging 5 points or more. The range requirement in this section could require the same plant have multiple brand names (i.e. 19 x .97 = 18.43; 19 x 1.03 = 19.57 – this is only a variance of .6%). This requirement is overly burdensome to both producers and the Department. Disclosure of the test results provides necessary information to patients to gauge potency, safety, and efficacy.

We suggest the Department consider at a minimum increase the range allowed to 90% to 110%. However, the Department may also want to consider replacing a brand name system which a batch testing process. Because each plant will have a variation in test results, a producer could be required to take a certain number of samples of from each batch (total samples required based on weight) and provide the average test result with the high and low range. This would allow patients sufficient information and allow producers to maintain historical strain names which often convey certain information about flavor and effect to some patients.

Thank you in advance for your consideration of our concerns and clarification of our questions. We appreciate the work of the Department and the focus on patient access and safety. Please feel free to call us to clarify any items presented or for any other reason.

Sincerely,



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