

**Maryland Medical Cannabis Commission**

**Policy Committee Meeting**

**Minutes**

**May 22, 2017**

**2:00 pm**

Health Care Commission Conference Room

4160 Patterson Ave,

Baltimore, Maryland 21215

**Commissioners Present:**

Eric Sterling (Chairman)
Harry (Buddy) Robshaw

Dario Broccolino

**Staff Present:**

Patrick Jameson

Heather Nelson

Mary-jo Mather

Lori Dodson

Kathy Nellius

**Call to Order**

Chairman Sterling called the meeting to order at 2:02 pm and explained that persons wishing to comment would be allowed 3 minutes to speak, after which Commissioners and staff would then ask any clarifying questions. He noted that the Commission will review all proposed regulations in the order they appear in COMAR to resolve all issues after the conclusion of the comments.

**Speakers**

**Gail Rand: (CFO ForwardGro)**

Ms. Rand proposed that the Commission consider the designation of a caregiver be done in a formal fashion such as a letter from the registered caregiver to eliminate any confusion.

She spoke on the distinction between bud and whole cannabis and whether they should be tested differently. She believes the end point prior to selling to the patient should be the only time a third-party lab is required. She also stated that renewing Patient ID cards every year is cumbersome and this date should be extended, possibly to every 5 years as for drivers’ licenses. Her additional comments: stability testing past the expiration date should not be a requirement and suggested testing on 6-month intervals until the date of expiration is reached; removing subsections D and E under 10.62.15 regulation .06, Grower Determination That a Batch May be Released, stating that this contradicts what is written in regulation .05 Contents of Certificate of Analysis and that the cannabinoid and terpene content should be defined by the Grower, not by the lab. She suggested that the regulations refer to the Technical Guidance. She would also like to see the ITL (Independent Testing Laboratory) issue a Pass/Fail report based on the standards in the Technical Guidance and would like to see the definition of green waste exclude roots as it is cumbersome for the cultivator to pull out the roots from the soilless media as there is no medicinal value to the roots. She stated that the definition of Clinical Director of the Dispensary should reflect the definition referenced throughout the regulations for Medical Provider for consistency. Last, she requested that autism and opioid addiction disorder be added to the list of qualifying conditions.

**Philip Stripling (founding member and partner for Steep Hill Maryland)**

Mr. Stripling stated that ITL’s storing samples for stability testing is outside the purview of the independent testing laboratories, and stated that the samples should be stored by the producer of the product. His second concern was in regard to batch size; he does not feel that a larger batch size does more for patient safety and it would ease burden on the cultivators and processors if a batch does not meet specifications, such as pesticides and heavy metals. Mr. Stripling also had comments regarding specifications and 15% variance. He further stated that establishing a chemical specification for a plant is arbitrary and does nothing for patient safety and only causes hardships for cultivators and processors, and believes cannabis should only be labeled with the ITL label to reflect what is in the product and to allow the patient to make a decision, and that the cannabinoid and terpene information should be included, and whether it falls inside the 80-110% is not necessary. He agreed with Mrs. Rand that technical values should have a pass/fail scale; either a batch is below minimum allowable limits or it is not. He believes scale is more important for public safety rather than a potency of 22% v. 18%, and he argued for the removal of the 15% variance as well.

**Review of Proposed Regulations**

**10.62.01 Definitions-**

B. Terms Defined-

(2) Batch- it is proposed that batch of plants be not more than 10 pounds as a definition. Steep Hill and other laboratories have suggested a batch size of 5 pounds because of the heterogeneity of plants, and that it is very difficult to get a good representative sample from a larger amount of product. Testimony from cultivator’s state that the batch size should be larger, and that suggestions of 20 pounds as anything less would hinder objectives to strive for cost effective, quality medication. Growers feel that as they are producing cannabis on a large-scale production basis, meaning harvesting hundreds of plants and multiple strains per week, batch weight of 10 pounds would require them to split single harvests of the same strain into multiple batches. It is proposed that 10-pounds be a batch size.

(4) Caregiver-it is proposed to add “and those persons designated by a parent or guardian” or more specifically “those persons designated *in writing* by a parent or guardian”. There are concerns as to whether a designated caregiver needs to be registered with the Commission and whether they are allowed to transport cannabis or solely be in possession of it. Also, in regard to a school nurse or daycare provider, there are legal protections afforded to individuals registered with the Commission. It was suggested the regulations provide a designated caregiver status to the school or daycare center as an entity to avoid needing to redo registrations if the school nurse changes. When authorization is given to administer medication in a school, it is given to the school, not to a particular person at the school. It was determined that any decisions regarding caregivers would be deferred at this time.

(6) Certifying Provider- has been modified to include all of the other providers who have the ability to certify patients. -Dentist, Podiatrist, Nurse Practitioner/Nurse Midwife and includes the Boards in which they are licensed.

(11) Independent Testing Laboratory- proposed change to clarify that the accreditation body is signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement and that the Independent Testing Laboratory is independent from all other persons.

(17) Lot- proposed change in definition to include not more than 10 pounds, 5 quarts, or 144 packaged units. There were comments received regarding lot size stating that 144 units would add cost to each medical cannabis product produced. It is decided that the definition of lot size would also be deferred in order to prepare language to the criteria other states used in writing the definition.

(18) Medical Cannabis – A question was asked if the Commission should distinguish between bud or whole cannabis provided to patients and harvested cannabis used for medical cannabis infused products. It was determined that no changes needed to be made to this definition.

(19) Medical Cannabis Concentrate – Proposed change to eliminate the way in which the concentrate is produced. There were no comments regarding this change.

(21) Medical Cannabis Infused Product – Proposed removal of “that has been processed so that the dried leaves and flowers are integrated into other material.” No comments regarding this change.

(23A) Medical Facility – is intended to be defined as a professional office in which the certifying provider engages in professional practice. A question was raised that if a provider’s office is a medical facility, what can be done about patients from out of state visiting such offices to become certified for cannabis, obtain said cannabis and return to their home state. The proposed change is to change the definition to “a hospital, hospice, continuing care nursing facility, outpatient clinic or professional office in which a written certification authorizes medical cannabis to be administered in Maryland”.

(29) Serious Adverse Event – revised to use the latest FDA regulatory language. No comments were received on this change.

(32) Usable Cannabis – narrowing the definition to say it does not contain seeds, stems, stalks or roots of the plant.

(33) Variety – proposed change to change “variety” to “varietal of medical cannabis used by a licensed grower to consistently identify medical cannabis from batch to batch”. No comments regarding this change.

(34) Written Certification – modified to include new definition of “certifying provider”.

**10.62.02 – General Regulations**

The only proposed change is to change any reference to “physician(s)” to “certifying providers”.

**10.62.03 – Certifying Providers**

The proposed change broadens various references to physicians and the Board of Physicians to Certified Provider and the Board in which they are licensed.

**Proposed modification to Regulation .01 (2) (c) (ii)** “Appropriate physical or mental health examination of the patient physically present”.

**Proposed Changes to Regulation .02 Compensation from a Licensed Grower, Licensed** **Processor or Licensed Dispensary** - Removed B (2) (a) Maryland Medical Practice Act, codified at Health Occupations Article, §14-101 et. seq., Annotated Code of Maryland; as this only covers physicians not all providers, and is redundant to what is written in Health Occupation Article §1-301.

**Proposed modification to Regulation .03 Renewal of Certifying Provider Registration to Certify** – Change verbiage from “approval” to “registration” and also “physician” to “provider”.

**10.62.05 Written Certifications**

Modification throughout to change “physician” to “provider”.

Proposed addition to Regulation .01 C (5) “Certifying provider believes that the medical cannabis will be administered in Maryland”.

Change to .02 Written Certification Duration and Renewal – Strike existing A, B, and C. Addition of A. As determined by the certifying provider, a written certification may remain valid for up to 365 days after it is issued. Re-letter existing D to B.

**10.62.30 Dispensing Medical Cannabis**

Addition in Regulation .05 C. (4) It is a violation of Federal law to carry or transport cannabis from Maryland to any other place.

**10.62.15 Medical Cannabis Grower Quality Control**

Modification to Regulation .01 Subsection D is unnecessary because the only criterion for release is a satisfactory ITL report.

Rewriting of Regulation .04 A. A licensed grower shall use an independent testing laboratory that is registered with the Commission. B. An independent testing laboratory shall comply with the Commission’s current version of Technical Guidance for Medical Cannabis Testing and: (1) Provide trained staff to obtain samples of each batch according to a statistically valid sampling method; (2) Analyze the samples according to a scientifically valid methodology; (3) Provide a certificate of analysis for each batch; and (4) Destroy the remains of the samples of medical cannabis after analysis is completed.

Modification to regulation .05 A. A single percent concentration for each cannabinoid that represents an average of all samples within the test batch for the following compounds:

Modification to subsection B. removal of “AHP monograph”, and reworded to say “provided in the Commission’s current version of Technical Guidance for Medical Cannabis Testing”. Reword (3) to Microbiological impurities such as: Remove (c) P. aeruginosa (d) Aspergillus spp. (e) S. aureus and (h) Pesticide Residue. Add (c) E. coli (d) Salmonella spp. (4) Pesticide residue. Create subsection C. for Whether the batch is within specification for the characteristics of: and add (e) Water Activity.

Modifications to .06 A. addition of “licensed grower may release the batch for distribution”; and shall (1) Assign an expiration date to the batch and (2) Revise the status of the batch in the inventory control”. Strike “to ensure that all required specifications are met” from subsection B (2) and add “according to the licensed Grower’s Standard Operating Procedures for reworked or reprocessed medical cannabis”. Addition of (3) “If upon review of the certificate of analysis, determines that the batch meets the specification for reworked and reprocessed medical cannabis the grower may: (a) Assign an expiration date to the batch; (b) Release the batch for distribution as reworked or reprocessed medical cannabis; and (c) Revise the status of the batch in the inventory control”. Proposed subsection D and E were stricken.

Regulation .07 Reworded to indicate the Grower will store samples for stability testing not the lab.

**10.62.16 Independent Testing Laboratory Registration**

Regulation .01 in the definition of Accreditation Body has been altered to remove “nonprofit”.

Included definitions for “Laboratory Director” “Technical Lead” and “Quality Assurance Manager” and included educational and experience required for all positions.

Modification to Regulation .02 added requirements of submissions of fingerprints and background checks. In subsection C included information that a laboratory may apply for a provisional registration with the Commission. Included information in subsection G that if the accreditation body denies, we are talking about the accreditation body which is not registered with us, if the accreditation body denies, restricts, suspends, revokes or fails to renew the accreditation of an independent testing laboratory, the accreditation body and the independent testing laboratory shall notify, within 1 business day of the determination, the Commission and all licensees for which it has been providing analyses, the registration of the independent testing laboratory shall be suspended, and no licensee shall provide medical cannabis or products containing medical cannabis to such independent testing laboratory.

Regulation .03 Subsection F was relocated to 10.62.16.02G and has been expanded.

Regulation .04 subsection B was reworded to include “The Commission may renew the registration of an independent testing laboratory after reviewing the application for renewal of registration by the independent testing laboratory including:”

Regulation .05 all subsections A-D have been stricken.

**10.62.17 Complaints, Adverse Events, and Recalled**

Modified language to include all providers.

**10.62.23 Medical Cannabis Concentrates and Medical Cannabis-Infused Products**

The Definitions have been stricken, and all regulations have been renumbered.

Regulation .01 Subsection A. (2) (c) spells out U.S. Occupational Safety and Health Administration. Removal of Subsections B as the language is redundant. Removed C and combined with subsection now B. Rewrote subsection to include (1) Any solvents used be at least 99 percent pure, and used in a professional grade, closed-loop extraction system designed to recover the solvents; (2) Processing to be done in -- (I) A spark-free environment; (2) With proper ventilation; (3) Following all applicable U.S. Occupational Safety And Health Administration regulations; (4) Following all local and State fire, safety and building codes in the processing and storage of the solvents and (5) In the case of carbon dioxide gas extraction, use of vessels rated to a minimum of 900 pounds per square inch. Removal of Subsection E.

Rewrote regulation .02 Independent Testing Laboratory Selection and Requirements to include A. A licensed processor shall use an independent testing laboratory that is registered with the Commission. B. An independent testing laboratory shall: (1) Provide trained staff to obtain samples of each lot -- (a) According to a statistically valid sampling method; and (b) Such samples in total may not be less than 0.5% of the mass of the lot; (2) Analyze the samples according to a scientifically valid methodology that complies with the Commission’s current version of Technical Guidance for Medical Cannabis Testing; (3) Provide a certificate of analysis for each lot; (4) Destroy the remains of the samples after analysis is completed. Existing language has been stricken.

Regulations .03 .04 and .05 have been reworded to mirror 10.62.15

**10.62.33 Inspection**

Modified Regulation .05 subsection C to remove that the materials shall conform to the American Herbal Pharmacopeia and shall instead comply with the Commission’s current version of the Technical Guidance for Medical Cannabis Testing.

Regulation .08 included language to reflect registrant.

The meeting adjourned at 5:05 pm.