



**Maryland Medical Cannabis Commission
Policy Committee Meeting Minutes**

October 5, 2017

1:00 pm

Department of Legislative Services Building
Joint Hearing Room
90 State Circle
Annapolis, Maryland 21401

Commissioners Present:

J. Charles Smith (Chairman)
Rachel Rhodes
James Pyles
Brian Lopez (Chairman of Commission)
Barry Pope

Commissioners Absent:

Charles LoDico

Staff Present:

Patrick Jameson, Executive Director
Heather Nelson, Assistant Attorney General
Lori Dodson, Director of Compliance for Independent Testing Laboratories
Mary-jo Mather, Director of Administration
Myesha McQueen, Administrative Specialist
Kristen Shreves, Quality Assurance Specialist
Fakiza Rahman, Quality Assurance Manager

Call to Order

Chairman Smith called the meeting to order at 1:14 pm and welcomed the attendees.

Approval of Minutes

Chairman Smith asked if Commissioners had time to review the draft minutes of the September 7, 2017 meeting and if there were any comments. Hearing none he asked for a motion to

approve the minutes which was offered by Commissioner Pyles and seconded by Commissioner Rhodes. The September 7, 2017 minutes were approved unanimously.

Public Comment

Chairman Smith announced that the Policy Committee would be hearing public comment on limited issues, and asked that the comments remain on topic during the meeting and that he aware that there are numerous policies that need to be addressed and the Committee will hear those in the future.

Out-Of-State Patient Issue

The first topic upon which the Committee received comment pertained to the issue of out-of-state patients' participation in Maryland's medical cannabis program. Prior to hearing public comment Chairman Smith asked if Chairman Lopez and Executive Director Jameson if they had any preliminary statements. Mr. Jameson began by stating that the Commission is aware that this is a very controversial issue, and that clarification in the regulations is needed.

Mr. Jameson read a portion of the transcript from the May 22, 2017 Policy Committee meeting, where he had stated at that meeting that he had consulted with three Commissioners who were appointed as physicians as to what they thought about out-of-state patient access and the qualifying patient definition. He reported that Dr. Horberg, Dr. Lavin, and Dr. Davies had very strong opinions on this issue. Dr. Horberg stated that it was never the intent for out-of-state "folks" to be part of the program, and that the intent was that only Maryland residents receive this care and the medical cannabis be administered only within the State's boundaries. Dr. Lavin stated that the Maryland Medical Cannabis program should be limited to patients who are Maryland residents only, and Mr. Jameson requoted Dr. Lavin's statement: "I realize they are hospitalized and may be coming from out of state, but I think it is a lot simpler considering the current federal climate, to limit Maryland's cannabis program", and suggesting further that "proof of residency should be requested when applying for a card and picking up medical cannabis in the dispensary". Further Dr. Davies stated that he recognized the same issues and wanted to add to the definition of "qualifying patient" that the definition only qualifies that they are physically present in the state while they are receiving the treatment, and administered the cannabis treatment while in the state. He also stated that the Commission did not want to put any of the patients at risk, and obviously they are all acknowledging that they know that it is against federal law to transport cannabis across State lines.

Mr. Jameson restated from the previous Policy Committee Meeting Minutes, that all physician Commissioners concurred that whatever treatment is being administered should be administered in State at a bona fide medical program. Mr. Jameson stated this is one of the issues that the Commission needed to resolve due to the ambiguity for out-of-state patients trying to register as medical cannabis patients and who did not completely understand what the parameters are in this area. Mr. Jameson further added that the previous Vice Chairman, Commissioner Robshaw, among several points stated that "We intend that Medical Cannabis obtained in the State of Maryland has to be administered in the State of Maryland." Mr. Jameson also restated Commissioner Sterling, at that at the last Policy Committee Meeting when Commissioner Sterling stated: "So the history of this is that the General Assembly in the 2013 law or the 2014 law provided that you had to be a Maryland resident; they [the Maryland Legislature] changed the 2015 law to strike out that to say "individual", and we in our discussions in our regulatory approach came up with an effort to try to limit this to people who would be in Maryland for medical purposes. Commissioner Sterling continued by suggesting an amendment with language that defined "medical facility" and suggested that the Commission use new language which identifies the facilities or the particular outpatient clinic or professional office in which a written certification authorizes medical cannabis to be administered in

Maryland. He stated further that this language would attempt to create a clarification that we are not requiring medical cannabis to be administered in the physician's office if, for example someone is staying in a Maryland hotel, but the regulation would state that the written certification authorizes medical cannabis to be administered in Maryland. Commissioner Sterling then suggested at the previous meeting that this topic should be tabled until the next Policy Committee Meeting. Mr. Jameson and the Commission are aware of what the Cole Memorandum ("Memorandum") states and as a regulatory agency the Commission would have to abide by the Memorandum and did not want any federal involvement in the State of Maryland and would like to run the program legally.

Chairman Smith continued the meeting by inviting public comment, indicating that comment would be limited to 3 minutes and that a verbal 30 second warning would be given.

Public Comment * was heard from:

- Jake Van Wingerden – SunMed Growers
- Gail Rand – ForwardGro
- Greg Pappas – Allegany Medical
- Anand Dugar – Green Health Docs
- Anthony Darby – Peninsula Alternative Health
- Maggie Faver – CannaCare Docs
- Marita Hardy – Grow West
- Daniel Kulakowski – Steep Hill Maryland
- Justin Pottenger – Arizona Facilities Supply

Questions were posed by Commissioners once comments were offered.

Questions relating to reciprocity laws, alternate solutions to prevent transportation of cannabis across state lines, were posed by Commissioners once comments were offered

Definitions of Standards for Individuals and Entities for Registration and Licensing

The second topic upon which the Committee offered the opportunity for public comment pertained to the issue of definitions of standards for individuals and entities for registration and licensing. Prior to hearing comment Chairman Smith advised that the current regulations contain language about demonstrating an absence of good moral character when it comes to pre-approval of applications. The Policy Committee feels that this language is rather undefined and does not give much guidance to the Commission. The Policy Committee is considering whether to leave the language as it is or use language that is more defined.

There were no requests for public comment on this issue.

Retention Sample Storage and Stability Testing

The third topic upon which the Committee offered the opportunity for public comment pertained to the issue of retention sample storage and stability testing. Prior to hearing comment Chairman Smith asked Lori Dodson, Director of Compliance for Laboratories, for preliminary comment. Currently, per COMAR the grower or processor will store their own retention samples for testing at six month intervals. There has been proposed language that this will go back to the Independent Testing Laboratories.

Public Comment regarding stability testing and retention samples were heard from:

Daniel Kulakowski – Steep Hill Maryland

Questions were posed regarding security of samples and quantity of samples by Commissioners once comments were offered.

Disposal of Green Waste

The fourth topic upon which the Committee offered the opportunity for public comment pertained to the issue of disposal of green waste. Prior to hearing comment Mr. Jameson advised that there are currently several sections in COMAR that address green waste. The Commission would like to make the language in COMAR to be more consistent and to further define the requirements.

Public Comment regarding disposal of green waste was heard from:

Gail Rand – ForwardGro

Revocation of Licenses and Registration

The final topic upon which the Committee offered the opportunity for public comment was on revocation of licenses and registrations. Prior to hearing public comment Mr. Jameson mentioned that the Commission may deny or revoke a license or registration if the applicant or licensee does not meet the requirements stated in the regulations. The Commission will also give the applicant or licensee the opportunity to appeal the decision prior to the revocation.

There were no requests for public comment on this issue.
Comment on off topic issues were heard from:

Jake Van Wingerden – SunMed Growers
Justin Pottenger – Arizona Facilities Supply

Adjournment

Chairman Smith advised that there was no new business and that he looks forward to seeing everyone at the next Policy Committee Meeting on October 23, 2017. He adjourned the meeting at 2:20 pm.

*Public Comments received are attached to these Minutes.

Comments
Received
For
Policy Committee
Meeting
September 27/October 5, 2017



MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Comments for Policy Committee Meeting 10/5/17

3 messages

Greg Pappas <gpappas@alcommd.com>

Mon, Oct 2, 2017 at 12:25 PM

To: Mary Jo Mathers <maryjo.mather@maryland.gov>

Cc: Patrick Jameson -DHMH- <patrick.jameson@maryland.gov>

Hi Mary Jo,

Attached are my comments for the policy committee meeting on 10/5. Please share these comments with the policy committee as well as the rest of the commission. I look forward to addressing the committee at the meeting. Please acknowledge receipt of this email and my attachment. Fee free to contact me if needed.

Greg Pappas - Partner
Vice President of Marketing

100 Beall Street
 Cumberland Maryland 21502
 (888) 446-3420 Cell (301 707-9439
www.alcommd.com

2 attachments



PastedGraphic-1.tiff
 29K

10517 Policy Meeting Comments .pdf
 77K

MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Mon, Oct 2, 2017 at 12:33 PM

To: Greg Pappas <gpappas@alcommd.com>

Cc: Patrick Jameson -DHMH- <patrick.jameson@maryland.gov>

Confirming receipt. We'll see you on Thursday.

[Quoted text hidden]

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 Mary-jo Mather
 Director of Administration
 Maryland Medical Cannabis Commission
 Department of Health
 849 International Drive, Suite 450
 Linthicum, Maryland 21090
mmcc.maryland.gov
 Email: maryjo.mather@maryland.gov
 Direct Line: 410-487-8052

PLEASE NOTE MY NEW ADDRESS AND TELEPHONE NUMBER, EFFECTIVE 9/22/2017.

MMCC is committed to customer service. [Click here](#) to take the Customer Satisfaction Survey.

Greg Pappas <gpappas@alcommd.com>

To: MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Cc: Patrick Jameson -DHMH- <patrick.jameson@maryland.gov>

Mon, Oct 2, 2017 at 1:44 PM

Thanks

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[Quoted text hidden]

Comment for Policy Committee Meeting 10/5/17
Subject: Out-of-State Patient Policy

Introduction

In this great nation we are free to cross state lines to shop, to eat, to vacation, to gamble, and to seek the best health care possible for ourselves and our loved ones. If we have a sick child, spouse, partner, parent, or close friend, we will travel to wherever necessary to acquire care to stop the pain and suffering of our loved ones in need. That includes risking what's needed to achieve that end. I don't think anyone making policy decisions on health care can fully understand this mindset until it becomes personal. If medical cannabis is part of that solution for people with a qualifying condition, we have a moral obligation to help our neighbors.

The Out-of-State Market

Within a 75-mile radius of Maryland's 11 counties that border WV, PA, VA, and DE, over 8.4 million people reside. We conservatively estimate that .05 percent, or over 42,000 men, women, and children, have qualifying conditions and would register as patients. If we use the national average number of 1.5 percent of the population, that number rises to 126,000 patients who will be denied needed treatment under our current out-of-state policy. Allegany County, Maryland, which is a tri-state region, services Mineral and Hampshire counties in WV, as well as Bedford and Somerset counties in PA. The city of Ridgeley, WV is literally just across a 300-foot bridge that adjoins the City of Cumberland. About 20 percent of our 950 enrolled Cumberland dispensary patients are from WV and PA. We receive daily inquiries through calls, emails, and walk-ins from ill out-of-state patients pleading with us and wanting to know when they can acquire medical cannabis and complete their Maryland registration

Out-of-State Policy Interpretation

In my opinion, the commission's current out-of-state policy does not reflect the intent of the language defined below:

(25) "Qualifying patient" means an individual who:

(a) Lives in the State or, during that time an individual is present in the State, is physically present in the State for the purpose of receiving medical care from a medical facility in the State;

We feel the intent was to allow out-of-state patients to register and acquire medical cannabis if they were visiting a Maryland doctor or medical treatment facility. The intent was not to allow mere out-of-state passing visitors to register and acquire

medical cannabis; thus the point of a bonafide doctor-patient relationship. A bonafied relationship is not based on geography. In point, since Allegany County is a tri-state economy, many doctors in Cumberland, as well as the WMHS, service patients from WV and PA. The City of Cumberland and Allegany County would not be on the map and could not survive solely on the population of the Allegany and Garrett County markets. Many other border counties in our state rely on the regional market for their survival, as well.

The Compromise/The Solution

We are well aware the commission is concerned about federal law and upholding the Cole Memorandum. I am, therefore, proposing that all Maryland dispensaries be allowed to service the out-of-state need by requiring each certified out-of-state patient to sign a disclaimer that states they are aware that transporting medical cannabis across state lines is a federal offense and they are subject to prosecution. If they assume the risk, the state as well as the dispensary is no longer liable. We should allow the patient to assume the risk and not deny them the needed medicine they so desire.

Expectation of the Commission

Maryland, along with 28 other states, agrees the federal law is wrong and medical cannabis has great benefits for those with qualifying conditions. It is our expectation that the appointed commissions and policy committee make sound, logical decisions that are in the best interest of patients, the state of Maryland, and a new industry in our state that may be an economic boon to all 96 senatorial districts, and not just look at policy from a law enforcement perspective.

Recommendation

Finally, the commission would be well served if six members of the commission (two from each segment) were appointed from the industry stakeholders to assist in establishing policy decisions from a broader perspective.

I respectfully submit my comment and hereby request a time slot to present my comments in person. I will also be signed up at 12:30 pm on 10/5/17.



Greg Pappas - Partner
Allegany Medical Marijuana Dispensary
100 Beall St. • Cumberland, MD 21502



MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Sent on behalf of Paul Flamino

2 messages

ParcelandOfficesolutions Odenton <parcelandofficesolutions@comcast.net>
Reply-To: ParcelandOfficesolutions Odenton <parcelandofficesolutions@comcast.net>
To: maryjo.mather@maryland.gov

Tue, Oct 3, 2017 at 2:40 PM

Joji Barsa
Parcel and Office Solutions
Phone: 410-519-3131
Fax: 410-519-3535

----- Original Message -----

From: ParcelandOfficesolutions Odenton <parcelandofficesolutions@comcast.net>
To: maryjomather@maryland.gov
Cc: pdflamino@aol.com
Date: October 3, 2017 at 2:32 PM
Subject: Sent on behalf of Paul Flamino

From Pasul Flamino:

Request to verbally comment at October 5, 2017 Policy committee meeting with extracts of pertinent comments of Paul D. Flamino - Paul D. Flamino June 19, 2014 Letter re: Medical Marijuana attached

Kindest Regards - Paul D. Flamino - pdflamino@aol.com Tel 410-305-0807

Parcel and Office Solutions
Phone: 410-519-3131
Fax: 410-519-3535

flamino.pdf
2553K

MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>
To: ParcelandOfficesolutions Odenton <parcelandofficesolutions@comcast.net>

Wed, Oct 4, 2017 at 4:26 PM

Confirming receipt. Thank you.

[Quoted text hidden]

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Mary-jo Mather
Director of Administration
Maryland Medical Cannabis Commission
Department of Health
849 International Drive, Suite 450

10/4/2017

Maryland.gov Mail - Sent on behalf of Paul Flamino

Linthicum, Maryland 21090

mmcc.maryland.gov

Email: maryjo.mather@maryland.gov

Direct Line: 410-487-8052

PLEASE NOTE MY NEW ADDRESS AND TELEPHONE NUMBER, EFFECTIVE 9/22/2017.

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Paul D. Flaminio
8600 Roaming Ridge Way # 308
Odenton, MD 21113
Tel. No. 410-305-0807
pdfaminio@aol.com

June 19, 2014

Honorable Eric Holder, Jr.
US Department of Justice
Attorney General
950 Pennsylvania Avenue NW
Washington DC 20530

Subject: Request for Medical Marijuana Relief to the Schedule 1 Substance Abuse Act

Dear Mr. Holder:

As you are aware, a large group of the medical community and many states have approved the use and legalization of medical marijuana for controlling childhood epileptic seizures. The debilitating seizures of many young children with epilepsy, have not been able to be controlled. Even with all the varied medications and under the care and direction of the finest medical professionals, their seizures continue. Some children diagnosed with the Lennox Gestalt Syndrome have upwards of 100 seizures or more throughout the day and night.

Moreover, these children must be monitored almost continuously, a difficult situation especially during night time hours.

As mentioned previously, many States, and others following are keenly aware of this childhood crisis and after passing medical marijuana laws have initiated the process of establishing workable guidelines and controls. However, there is the long lead time to structure permit guidelines and procedures for monitoring growers, processors, dispensaries and required medical oversight. After the actual approvals are in place there is also the long time lag for planting and harvesting the special medical marijuana plant species. This all could take over one to two years or longer!

Parents and caregivers cannot bear the many sleepless nights and lingering seizure emergencies for another year or two while waiting for receipt of the medical marijuana medication. A mother's mighty plight for the welfare of her child will surmount many barriers. Some families in desperation are uprooting their homes and lives by moving and taking up residence in States with approved medical marijuana dispensaries. Oftentimes, this causes a breakdown in the family structure. And other families, because of financial and job constraints coupled with the loss of local family support, precludes this desperation move.

The solution to this critical childhood health crisis can be resolved quickly and humanly with some relief of the current Schedule 1 Substance Abuse Act by your office. Whereby children living in states already approved for medical marijuana, yet not readily available, be provided the capability to obtain their medically prescribed marijuana from states such as California and Colorado. All of our children affected with epilepsy and their parents, grandparents, family members and caregivers, as well as the medical and local community would benefit from the impact of this proposed relief of the

Schedule 1 Substance Abuse Act. It would be noted far and wide in reducing family stress and drastically lowering medical and educational costs.

This request, in many cases would also result in the relief in the care and normalcy of growth of these affected children, and in some extreme cases, life saving. It is heart breaking when you read about a mother's loss of a child, while unduly waiting for medical treatments that could have saved her child.

Enclosure (No.1) is an internet transcript from the Washington Post depicting this lingering pain of a mother losing her child, on Mother's Day no less, for the want of medically prescribed medical marijuana that was not readily available in her state.

Similarly, as an 84 year old grandfather, I am deeply concerned for our two special needs grandchildren, who are suffering with constant epileptic seizures. Their parents hurt and pain never stops and we await the evening and morning calls for the report that these children made it through another day and night.

The emotional impact from catching and caring for a small child during a seizure episode can test the resolve of the very strongest, as expressed during my testimony (enclosure no. 2) before the State of Maryland General Assembly on February 28, 2014.

The length and breadth of the numbers of children with uncontrollable epileptic seizures is quite extensive and in some rare occasion, death occurs. Please note enclosures no. 3 and no. 4.

Enclosure No. 3 – Excerpt Medical Marijuana for kids with epilepsy

Enclosure No. 4 – SUPED (Sudden Unexpected Death in Epilepsy) Information for Health Providers

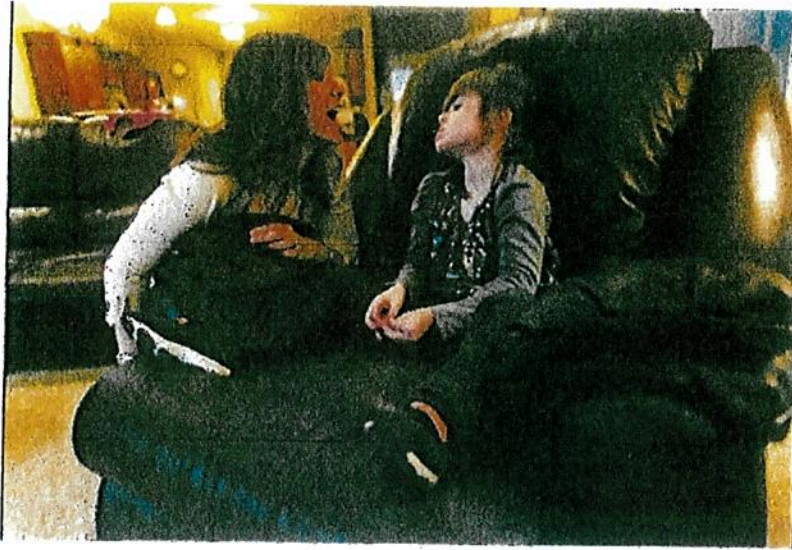
We trust President Barack Obama and you and your staff, will recognize this urgent request and act with understanding and compassion. Thank you kindly.


Paul D. Flaminio

Cc: Honorable President Barack Obama
Honorable Governor Martin O'Malley
Honorable Senator Barbara Mikulski
Honorable Senator Benjamin L. Cardin
Honorable Congressman John Sarbanes

Encl: 4

Girl at Center of Fight to Legalize Cannabis Oil Dies at Age 7



Feb. 23, 2014 | Sally Schaeffer plays with her daughter Lydia, who suffers from life-threatening seizures, at their home in Burlington. *Wis.* Parents of children suffering from seizure disorders are fighting for access to marijuana, and they have changing public attitudes on their side. For the first time, a majority of Americans in opinion polls say they support the full legalization of the drug. (Darren Hauck For The Washington Post)

BY ARIANA CHA May 14

Lydia Schaeffer, the 7-year-old girl with a rare genetic disorder whose plight inspired lawmakers in Wisconsin to legalize a marijuana extract to treat her condition despite their opposition to medical marijuana, has died.

Lydia's mother, Sally Schaeffer, had been lobbying the state legislature to legalize the drug, an experimental extract from cannabis plants known as Charlotte's Web, for use on children with seizure disorders. The lawmakers moved to pass the law in record time and Gov. Scott Walker (R) signed the bill into law in April.

But Lydia, who died in her sleep on Mother's Day, never got a chance to try the treatment because the law's implementation was still being worked out.

The efforts by the Schaeffers are being replicated throughout the country-- in Oklahoma, Florida, Georgia, Utah, New York and other states-- by other parents who have shared their stories through Facebook, Twitter and the media.

In her obituary, her parents said Lydia taught them "about patience, what it's like to be inspired, and most of all we were blessed to witness miracles that otherwise we may have been too busy to notice." In a column by Jim Stingl in the Milwaukee Journal Sentinel, Lydia's mother says she wishes she could have done more to help her daughter live.

But, Stingl comments, "I witnessed Sally Schaeffer in action, and I can tell you it's not for lack of trying or the love of a mother for her child."

ENCLOSURE # 2

Testimony – Maryland General Assembly

Medical Marijuana – February 28, 2014

My name is Paul Flamino – 84 year old resident from Odenton, MD and the grandfather of two special needs children – Maxwell and Mimi Pippen. I have been blessed during my retirement years to help and nurture these two children during their early stages of life. The joy and love I've received from these children was overwhelming.

But this joy was shattered when holding Maxwell, he experienced his first seizure with many more thereafter at varied times and places – at home, at school, during playground activity and in shopping malls and even in doctor's offices and in hospital visits.

What more could happen? His sister Mimi at an early age started to have seizures as well with all the typical manifestations coupled with her eyes moving upward, later diagnosed as Lennox Gestalt syndrome. I called upon all of my strength and composure to hold back my cry for mercy and relief. But, the sight of these children falling before me in so many locations and having to monitor all their movements in readiness to react began to build such anguish within me and with their parents and whole family structure as well.

I thought I was strong and wouldn't weaken. After all, during my AirForce service, I experienced so many aircraft accidents – engines exploding, fires erupting, emergency landings, crash landings and an engine flame out, but still overcame all my fears without notice. But to me, these accidents and emergency situations were handled well without any residing effect. However, to hold and see your precious grandchildren falling before you with such frequency shook my resolve and demeanor more so than during my Air Force service. We fixed the airplanes and went on to greater glory.

However the fix is not in yet for my grandkids seizures. Now the medical community has a fix. Let's help now before my retirement period ends. Our family and our community will be most grateful for your help in this fix.

Respectfully,


Paul D. Flamino



MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Proposed Revisions

1 message

Joseph Curtis PhD <jcurtis@bioquantlabs.com>

Tue, Oct 3, 2017 at 5:29 PM

Reply-To: Joseph Curtis PhD <jcurtis@bioquantlabs.com>

To: "maryjo.mather@maryland.gov" <maryjo.mather@maryland.gov>

Stability Testing and Retention Sampling.

After a thorough review of the current requirements and comparison against other states, Maryland's proposed regulations provide a baseline from which to protect the patients and enable the community to identify potential conditions affecting product stability. Both COMAR 10.62.15.07.07 and COMAR 10.62.23.05 support a risk management approach to ensure the effectiveness and safety of medical marijuana products.

I would encourage the legislative body to take a risk management approach to consumer product safety. Each product developer is acting as their own cannabis pharmaceutical formulary, and as such they are trying to develop new product configurations with varying chemistries, components and packaging materials. Requiring product sample retention is a component of quality management and as such should be retained as a requirement.

Joseph Curtis MS, PhD
Chief Scientific Officer

BioQuant Laboratories, Inc.
Email: jcurtis@bioquantlabs.com
URL: www.bioquantlabs.com
Ph: (855) 835-2239



MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Md medical cannabis

1 message

tillysubie@aol.com <tillysubie@aol.com>

Tue, Oct 3, 2017 at 5:03 PM

To: maryjo.mather@maryland.gov

The delays due to the laboratories not being approved and running in a timely manner may have added to the unavailability of the most appropriate medicine for my daughter.
The lack of education available to patients and physicians may be adding to the medical epidemics facing our state.
The hold on out of state applications has adversely affected children of friends that would benefit from access to medical al cannabis.

Carey Tilghman
Sent from my iPhone



MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Testing Policy Comments

2 messages

Justin Pottenger <justin.pottenger@azfac.com>
To: maryjo.mather@maryland.gov
Cc: "gm@azfac.com" <bill.brothers@azfac.com>

Tue, Oct 3, 2017 at 5:31 PM

Mary Jo,

I would like to present the attached comment in person at the Oct 5th policy meeting.

Please let me know if anything else is required for me to do so.

Thank you very much,

--

Justin Pottenger

 **Testing Comments.pdf**
33K

MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>
To: Justin Pottenger <justin.pottenger@azfac.com>
Cc: "gm@azfac.com" <bill.brothers@azfac.com>

Wed, Oct 4, 2017 at 4:22 PM

Confirming receipt. Thank you.

[Quoted text hidden]

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Mary-jo Mather
Director of Administration
Maryland Medical Cannabis Commission
Department of Health
849 International Drive, Suite 450
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The current language used in the “Final Draft MMCC Technical Authority” for the definition of “Lot” is inconsistent not only with itself but also with physical circumstances surrounding the cultivation and manufacture of both cannabis inflorescence and cannabis concentrates.

The document gives the definition of a lot as: *“Not more than 10lbs, 5 quarts, or 144 packaged units of all of a medical cannabis finished product that is uniform, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.”*

Suppose a grower cultivated 100 pounds of cannabis of the same strain, which was planted at the same time, in the same greenhouse, exposed to the same pesticides, given the same nutrients, harvested at the same time, trimmed at the same time, and ultimately packaged in one pound increments for wholesale. In this scenario, the identical and homogeneous grouping of cannabis would be sampled 10 times by an independent testing laboratory creating 10 **identical** certificates of analysis.

Suppose that instead of wholesaling in bulk the grower chooses to offer the medicine in final retail packaging, thereby providing a service to the licensed Dispensaries who purchase the medicine and saving them the labor of breaking down pounds and repackaging. Those 100 pounds of homogeneous cannabis could be broken into 45,400 one gram packages, 12,971 “eighths” (3.5 grams), or 1,621 “ounces” (28 grams). Under the current definition of a lot the grower would need to have an independent testing laboratory perform 316 unique tests of the one gram packages, 90 tests of the 3.5 gram packages, or 11 tests of the 28 gram packages. The literally hundreds of certificates of analysis would prove to be **identical** since all source material is *“uniform, manufactured, packaged, and labeled together during a specified time period.”*

Furthermore, suppose a processor manufactures 10 pounds of distilled cannabis concentrate and that the volume of this concentrate is less than 5 quarts (a real-world scenario). The distilled cannabis concentrate must still be injected into cartridges for final use in a vaporizer. The cartridges are commonly sold in ½ gram increments and combined with medium-chain triglycerides at a ratio of 1:1. That 10 pounds of distilled cannabis concentrate would become 9,080 vaporizer cartridges which under the “144 packaged units” clause of the lot definition would require 63 unique tests to be performed, creating 63 **identical** certificates of analysis, even though all material is *“uniform, manufactured, packaged, and labeled together during a specified time period”*

In summary, the definition of a lot is most appropriately communicated as *“a medical cannabis finished product that is uniform, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.”* Introducing further limitations by weights, volumes, and especially by packaged unit counts imposes undue and significant limitations on the activities of the industry without a clear benefit to the patients of the program. Further imposing these limitations in weight, volume, and packaged units is inconsistent with the idea of homogeneous sampling communicated in the rest of the standing definition and only serves to take money from the pockets of the patients who need their medicine and deliver it straight to the pockets of independent testing laboratories.



MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Comments for Policy Meeting 10/5

2 messages

Tracey Lancaster Miller <tracey@peakereleaf.com>

Wed, Oct 4, 2017 at 11:52 AM

To: maryjo.mather@maryland.gov

Maryjo Mather,

Below is the comment from Peake ReLeaf for the policy meeting tomorrow:

As the policy committee debates changes to medical cannabis regulations, I ask the Commission to consider green waste disposal regulations similar to Colorado and Washington. These states, among others, require all green waste to be made unusable or unrecognizable by mixing the waste with at least 50% non cannabis waste such as paper, cardboard, food waste, plastic, grease, bokashi, or soil and all waste must be stored in a secured receptacle (see Colorado regulations: ccr 212-1 m 307 and ccr 212-2 r 307; Washington regulations: WAC 314-55-097).

Additionally, I strongly support regulations allowing out of state patients to receive medicine in Maryland. Maryland's physicians should have every state approved tool possible at their disposal to adequately and effectively treat patients.

Thanks,

Tracey Lancaster Miller
Executive Vice President
Peake ReLeaf, LLC
peakereleaf.com
tracey@peakereleaf.com
410.852.4724

MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Wed, Oct 4, 2017 at 1:25 PM

To: Tracey Lancaster Miller <tracey@peakereleaf.com>

Received. Thank you.

[Quoted text hidden]

--

Mary-jo Mather
Director of Administration
Maryland Medical Cannabis Commission
Department of Health
849 International Drive, Suite 450
Linthicum, Maryland 21090
mmcc.maryland.gov
Email: maryjo.mather@maryland.gov
Direct Line: 410-487-8052

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MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Comments from Steep Hill Maryland for MMCC meeting 10/5/17

Phil Stripling <phil.stripling@md.steePhill.com>

Wed, Oct 4, 2017 at 2:56 PM

To: maryjo.mather@maryland.gov

Cc: lori.dodson1@maryland.gov, Andrew Rosenstein <andrew.rosenstein@md.steePhill.com>, Marc Rosenstein <marc.rosenstein@md.steePhill.com>, Daniel Kulakowski <daniel.kulakowski@md.steePhill.com>

Hi Mary-Jo,

Daniel Kulakowski will be offering public comment at tomorrow's MMCC meeting, and thank you for accepting the following comments on ITL regulations:

1. Storage of samples for stability testing

It is well beyond the storage capacity of ITLs to store the many thousands of retention samples that the state's program will ultimately generate. ITLs have a very modest square footage, usually between 1500 and 2500 square feet, and it would be an almost impossible burden to dedicate the storage space necessary to store all of the retention samples. We advocate strongly that the cultivators and processors, whose total square footage can vary from 20,000 to 150,000 square feet, be responsible for the storage of their own samples for retention according to their own storage SOPs.

2. Number of sample required for stability testing

We advocate that there be a reasonable but modest number of samples required for stability testing per unique strain of flower. Our current understanding is that 2 separate retention samples will be required for *each and every* unique batch of flower sampled, i.e. 1 sample required for the full panel certification test, 1 sample for stability test at 6 months, and 1 sample for stability test at 1 year. For example, let's say a cultivation facility produces 10,000 pounds per year equally divided among 4 strains. The testing would work out like this:

Strain 1	2500 lbs	250 initial certifying full panel tests	250 potency tests at 6 months	250 potency tests at 1 year
Strain 2	2500 lbs	250 initial certifying full panel tests	250 potency tests at 6 months	250 potency tests at 1 year
Strain 3	2500 lbs	250 initial certifying full panel tests	250 potency tests at 6 months	250 potency tests at 1 year
Strain 4	2500 lbs	250 initial certifying full panel tests	250 potency tests at 6 months	250 potency tests at 1 year

If the above is the case, then there could be an unnecessarily large number of samples retained for stability testing for the exact same kind of product. We advocate that the MMCC pick some number of retention samples required per unique strain, perhaps 10 or 20 samples, to be stored for stability testing. This can provide MMCC with the stability data is seeking but can also relieve the burden of an unnecessarily large amount of testing required for cultivators and processors.

Once again, thank you for accepting these comments for inclusion.

Have a great day!

--
Phillip Stripling
Business Development
Steep Hill Maryland
M: 410-299-7531
E: phil.stripling@md.steePhill.com
W: steephill.com





MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

questions for policy meeting

1 message

Philip Goldberg <phil@gleaf.com>
To: maryjo.mather@maryland.gov

Wed, Oct 4, 2017 at 11:59 AM

Hi Mary Jo, below are questions for the policy meeting.

1) What is the expiration date for flower once harvested? I assume one year, but haven't found any specifics in COMAR.

2) If a test batch sample fails, what is the exact meaning of a product/harvest batch being reworked or reprocessed? I assume they are talking about remediation when they mention a product being reprocessed, but am confused on how a harvest batch can be reworked... I don't think a product can be reworked if it fails for contaminants.

3) Stability Testing - Under the potential revised rules, it says we need to keep three stability test samples: 6 month, 1 yr, and 2 yr. Under the MMCC Technical Authority for Medical Cannabis Testing it only states there should be stability samples kept for 6 months and 1 yr. Do we need to keep/store two or three stability test samples?

4) 10.62.15.08 - "A licensed grower shall submit to the Commission quarterly a list of the products and their specifications that the licensed grower offered for distribution in the previous quarter."

How do we report this to the Commission?

Is this a list of Harvest Batches that are in our Shipping Vault? Is this a list of Harvest Batches that were actually sold and manifested?

Thanks

Phil

Philip Goldberg

CEO

Green Leaf Medical, LLC

Facebook.com/greenleafmedical

10/4/2017

Maryland.gov Mail - questions for policy meeting

Phil@gLeaf.com

P 240.888.6780



MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Fwd: COA letter

1 message

Lori Dodson -MMCC- <lori.dodson1@maryland.gov>
To: Mary Jo Mather -DHMH- <maryjo.mather@maryland.gov>

Tue, Oct 3, 2017 at 2:51 PM

Last public comment sent to me

----- Forwarded message -----

From: **Debra Kimless** <drdeb@forwardgro.com>

Date: Saturday, September 16, 2017

Subject: COA letter

To: lori.dodson1@maryland.gov

Hi Lori,

Hope that you are enjoying the weekend.

Attached is the letter I wrote to the policy committee regarding certificate of analysis.
Please know that I welcome the opportunity speak directly with them if you think that would also be useful.

Thanks again!

Deb

--

Lori Dodson, M.S. MT(ASCP)

*Director of Compliance for Independent Testing Laboratories
Maryland Medical Cannabis Commission
Maryland Department of Health
849 International Drive, 4th Floor
Linthicum Heights, MD 21090*

E-mail: lori.dodson1@maryland.gov

Office Phone: 410-487-8065

Office Fax: 443-681-1033

Office Cell: 443-813-1195

mmcc.maryland.gov

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 Letter to the policy committee COA.docx
131K

Dear members of the policy committee,

My name is Dr. Debra Kimless, and I am the medical director for ForwardGro. It has come to my attention that a complete certificate of analysis is required anytime there is a transfer of material from a cultivator to a processor.

I would like you to reconsider this policy for the following reasons:

1. If plant material is cultivated for the sole purpose of extracting into oil and then creating a final product, the COA at the point prior to when the cultivator sells the plant material to the processor is excessive and will only increase the cost of the end- product to the patient. The water activity, moisture content, microbials, organoleptics, and even the cannabinoid and terpene profiles (which the processors will be able to assess with their own equipment) will only delay patient access to medicine and unnecessarily increase the cost of the products.
2. Going through the process of “failing” a test and then returning it for “rework or reprocessing” doesn’t make sense if the raw material is specifically intended for processing only.
3. The METRC statistics will not accurately represent information that could be useful. Example- a cultivator fails for moisture content when the processor specifically requests fresh material for rosin pressing will not reflect and will inaccurately reflect how well that cultivator dries/cures the flower.
4. The only essential COA is the final product that will be sold to the patient.
5. The level of testing between licensees should be a business decision based on specific information needs and not mandated by regulation.

I would love the opportunity to discuss this matter further.
Thank you for your consideration.

Debra Kimless, M.D.



MARY-JO MATHER -MMCC- <maryjo.mather@maryland.gov>

Fwd: letter to the policy committee

1 message

Lori Dodson -MMCC- <lori.dodson1@maryland.gov>
To: Mary Jo Mather -DHMH- <maryjo.mather@maryland.gov>

Tue, Oct 3, 2017 at 2:50 PM

Public comment sent to me

----- Forwarded message -----

From: **Debra Kimless** <drdeb@forwardgro.com>

Date: Thursday, September 14, 2017

Subject: letter to the policy committee

To: lori.dodson1@maryland.gov

Hi Lori,

Thank you for your clarifications and understanding as we figure out the details.

Attached please find the letter to the policy committee regarding research material.

I will send you a letter to the policy committee regarding COA for material for the sole purpose of processing in a separate email.

I enjoy our conversations!

Deb

--
Lori Dodson, M.S. MT(ASCP)

*Director of Compliance for Independent Testing Laboratories
Maryland Medical Cannabis Commission
Maryland Department of Health
849 International Drive, 4th Floor
Linthicum Heights, MD 21090*

E-mail: lori.dodson1@maryland.gov**Office Phone:** 410-487-8065**Office Fax:** 443-681-1033**Office Cell:** 443-813-1195**mmcc.maryland.gov**

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 Letter for Policy Committee re-1 research.docx
16K

Dear members of the policy committee,

My name is Dr. Debra Kimless, and I am the medical director for ForwardGro. It has come to my attention that the results of research material submitted for testing by a grower to an independent testing lab must be reported in the METRC system.

I would like you to reconsider this policy based on the following reasons:

1. The FDA encourages freedom to research and investigate products without having to formally report until that product is ready to be released to the public. The MMCC policy is more stringent than what the FDA requires from the traditional pharmaceutical industry.
2. The reported information is meaningless to anyone other than the grower. The samples are not chosen in a statistically significant manner as is required for release testing. The business chooses the sample for specific research and informational purposes only, and therefore the results only have context and meaning for the business. Therefore, the results should remain with the business and not shared within METRC.
3. This policy provides an unfair advantage to growers who also have a processing license. They have the freedom to use their lab equipment for research and development without having to share that information within METRC.
4. We are one of few growers who applied for a processing license and did not receive it. Our business plan specifically included a processing business with a laboratory for research and development. If we were awarded a processing license we would have the ability and freedom to test our material without having to report the results to anyone outside of our business. Since we don't have the processing license, it makes sense that we should have that same level of privacy to conduct research using an independent testing lab.

Please remove this policy and allow us the freedom to experiment and research our material so we may gather the best possible information to create the safest and most consistent medicine for our patients in Maryland.

Thank you,

Debra Kimless, M.D.



Mary Jo Mather -MDH- <maryjo.mather@maryland.gov>

Oct 5th Policy Committee Meeting

2 messages

Anand Dugar <adugar12@yahoo.com>

Wed, Sep 27, 2017 at 12:46 AM

To: "maryjo.mather@maryland.gov" <maryjo.mather@maryland.gov>

Cc: Shivangi Amin <aminshivangi@gmail.com>

Hi Mary Jo! I hope you are doing well. I was glad to see your name on the MMCC website re: Oct 5th policy meeting.

As you know, I am an owner of Green Health Docs, with my partner, Dr. Shivangi Amin. We would both like to speak on Oct 5th about allowing out-of-state patients into the MMCC program. I understand that we are required to present a written version of our comments and am providing this below:

As physicians and also residents of Maryland and Washington DC, Dr. Amin and I are very passionate about the medical cannabis program in Maryland and have quit regularly practicing medicine to focus full time on expanding our centers to provide access to thousands of patients all over Maryland and neighboring states. Many physicians are scared to sign on with the MMCC and many patients are scared to have this discussion with their current providers. Because of these issues, we feel that clinics like ours, dedicated to this cause, are extremely important and are the main catalysts for a successful and healthy medical cannabis program.

We have been seeing patients at our Frederick location since Feb 20, 2017 and have certified over 1000 patients to date. We have already certified many out of state patients prior to recent events and we think it would be extremely unfair to these patients to now say that they are no longer allowed to be certified in Maryland. At this time, we have 5 locations open - Baltimore, Frederick, Hagerstown, Cumberland, and Rockville. As physicians who have seen firsthand how devastating the opioid epidemic has been, Dr. Amin and I both feel very strongly that out of state patients should not be denied this amazing opportunity to get off opiates, prevent themselves from getting addicted to opiates, and finally get access to a medication that will actually help them instead of taking medications with a long list of side effects and minimal benefits.

We do hope that the commission will take the thoughts of two dedicated physicians into consideration and allow out of state patients to be seen in Maryland so Maryland can lead the charge in this area of the country!

Thank you for your time, Mary Jo and I hope to actually meet you in person on Oct 5th.

Best,
Anand Dugar
215-287-3607

Mary Jo Mather -MDH- <maryjo.mather@maryland.gov>

Wed, Sep 27, 2017 at 9:26 AM

To: Anand Dugar <adugar12@yahoo.com>

Cc: Shivangi Amin <aminshivangi@gmail.com>

Thank you Dr. Dugar. I will make sure to include your comments for Commissioner review in advance of the meeting.

[Quoted text hidden]

--

Mary-jo Mather
Director of Administration
Maryland Medical Cannabis Commission
Department of Health
849 International Drive, Suite 450
Linthicum, Maryland 21090
mmcc.maryland.gov
Email: maryjo.mather@maryland.gov
Direct Line: 410-487-8052

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Mary Jo Mather -MDH- <maryjo.mather@maryland.gov>

Next week policy meeting

Jake Van Wingerden <jakevw@sunmedgrowers.com>
To: Mary Jo Mather -MDH- <maryjo.mather@maryland.gov>

Tue, Sep 26, 2017 at 4:23 PM

~~Ok thanks. Hold off on giving my letter than....~~

Jake Van Wingerden

SunMed Growers

jakevw@sunmedgrowers.com

From: Mary Jo Mather -MDH- [mailto:maryjo.mather@maryland.gov]

Sent: Tuesday, September 26, 2017 4:21 PM

[Quoted text hidden]

[Quoted text hidden]

SUNMED GROWERS

Medicine from the Sun

9/26/17

Dear Policy Committee,

I appreciate the ability to submit written comments on the proposed revised regulations and I look forward to giving oral comments at the September 27, 2017 meeting as well.

The opportunity to comment is always appreciated but I would like to ask for more input into all meetings and discussions relating to revising regulations and technical guidance in the future. The 22 companies that make up the growers and processors that were selected in August of 2016 represent a broad cross section of companies and people with expertise in many different fields in the cannabis industry. Many of the companies have now passed the Stage 2 licensing process and have proven that they are of good moral character and have the ability to execute complex business plans.

I would formally ask that you include members of this very small industry to all current and future policy meetings and discussion and allow us the ability to contribute in a meaningful and constructive way in the shaping and building of this new industry. This public/private partnership is unique as we are both fully reliant on each other to make this program a success for the people of Maryland.

I would also like to comment on the issue of the proposed batch size of 10 lbs. for testing purposes. I believe it is too small and limits different growing and processing practices. When cannabis is harvested, it is typically cut down at the root ball and the plant is dried in one form or another. Over its 2-3 week long drying process, the plant material loses about 70-80% of its water weight. So a wet plant of 50 lbs ends up as 10lbs of dry material. The testing of that 10lbs would then begin.

We have a potential processor customer that has asked if we can sell him the whole plant that has been freeze dried on the day that it has been harvested. This processor would then take that whole plant and "grind" it up and process the whole thing. This company has been successfully doing this process in other regulated states with great success and wants to bring their forward thinking technology and best practices to Maryland. The current testing guidance of 10 lbs of dried product does not envision this type of system and would appear to be unworkable if we are required to test every 10lbs of wet or dry product.

I would ask that further research and dialog take place with the growers and processors before this batch size of 10lbs is put into place.

Sincerely,

Jake Van Wingerden
President

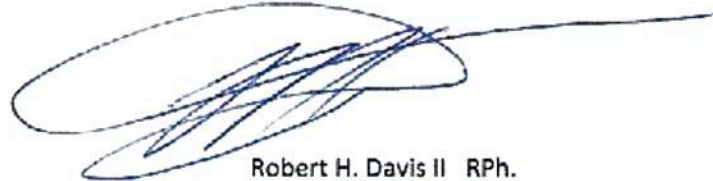
To whom it may concern,

My name is Robert Davis I have been licensed practicing pharmacist in both the state of Maryland and Delaware for 23 years. I am owner of OC botanicals LLC which has been granted phase 1 license to pursue dispensary operations in Senatorial district number 38.

I like to express my views and experience as it pertains to potential delivery service and most importantly satisfying patient needs. In my experience as a registered licensed pharmacist providing delivery from my pharmacies, delivery service is of vital need to the patients that are unable to drive and pickup their medications or do not have access to caregivers and or are too sick to leave their home.

In Worchester and Wicomico counties in Maryland I have been serving Coastal Hospice and palliative care. Over the past 4 years have been fulfilling medication orders for hospice patients and have been an on call pharmacist in the evenings and on the weekends for Coastal Hospice patients. I want to strongly express the need for delivery service within this industry, in many cases patients that are most in need of this medicine are the ones that will not have the ability to gain access to the medicine by coming to the licensed dispensaries. Delivery services are performed in every state in the United States within the industry of pharmacy as a vital service to patients in the highest need. It is operated effectively and protects patient safety and welfare. That same model can be utilized and instituted within the Maryland medical cannabis program.

Sincerely,

A handwritten signature in blue ink, appearing to read "Robert H. Davis II", with a long horizontal flourish extending to the right.

Robert H. Davis II RPh.



Mary Jo Mather -MDH- <maryjo.mather@maryland.gov>

Delivery Letter.

Robert Davis <rhodavis@comcast.net>
To: maryjo.mather@maryland.gov

Tue, Sep 26, 2017 at 12:09 PM

Good morning Mary Jo,

I realize this is being sent to you past the deadline but I still wanted to submit my opinion. I was indisposed and unable to provide in the timeframe necessary. Thank you and have a great afternoon.

Robert Davis

410-430-5790

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 **OCB Delivery Signed.pdf**
179K

9/26/2017

Maryland.gov Mail - RE: SKU for Maryland MMCC

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Mary Jo Mather -MDH- <maryjo.mather@maryland.gov>

comment to : Purpose: To discuss proposed revised regulations

1 message

frank willson <ffw492@gmail.com>
To: maryjo.mather@maryland.gov

Mon, Sep 25, 2017 at 3:43 PM

My name is Frank Willson IV and I was raised on pills from six years old the school systems couldn't handle a hyperactive kid my parents were both alcoholic drug addicts after being restrained at schools AFTER A LONG DAY I WOULD THEN COME HOME AND BE BEATEN UNTIL I SAW ORANGE I DEALT WITH THERAPIST HOSPITALS and was just a young kid who was traumatized and forced to take pills I have been clean off pills since 2014 after completing a 25 day rehab program I went to AA and NA meetings got a sponsor stayed clean for five months then got drunk never got laid gave everyone a ride so you can see why I'm annoyed since then I followed my own path have stayed clean smoked weed found my wife and I OWE it all to pot and my awesome wife this 2017 I have gotten my masters also known as a Postsecondary nondegree award I'VE JUST BEEN THROUGH A LOT OF STUFF OK AND I'VE MADE SOME ACCOMPLISHMENTS NEVER GRADUATED HIGH SCHOOL BUT I WAS RAISED AROUND WEED AND PILLS AND ALL THIS CRAP I NEED MARYLAND TO MAKE MARIJUANA JOBS and I want to be a master grower and be in the extracting field stop making people like me feel alienated from the outside world the power is in the people in politics we address thank you make it decriminalized for people 21 and up .



Mary Jo Mather -MDH- <maryjo.mather@maryland.gov>

Comments on proposed revised regulations

1 message

Maggie <maggie@cannacaredocs.com>
Reply-To: maggie@cannacaredocs.com
To: maryjo.mather@maryland.gov

Mon, Sep 25, 2017 at 4:35 PM

Good afternoon Mary Jo,

Please see the attached comments I would like to submit for the Policy meeting being held on Sept. 27th. I will arrive prior to the scheduled time with copies of my comments ready to distribute.

Have a great day!

--

Take Care,

Maggie Fauver

Mid-Atlantic Operations Manager
Canna Care Docs

A Division of MedEval, Corp.

443-240-9991 (cell)

410-412-3470 (office)

Maggie@CannaCareDocs.com



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Out of state regulations.docx
36K



Canna Care Docs

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CannaCareDocs.com

410-412-3470

MD@CannaCareDocs.com

Good afternoon ladies and gentlemen of the commission,

My name is Maggie Fauver, and I represent Canna Care Docs. I am also here today as a voice for patients. Thank you for the opportunity to comment on the proposed revised regulations. As published, the regulations call for out of state residents seeking medical care in Maryland to be granted certification into the program. The original writers of this law were wise to include this feature of the law. I would like to highlight several reasons why this should be implemented as intended.

Patients traveling to receive life sustaining care at our world renowned medical facilities in Maryland deserve world renowned access to care. Cannabis therapy has been found to make profound differences in outcomes and in quality of life issues. These patients deserve all proper options, and the best available care.

Continuity of medical care is also of utmost importance. Patients are constantly advised to adhere to the medical plan they have worked to establish with their provider; as lapses in treatment can lead to setbacks in patient outcomes. This becomes problematic for medical cannabis patients that have reduced or even eliminated their use of prescription medications, using cannabis instead to treat their medical condition. Medical cannabis programs exist in well over half of the United States, and are flourishing in neighboring states and the District of Columbia. Maryland is a very inviting state, that many of these patients will travel to for business or pleasure. Patients using potentially deadly substances like oxycontin, are free to legally travel throughout the country with medicine they purchased in their home state. However, this is not the case with cannabis; as it is illegal to transport cannabis over state lines.

If this regulation were revised; patients would be faced with the dilemma to either abstain from using their medication risking setbacks and flare-ups, or illegally transport medication from their home state into Maryland. A far more compassionate and medically sound approach would be allowing these patients to receive medical care while in Maryland.

Federal regulators have issued guidance instructing states to ensure that legal cannabis does not cross state borders. Current regulations ensure that patients from out of state need not transport cannabis into Maryland. As I am extremely focused on compliance issues, I would like to humbly suggest a minor addition to the regulations. It could be ensured that cannabis does not exit Maryland state borders with an additional requirement that out of state patients sign an attestation, acknowledging this is strictly prohibited.

Thank you for your time, it is sincerely appreciated.

Sincerely,

Maggie Fauver

Mid-Atlantic Operation Manager

Canna Care Docs

443-240-9991

Maggie@CannaCareDos.com



Mary Jo Mather -MDH- <maryjo.mather@maryland.gov>

Questions for the Policy Meeting

Robin Belsaas <rbelsaas@magothygroup.com>

Sat, Sep 23, 2017 at 9:45 PM

To: "maryjo.mather@maryland.gov" <maryjo.mather@maryland.gov>

Cc: Don Treacy <dtreacy@magothygroup.com>, Marcus Schestopol <mschestopol@magothygroup.com>, Ted Dumbauld <ted.dumbauld@curiowellness.com>, Brad Friedlander <brad.friedlander@curiowellness.com>

Hi,

My name is Robin Belsaas and I am with Magothygroup, a consulting group for Curio Wellness. I just have a few questions and comments for the Policy meeting on Sept 27th:

1) Proposed amendment 10.62.150.06 Grower Determination That a Batch May be Released

D. A batch meets specification if the certificate of analysis reveals that no criterion exceeds or is below specification by 15 percent

Examples: TYMC Specification is >10,000 CFU/g then if result is 11499 CFU/g, this would pass?

Or Arsenic Specification is <0.4ppm then if the result is 14% above specification the value would be 0.456 ppm. This is rounded to 0.5%. Does this pass?

Does this <+/-15% of specification apply to stability testing as well?

E. If any part of a batch that is offered for sale is found to exceed or is below specification by more than 15 percent. The grower shall order a recall of the entire batch.

This implies that the batch was released into distribution prior to QC release? If that possible?

2) Proposed amendment 10.62.150.07 Stability Testing and Retention Sampling

B. The independent testing laboratory shall hold samples for stability testing and conduct analysis of the stability testing samples at the following intervals after harvest- 6months, one year and two years.

Do the ITLs have the capacity to store stability samples? Can the cultivator or processor store the stability samples if they have the proper environmental storage conditions?

The technical guidance draft May 30 states ...

The design of the laboratory's stability studies must include the following factors as standard requirements (ICH 2003):

- Samples from at least 3 batches of medical cannabis stored in a secure, climate controlled environment
- Samples must be stored undisturbed at the designated storage temperature for the appropriate time interval
- Stability samples must reflect a representative sample of the entire batch

a) "...at least three batches of medical cannabis...". So that means only 3 batches the cultivator grows per year should be on stability? Of each strain for the grower? Or just three batches of various strains?

b) Same question as bullet a), with at least three batches of process concentrates (i.e. oil) and infused products (i.e. Tincture, salve, lozenges)?

c) What if the oil (intermediate product) was tested for release and used in the infused products such as salve, tincture etc.. do the final infused products have to be tested again for release?

d) *Bullet 3 of the excerpt above, "Stability samples must reflect a representative of the entire batch..." so if a batch is 100lbs, that will be 10 samples for testing at release. Not all of those 10 samples must be placed on stability but just one(1)? Not sure which one of the 10 samples is "representative" but the idea is that any one of them should be?*

C. A licensed grower shall retain a sufficient sample from each released batch to:

- 1) Provide for follow-up testing if necessary; and
- 2) Store the sample properly for one year past the date of expiration of the batch...

Does that mean that there are three set or types of samples per batch (if that batch is one of the three batches must be on stability)

- 1) *Testing for release*
- 2) *Stability testing (6, 12 and 24 months)*
- 3) *Retain samples for one year after the expiration date (this set could be part of the extended stability)*

3) Proposed Amendment 10.62.23 Medical Cannabis Concentrates and Medical Cannabis-Infused Products

01.A.4 Carry out a validation process on the first 10 lots of any new medical cannabis concentrate, medical cannabis-infused product, or process, to establish the validity of the production process.

What other testing besides release testing is expected for the first 10 validation lots?

Can grower/processors distribute/commercialize the first validation lot once the data is deemed acceptable or do ALL ten validation lots must be released before any lot can be distributed/commercialized?

Once 10 validation lots passed the acceptance criteria, does every lot must be tested for release testing thereafter? If that is the case, then what's the difference between the validation lots and just routine lot testing?

For infused products, would the commission open to requiring to test only the oil used in the infused products and reduce the number of batches of the infused products to be tested so that not every batch of the infused products must be tested?

Thank you for your time.

Robin Belsaas (301-693-1940)

Consultant for Curio Wellness



Mary Jo Mather -MDH- <maryjo.mather@maryland.gov>

Policy Committee Meeting - 27 September 2017

1 message

Bryan Hill <bryan.hill@charmcitymedicus.com>

Mon, Sep 25, 2017 at 3:58 PM

To: "maryjo.mather@maryland.gov" <maryjo.mather@maryland.gov>

Mary Jo –

Please see attached comments for the policy committee meeting on Wednesday. It is my intent to get there before 130pm and sign in to read these comments in person.

If you could confirm receipt of this email I would greatly appreciate it.

Thanks and please let me know if you have any questions.

Bryan

Bryan Hill

President / CEO

Charm City Medicus, LLC

804-852-5481 (Mobile)

bryan.hill@charmcitymedicus.com



09272017 Policy Meeting Discussion Points.docx

144K

Good Afternoon and thank you for the opportunity to speak.

My name is Bryan Hill – I am the owner of Charm City Medicus, a dispensary in District 6, and the Director, Government Relations for the Maryland Medical Dispensary Association (MDMDA). We recently had a meeting with several inspectors and MMCC staff members to address questions from our Maryland Dispensary members and discuss best practices going forward. We look forward to continuing to build on this partnership as we all diligently work to get this industry established in Maryland and make it one of the most successful in our country.

In a continued effort to streamline inputs from our dispensary members, we have three (3) items we would like to see addressed from a policy standpoint.

One is the out of state patient issue – as you know there are several dispensary businesses who developed their business plans and models based on the ability to support out of state patients. We would like to get a better understanding of MMCC’s intent for addressing this issue now that dispensaries are going through their build outs and developing relationships with potential patients.

The second issue revolves around delivery of medical cannabis products to registered patients. We have been made aware patients requesting delivery will need to be approved to receive this service. Some dispensaries have developed business models to support delivery services and understood that delivery to any patient would be allowed. Can MMCC provide further guidance on the delivery service to patients from dispensaries?

The third issue involves ownership thresholds. We have become aware of two specific scenarios on how some dispensaries are getting their capital which may circumvent the 5% ownership threshold. One is they are raising money through “management agreements” structured in a way where the breakout of ownership says one thing on paper but in reality, the majority of profits will be paid out to the beneficiaries listed in these management agreements.

The second scenario is where a business takes out a loan that then becomes debt free and converted to equity after certain milestones and timeframes are hit. We feel both scenarios could create situations where dispensaries will have more than 5% ownership interest by individuals who haven't been properly screened from the beginning. Additionally, if a large company (particularly one from out of state) has done these things then they could have interest in multiple dispensaries and could create price fluctuations that could either hurt the patients, other small business dispensary owners who have followed COMAR, or both...

Thank you for your time today...



ForwardGro

To: Natalie M. LaPrade Maryland Medical Cannabis Commission (MMCC or the Commission)
Policy Sub-Committee

From: Gail Rand, CFO and Patient Advocate for ForwardGro

Date: September 27, 2017

Subject: Suggestions for changes to the medical cannabis regulations

I would like to thank the Commission for taking the time to listen to our input. I am pleased that you hear us and have implemented a number of requests from advocates and the industry in the past.

Below are some specific comments, but I wanted to start with general comments:

Allow for delegated caregivers to administer this medication

Explanation and Rationale: I am pleased that the draft regulations allow for delegated caregivers for children under 18 and encourage you to make this process less burdensome for the caregivers. Caring for a child with special needs and/or medical issues is costly and time consuming. Setting up a system for delegated caregivers facilitates the legal guardians' ability to work while still giving their child the medicine the child needs. I encourage this process to not be restrictive. We especially do not want to limit this kind of caregiver to administration in specific locations as kids with medical or special needs should have the same opportunity as others. They should be allowed to access their medicine as needed, with no additional limitations than are provided to other medications on the Controlled Substance Act. Consider limiting the pick-up of the medicine at a licensed dispensary only to the main caregiver(s).

Ability of non-residents to access the program

Explanation and Rationale: I ask that the Policy Sub-Committee of MMCC draft sensible regulations that will encourage the staff of the Commission to process the applications of non-residents. I understand the concerns of the Commission that non-resident patients could bring medical cannabis across state lines. I especially appreciate the importance of compliance with the Cole Memo, specifically the provision that states "Preventing the diversion of marijuana from states where it is legal under state law in some form to other states".

Specifically, I do believe the definition of Qualifying Patient should remain as it is currently "for the purpose of receiving medical care from a medical facility".

Given the importance of the issue of non-resident patients having access to the Maryland program, the General Assembly in 2015, made a conscious, affirmative decision to any patient who met the requirements of the statute, to be able to become patients. This was done with careful consideration to the military personnel that live in this state as well as the families and patients who come to Maryland from all over the world for our first-class medical care.

When this issue was brought up at the May meeting, there was some discussion of an attestation from the medical provider, who cannot control what happens after a patient leaves his/her office. Asking the medical providers to attest to this could become a major deterrent from having medical providers



participating in the program at all; therefore, I believe this could do some serious harm to this program that has already had many challenges and delays. This Policy Committee could build in reasonable protective measures such as an attestation by the patient/caregiver.

Allow for delivery from dispensaries without undue burden to patients

Explanation and Rationale: I have heard that there is some discussion around delivery. I personally know of several families that have children in wheelchairs that make it difficult to travel anywhere. It is crucially important that these families have an easy way to get this medicine delivered without any undue burden.

Include cannabis infused products, such as edibles as part of the program.

Explanation and Rationale: Some patients may benefit from different routes of administration. Although this can be handled through regulations, I believe the General Assembly should expedite this process for the patients. Specifically, I need to ensure that the food safety regulators will cooperate with the Commission, so that edibles can be produced.

Include autism as a condition.

Explanation and Rationale: Gail Rand, our CFO/Patient Advocate is pleased that a Commissioner brought this up as new business. She is familiar with children who have autism who have benefited from medical cannabis. She is also familiar with the challenges of raising a child with autism and this is something that the Commission should consider seriously.

Include opioid addiction as a qualifying condition.

Explanation and Rationale: I appreciate that pain is a condition, however the reality is that many patients continue to abuse opioids far after the pain is mitigated.

Specific Comments

Items I believe have been omitted or need to be clarified from existing regulations

*10.62.06 Patient and Caregiver Identification Cards
.01 Patient Identification Cards*

1. Increase valid timeframe for Patient ID cards to 5 years.

Explanation and Rationale: Certifications are proposed to be valid for 365 days, and ID card renewal every year is cumbersome. The minimum renewal for Driver's licenses is 5 years, so that period makes sense. There is a cost and effort to obtain these costs and that should be minimized.



*10.62.11 Medical Cannabis Growing Controls
B. Terms Defined*

2. Redefine Green Waste to exclude roots.

Explanation and Rationale: Green Waste should be defined to mean unused, surplus, returned, or out of date medical cannabis, recalled medical cannabis, and any plant debris, including dead plants, all unused plant parts. By including the roots, it would indicate that they, too need to be weighed and documented in METRC which is cumbersome for cultivators and is unnecessary to prevent diversion.

*10.62.15. Medical Cannabis Grower Quality Control
.06 Grower Determination that a batch may be released*

3. D and E should be stricken; it is contradictory to what is in the COA .05

Explanation and Rationale:

The cannabinoid and terpene content should be defined by the grower not the laboratory. Refer to technical guidance, as the ranges can differ and science evolves. Pass/Fail only from the independent laboratory no 15% variance.

*10.62.31 Licensed Dispensary Clinical Director
.01 Clinical Director Responsibilities.*

4. Restatement of the definition of who can function as a clinical director at a dispensary

Explanation and Rationale: A licensed dispensary may appoint an individual who is a ~~Maryland-licensed physician, nurse practitioner or pharmacist~~ meets the definition of a provider to function as clinical director.

Date: September 22, 2017

Maryland Medical Cannabis Commission
4201 Patterson Avenue
Baltimore, MD 21215

Via Email Transmission: maryjo.mather@maryland.gov

Ladies and Gentleman,

On behalf of Chesapeake Alternatives, LLC (processor licensee and dispensary pre-approval awardee) please consider the following comments regarding proposed amendments to the regulations in COMAR Title 10, Subtitle 62. We would be happy to discuss any of these comments at the Commission's convenience.

Sincerely,

Rebecca Brown

Rebecca@ChesapeakeAlternatives.com

301-943-0457

[Remainder of this page is intentionally blank. Comments begin on the next page.]

Amendment 1:

At proposed revised Section 10.62.01.02(17), the definition of “Lot”:

Current proposed version: “Lot” means *not more than 10 pounds, 5 quarts or 144 packaged units of all of a medical cannabis finished product that is uniform, ~~that is~~ intended to meet specifications, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.*

As revised – version 1: “Lot” means *not more than 10 pounds or 5 quarts or 144 packaged units of all of a medical cannabis finished product that is uniform, ~~that is~~ intended to meet specifications, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.*

Alternative revision – version 2: “Lot” means *not more than 10 pounds or 5 quarts or ~~144 packaged units~~ of all of a medical cannabis finished product that is uniform, ~~that is~~ intended to meet specifications, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.*

Explanation and Rationale. It is our view that the use of a specified number of packaged products to define a “Lot” will be burdensome on producers of medical cannabis products, particularly in cases where the packaged unit is a single dose. Thus, this requirement is certain to limit the variety of products and dosing levels available to patients, and drive up the cost.

Other states with robust testing requirement and programs do not define their batch or lot sizes by reference to the number of resulting packaged products. Rather, the focus is on testing each portion of product that has been made from the same methods, equipment, and ingredients and treated in a uniform manner.¹ We encourage the Commission to adopt this approach (as shown in version 1, above), or to place the focus on the total weight of product that is to be divided into individual packages, as the Commission has done with the references to “10 pounds” and “5 quarts” (as shown in version 2, above).

Additionally, the Code of Federal Regulations governing drug manufacturing processes defines a “Lot” as “a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within

¹ See Table: Sample definitions of a “Lot” (or functional equivalent) of medical cannabis product by state, below.

specified limits.”² Again, no reference is made to a specified number of packages or packaged products.

In light of the foregoing, we request that the proposed revised definition of “Lot” be revised to make the Maryland regulations on this matter consistent with those of other states and the analogous FDA rules shown above. In the alternative, we request that the definition be revised to eliminate the reference to “144 packaged units.”

Table: Selected definitions of a “Lot” (or functional equivalent) of medical cannabis product by state:

State	Definition
Alaska	lot" or "production lot" means a group of marijuana products that were prepared at the same time from the same batch of marijuana, using the same recipe or process
Massachusetts	“Production Batch” means a batch of finished plant material, cannabis resin, cannabis concentrate, or MIP made at the same time, using the same methods, equipment, and ingredients.
Minnesota	"Batch" means a specific quantity of medical cannabis that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling batch record.
New Mexico	“Batch” means, with regard to usable cannabis, a homogenous, identified quantity of cannabis no greater than five pounds that is harvested during a specified time period from a specified cultivation area, and with regard to concentrated and cannabis-derived product, means an identified quantity that is uniform, that is intended to meet specifications for identity, strength, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling protocol.
New York	“Lot” means a quantity of a medical marijuana extraction product that has a homogenous and uniform cannabinoid concentration and product quality, produced according to an approved and stable processing protocol specific to that brand and form of medical marijuana product, during the same cycle of manufacture.

² 21 CFR 210.3(10). Available here: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3>.

Washington	"Lot" means a definite quantity of marijuana, marijuana concentrates, useable marijuana, or marijuana-infused product identified by a lot number, every portion or package of which is uniform within recognized tolerances for the factors that appear in the labeling.
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Amendment 2:

Revise warning label for clarity and to remove redundancy.

10.62.29.01 Packaging Medical Cannabis for Distribution to a Qualifying Patient or Caregiver and 10.62.24.01 Packaging of Medical Cannabis Finished Product.

Current labeling requirements provide that a package of medical cannabis finished product must:

“(5) Bear a clear warning that:

(a) *The contents may be lawfully consumed only by a qualifying patient named on an attached label;*

(b) *It is a illegal for any person to possess or consume the contents of the package other than the qualifying patient; and*

(c) *It is a illegal to transfer the package or contents to any person other than a transfer by a caregiver to a qualifying patient;*

(6) *Bear a clear warning to keep the package and its contents away from children other than a qualifying patient;”*

We request that this language be replaced with the following:

“*Bear a clear warning that*

(a) *the contents may be lawfully consumed only by the qualifying patient named on ~~an~~ the attached label and*

(b) *the contents may be lawfully possessed only by the qualifying patient named on the attached label or a qualifying caregiver”*

Explanation and Rationale: This revised statement covers all of the substance set forth in the original version, but is clearer and easier to read and to print on a package. A shorter, simpler warning that is easier to read is more likely to fulfill its intended purpose.

Amendment 3:

Remove requirement that a processor package Medical Cannabis Finished Product in opaque packaging.

10.62.24.01 Packaging of Medical Cannabis Finished Product.

Current packaging requirements provide that a package of medical cannabis finished product shall: “(2) *Be opaque*”

We request that this requirement be removed as it pertains to products individually packaged by a wholesale licensee.

Explanation and Rationale: Certain patients may want to see the consistency or color of a medical cannabis extracted or processed product that they are planning to purchase at a dispensary. If a processor is required to use packaging that is opaque, a patient is not able to view the medical cannabis extracted or processed product he or she is purchasing prior to making the purchase. Any ends served by requiring opaque packaging can be reached by requiring all transport packaging to be opaque and by requiring a dispensary to package any product dispensed to a patient in an opaque bag or container.

Amendment 4:

Remove requirement that a qualifying patient or caregiver shall first telephone a registered dispensary to request the delivery of medical cannabis.

10.62.30.04 Dispensing Medical Cannabis - Delivery of Medical Cannabis to a Qualifying Patient or Caregiver.

Current version: “A. A qualifying patient or caregiver shall first telephone a registered dispensary to request the delivery of medical cannabis.”

Proposed Revision: “A. A qualifying patient or caregiver shall first ~~telephone~~ contact a registered dispensary to request the delivery of medical cannabis”

Explanation and Rationale: As we have seen in the past couple years, the cannabis industry continues to show promise for incredible innovation. Requiring patients or caregivers to only request delivery via the telephone is cumbersome and inefficient. There are many other modern methods of communication that could be preferred for patients and dispensaries. Patients may use the telephone to communicate with a dispensary, but this should not be required over other communication methods including email, text message or other electronic communications.