

Medical Marijuana Commission

Meeting Summary: March 24, 2015

The meeting took place at the Baltimore County Agriculture Center in Cockeysville, Maryland. The following Commissioners were present for the meeting: Chairman Paul Davies, Vice Chairman Buddy Robshaw, Chris Charles, John Gontrum, Robert Lavin, Shawn McNamara, Debby Miran, Cristina Paul, Nancy Rosen-Cohen, Eric Sterling, and Jon Traunfeld. Commissioner Michael Horberg joined the meeting by telephone. Staff members present included Hannah Byron and Mary-jo Mather. Kristen Neville, the DHMH Health Boards and Commissions Legislative and Regulations Coordinator, and Erin Purdy, the Commission's Assistant Attorney General, were also present. Approximately ninety people attended the meeting, including seven people who presented oral comments to the Commission.

Chairman Paul Davies offered a welcome to the attendees and thanked the staff of the Baltimore County Agriculture Center for their assistance. Chairman Davies stated that the meeting was being streamed and the link was posted on the Medical Marijuana Commission website. He asked speakers to speak into the microphone and asked that public commenters limit their remarks to three minutes.

Chairman Davies called the meeting to order at 2:00 pm, and requested a motion to approve the minutes from the January 27th Commission meeting. Commissioner Robshaw made the motion to approve the minutes, and Commissioner Rosen-Cohen seconded the motion.

Chairman Davies offered a welcome to Jessica Armacost, the Executive Secretary of the Maryland Agriculture Commission, who was representing Department of Agriculture Secretary Joe Bartenfelder. Ms. Armacost thanked the Commission, and reported that Secretary Bartenfelder had asked her to personally convey his interest in the Commission's work, and had requested that he be kept apprised of the Commission's ongoing efforts.

Chairman Davies extended a welcome to new Commissioner John Gontrum, who will be representing Comptroller Franchot's office. Chairman Davies also extended thanks to Andy Schaufele for his past work on the Commission. Chair Davies also thanked the Commissioners for all of their work on the regulations. Since the publication of the proposed regulations in the *Maryland Register* on January 23, 2015, fifty-seven comments were received during the formal 30-day comment period. The comments received were thoughtful and constructive. The Executive Committee and Policy Committee worked many hours, not only reviewing the comments, but revising the regulations. He also noted that there were also several related legislative proposals, including House Bill 490, introduced by Delegates Morhaim and Glenn, which were introduced this session. The newest draft regulations were posted on the Medical Marijuana Commission website on March 20, 2015, in addition to a Summary and a Table of Contents. Chairman Davies added that the Commission will be having a voting

session on the draft regulations in order to move the regulations to AELR. The Commission has proposed the next meeting for April 22, 2015, from 2:00-4:00 pm, to be held again at the Baltimore County Agriculture Center. Chairman Davies then concluded his report, stating that the Commission is looking forward to operationalizing the Program, and that Hannah Byron would then give a report on her progress in that regard.

Executive Director's Report: Hannah Byron

Ms. Byron thanked Jessica Armacost on behalf of the Commission, and stated the Commission is looking forward to working closely with the Department of Agriculture. She also thanked the staff of the Baltimore County Agriculture Center for their assistance and mentioned that she has a particular fondness for the location. As Commissioners Tina Paul and Jon Traunfeld are aware, she is proud to be a Baltimore County Master Gardener. The Master Gardeners have held many meetings here at the "Ag Center", and they do a great job.

Ms. Byron stated that her first Commission meeting was on January 27, two weeks after taking the Executive Director position and three days after publication of the draft regulations. She added that the public comment period ended just over a month ago. She went on to state that she has been so fortunate to have the incredible experience and commitment of the Executive Committee and Policy Committee members, including Eric, Debby, Nancy, Vice-Chair Buddy Robshaw, Chris, Tina, Allison Taylor of the Office of the Secretary, and the Commission's Assistant Attorney General, Erin Purdy. She stated that in all of her years working with Boards and Commissions, she has never experienced such dedication to public service. She also offered thanks for all of the support from the Administration and Secretary Mitchell.

She then stated that she was pleased to introduce the newest member of the Medical Marijuana Commission team, Mary-jo Mather. Mary-jo's bio is in the Commissioner's meeting packets. Ms. Mather has been on board for a little over a month, and brings a wealth of regulatory and legal skills to the Commission, and has done an incredible job keeping the comments and regulations organized in a compressed time frame. Ms. Byron also stated that while the regulations continue to move forward, she has been working with a former CFO, and a former procurement officer at DHMH. She also has been working with the DHMH IT team to develop the framework to get the Program operationalized. The in-house IT expertise provided by DHMH has resulted in huge savings. She mentioned that many hours have been spent developing the platforms that need to be in place. For the physician, patient, and caregiver registry applications, the Commission looks forward to beta testing the preliminary applications at a later date. Ms. Byron stated that she will be bringing on new staff to assist with the registries, licensing, and compliance functions.

Ms. Byron also mentioned that the Medical Marijuana Commission's website first introduced at the prior Commission meeting will be the focus for a communications plan.

She plans to bring on a communications team to assist in populating the data and the website FAQs. The MMC staff and the Education Committee will be working with the communications team to reach these goals. She is also working toward putting a review team in place who will assist in the review of the grower, processor and dispensary applications.

Ms. Byron also stated that while pending legislation is going through the General Assembly, the Commission is continuing to work closely with Delegates Morhaim and Glenn. House Bill 490 passed out of the House of Delegates with a 129/10 vote. The Commission will continue to work with the legislature as this measure goes through the Senate. April 13 is *sine die*, and House Bill 490, as an emergency bill, will be enacted if passed in the Senate, upon signature by the Governor.

Ms. Byron then noted the attendance at the meeting by Paula Hollinger, and went on to thank both she and Sharon Bloom for their support, and for all of the work they have done in the past.

She again thanked Eric Sterling for his leadership, his considerable commitment of time, his support for her personally, and also thanked the many stakeholders who have been such an inspiration for their continued input. Ms. Byron also mentioned that the March 20th draft regulations are posted on the website. She stated that the Commission used many of the suggestions and excellent comments received from the commenters to revise the January 23 draft regulations. Ms. Byron concluded by thanking the attendees, adding that she knows many of those present, either from Commission meetings, or from her meetings in Annapolis. She turned over the meeting to Commissioner Sterling, who would provide a brief summary of the changes in the new draft regulations.

Chairman Davies then asked Commission Sterling to provide his report.

Commissioner Sterling's Report

Mr. Sterling thanked the Ms. Byron and Ms. Mather for their intense work and all they have done to help him put together the newest draft regulations, and noted that the Commission attempted to take into account many of excellent suggestions from the public comments, as well as consideration of amendments which may pass in the General Assembly, which are incorporated into March 20th draft posted on the website.

Summary of Proposed Regulations

Mr. Sterling asked that the attendees draw their attention to the changes in the newest proposed regulations regarding the definitions of 30-day supply, and that the new proposed regulations recognize the concentration of THC concentrates. With respect to patients, in House Bill 490, patients need not be residents of Maryland. House Bill 490 would also make a number of proposed changes for physicians who would now be "registered" with the Commission. In particular, they would no longer have an annual reporting requirement. With respect to written certifications, physicians will be able to

indicate that the medical needs of the patient would be greater than the quantity specified in the 30-day supply. The new draft regulations also created a license for the processors of concentrates and medical Cannabis-infused products. There would also be a separate licensing procedure and a separate annual fee for licensed processors. House Bill 490 would change the licensing across the board for the classes of licensees, providing that the initial license period would be for four years, with renewals required every two years. The proposed regulations provide for a change in ownership, which could go forward after 45 days. There were a number of changes made regarding the details for licensed premises, in order to simplify and streamline the regulations, to provide the details applicants would be setting forth in their applications, and how to address these matters. House Bill 490 provides, with respect to growers, that the current limit to 15 licensees, which is set to expire in 2016, would be extended to the middle of 2018. The General Assembly recognizes the need for quality control, and House Bill 490 provides that independent testing laboratories would be registered by the Commission, inspected, and then the Commission can require their use for testing of medical Cannabis and Cannabis finished products. There were a number of changes to the dispensary regulations. The draft proposal clarifies that the location of a dispensary operated by a licensed grower would not count toward the two dispensary license limit per Senatorial district that the regulations are proposing. Dispensaries would not be required to have a licensed clinical director, but that an application reviewer would review the applicant's plans to counsel patients and caregivers on the use of medical Cannabis, and training for dispensary agents. The draft proposal would permit dispensaries to directly deliver medical Cannabis to patients who are in the home or are home-bound. House Bill 490 would remove the academic medical center programs from the medical Cannabis program. In the draft regulations published on March 20th, there are a number of features of House Bill 490 that were *not* included in the new draft of the regulations, and Mr. Sterling wanted to bring these to the attention of the public. House Bill 490 is amended to require that dispensaries gather data for submission to the Commission regarding the number of patients, county of residence and so forth, and this amendment language has not been included in the regulations. The draft regulations have not been directive in respect to the date 2018 versus 2016.

Commissioner Sterling then stated that he hoped this was an adequate summary. Chairman Davies thanked Mr. Sterling, and asked if there were any questions. Ms. Byron added that Secretary Mitchell and his team, as well as the Administration, have been very supportive, and the Commission has received additional funding in the budget to get the program up and running. She also added that there were some problems with the microphones and the streaming, and asked any speakers to speak into the microphone at the podium. Chairman Davies asked if there was any new business or questions for Eric.

Chairman Davies recognized Commissioner Lavin. Commissioner Lavin commended Commissioner Sterling on his excellent presentation and asked Commissioner Sterling what the training qualifications for a dispensary agent were in the draft regulations. Mr. Sterling responded that the regulations were not specific in that regard, and that the application would provide an opportunity for applicants to provide their training plan for dispensary agents. Commissioner Lavin then followed up as to dispensing specifics of high THC or CBD. Commissioner Rosen-Cohen then asked if the regulations were going to include a clinician who would be available to counsel patients and caregivers in the dispensaries. Mr. Sterling answered that the new draft regulations changed the language pertaining to a dispensary clinical director from being a requirement, but application review will include review of proposed plans to counsel patients and caregivers in the use of medical Cannabis, and dispensary agent training. The FAQs under development on the website will describe what the Commission hopes to see in terms of training for dispensary agents and providing information to patients in the licensed dispensaries. Commissioner Rosen-Cohen thanked Mr. Sterling for his response.

Commissioner Lavin then asked if individuals did not need to be Maryland residents to obtain medical Cannabis from a Maryland medical marijuana program. Mr. Sterling responded that he was correct, and in House Bill 490, as it passed in the House of Delegates, would amend this the requirement. Commissioner Lavin commented that if qualifying physicians could then write certifications for a patient living in Virginia, then medical marijuana would be crossing state lines. Mr. Sterling responded that he was not sure that question could be answered in terms of legal sufficiency. Mr. Sterling responded further that the Commission is not in any position to authorize non-residents obtaining medical marijuana, and this is outside the authority of the Commission.

Chairman Davies asked if there were any further business from Commission members, and introduced Commissioner Debby Miran, who would give a report on Education.

Education Chair Report

Ms. Miran stated that Med Chi had offered a workshop on Medical Marijuana which was given on March 14, which offered continuing education credits for physicians, and included a presentation given by Commissioner Eric Sterling. She reported that there were approximately 100 attendees, and speakers included a Food and Drug Administration representative. Persons wishing to further their education might consider attending the Americans for Safe Access Conference in Washington, DC taking place March 27-31, 2015. She also mentioned that the ASA representative Hunter Holliman had informed her that there would be physician training with CME credits from nationally known names in the field. At the end of May, Patients Out of Time will host a conference in Palm Beach, Florida. Ms. Miran added that Commissioner Chris Charles recently presented a talk to the Pharmacy Society and that the slides and notes from this talk are posted on the MMC website. Last, but not least, the Education Committee will be working with the Food and Drug Administration to share wisdom in upcoming

meetings. Ms. Miran also noted that earlier in the day, Dan Rodericks presented a radio show on NPR on the topic of Medical Marijuana with Corey Barnett. Ms. Miran noted that a Professor at Anne Arundel Community College had informed her that a class on the Science of Cannabis Growing currently has 27 students enrolled.

Chairman Davies thanked Ms. Miran for her report, and then invited the members of the public who had signed up to speak to come forward, noting that remarks were limited to three minutes, and that there would be no question and answer session.

Public Comments

1. Peter Unger, CEO of the American Association for Laboratory Accreditation (A2LA)

“Thank you very much Dr. Davies. My name is Peter Unger. I am the CEO of the American Association for Laboratory Accreditation. I’m here to support those references that you have in the regulations related to calibration, devices, the definition of independent testing laboratory, the definition of accreditation body, and the provisional registration of independent testing laboratories. We are very open to helping out the Agency in the implementation of this documentation for getting the laboratories up to speed during the provisional period, to make sure accredited laboratories provide credible results that support decisions and the quality of Cannabis products. Thank you very much for giving me the opportunity to speak. I have to run out to the airport at Dulles, so I can’t stay too long.”

Chairman Davies thanked Mr. Unger and asked if there were any questions from the Commissioners, and commented that the independent testing laboratories were a very important part of the medical marijuana program. As there were no questions from the Commissioners, Chairman Davies invited the next speaker to the podium.

2. Gail Rand, Stop the Seizures

“Hi. Commission Chairman and members, thank you again for the opportunity to speak with you all. I wish I could characterize how important your efforts are to my family and many families throughout the State. I hear from parents and speak at Cannabis programs and note that Maryland has a great program. I am encouraged that the new legislation does not limit the program to Maryland residents. As I’ve said many times, illness does not stop at State lines. I personally know many families who come to Hopkins for all kinds of treatment and end up staying in Maryland for treatment. I think this is one more option for them and I commend the Commission for that. I also wanted to appreciate the showing at the Med Chi Meeting mentioned earlier. I have had the opportunity to talk to many parents throughout the country who do not have a supportive Commission, so the fact that at least six of the Commission members took their time on an entire Saturday to further their education in this ever-changing industry to attend is extremely valuable and I think this should be recognized. I also wanted to mention some of the changes in your draft. I’ve spoken to you and to the General Assembly many times about the importance of accessibility for physicians. I appreciate the

changes that recognize this by removing the training requirement. I do believe that the likelihood of physicians participating will go up significantly. At the Med Chi event I mentioned I was thrilled to hear Dr. Vandrey explain that the Johns Hopkins administration has made a decision not to interfere with their physicians' ability to recommend or not recommend. I talked to Children's Hospital administrators about their physicians as to their support as well. I am really optimistic that Logan, my son, who has epilepsy, will get care with medical Cannabis from the same provider who provides his anti-epileptic drugs and manages his care and whole profile. That's really valuable to me. I am really optimistic about the physician exception for more than 120 grams or 30 (sic) grams of CBD concentrate. My little guy is only 40 pounds, but if it continues that would be an issue for him. I am happy that the clinical director part is removed. I don't speak about that industry a lot, but I am very concerned about how that cost would have been passed on to patients. I also feel very strongly that people who are educated and who deal with Cannabis on a daily basis are the face of the industry. I think it is very forward-thinking that the regulations now reflect the changes in a bill that's not even passed by law. That will save many months of effort when you're taking into account patient access to the treatment, and that's very valuable. I hope you'll continue to be so thoughtful, and will address the urgency that access to the treatment requires. Thank you for your tireless efforts and the progress made, especially in the last few months."

Chairman Davies thanked Gail. He added a comment (to follow up on the topic of physician education), that he had been asked by two hospitals to speak to their physician staff in the month of April at Sinai Medical Center and Anne Arundel Medical Center. He commented further that there is definitely a lot of interest from physicians who want to be educated on the use of medical marijuana.

Chairman Davies called the next speaker to the podium.

3. Gary Nusinov

"Hi Commissioners and hello everyone out in the audience. As the Commission already knows I'm one of those advocates with a thorn in his side who isn't standing here for big business. I'm standing here for patients and accessibility. This version of the regulations is heads and tails better than what we had a year ago, or even a few months ago. What the regulations have allowed is more potential patients. Unfortunately, one of the things I don't agree with in the newest proposed regulations, as well as House Bill 490, is the amount of licenses, and especially the fact that license expansion will not take place until 2018. This is simply a problem with mathematics. You have media here saying 2 plus 2 equals four, and time and time again, the Commission, as well as the members who are passing legislation, do not get that same math. They say 2 plus 2 equals 6, and we're going to make a wheel out of a square. There are professionals here that can tell you that no matter what you do to create this program, patients will never have full access to the medicine. With 36 THC limit coupled with 120 raw marijuana, now we have 480 plus grams allocated to them before the concentration

process. This is not something with the proposed amount of people in the program that 15 growers can provide. The math I've proposed to you is backed up by consultants in the marijuana field, the largest consultants in recreational marijuana field, who are paid hundreds of thousands of dollars. It behooves you to listen. Other than that the regulations are great going forward. One thing I would like to see is the redaction of proprietary information. I do like that they are streamlining the pre-approval process. I believe the people who are grading need to have control of the premises ahead of time and have the background checks. If you look throughout the industry in other states you'll see. If the applications are approved based on security and location and other details, and that location is approved, then you can't allow them to change. I have some more here but, as time does not allow, I would like to thank you very much."

Chairman Davies asked if there were any questions or comments, and after none were offered, invited the next speaker to the podium.

4. Tenzin Tashi

"Good Afternoon. I am Tenzin Tashi, and I am here to represent non-profit and for-profit interests. Governor Hogan has made it a priority to address the opioid crisis here in Maryland, and Cannabis is a solution for opioids. I haven't read the regulations in detail, but we are generally in favor. Gary's points as to the limitations of the licenses: I'm glad that those changes didn't make it into the draft and should stay out, as well as ___patient information. As for what's coming up, I hope to see you all at the conference in DC. Thank you very much."

Chairman Davies asked if there were any questions or comments, and after none were offered, invited the next speaker to the podium.

5. Darren Braude, Maryland resident, Principal Owner-Bluestone Benefits LLC (dba Blue Kamen Benefits) and Terrapin Health Center

"My name is Darren Braude. I have been a Maryland resident my whole life and a Maryland business owner for over 20 years as principal owner of an employee benefits firm called Bluestone Benefits, LLC. My mother has suffered from multiple sclerosis and its horrible effects my entire life. Likewise, my father has been suffering from Waldenstrom's Non-Hodgkin's lymphoma since 2009. I strongly believe that my parents and every other qualifying Maryland resident should have the right, if they so choose, to participate in this Commission's program to provide access to cannabis and cannabis related palliative care to help mitigate or treat the effects of their medical conditions. As principal member of Terrapin Health Center, I respectfully submit the following comment and question: Will a Medical Cannabis Concentrates and Medical Cannabis-Infused Products license (described in Regulation 10.62.23) only be awarded to a Medical Cannabis Grower Licensee or will it be completely separate, meaning a non-cultivation center third party applicant could potentially be awarded a license and how many of these licenses do you plan to award thru year 2018?"

Chairman Davies thanked Darren for his comments.

6. Debra Kimless, Bayside Group MD LLC

“Good Afternoon. My name is Dr. Debra Kimless. I am a board certified Anesthesiologist and Pain Medicine Specialist and I am testifying on behalf of Bayside Group. Creating regulations from scratch is not an easy task-a tremendous amount of energy and effort and passion goes into drafting such a document. Comments and suggestions are always expected-rewrites happen-especially regarding a topic where the constituents are as equally passionate as the crafters. With that said, I want to acknowledge Hannah Byron and the entire Commission for their hard work and for an excellent job of advancing the regulations in a positive direction. The new draft clarifies the process and minimizes the barriers that would have created an obstruction and interfered with taking the program from concept to reality. I especially want to mention a few things: 1. The name change from marijuana to cannabis: words matter, and using the word cannabis acknowledges that the purpose of this program is to provide alternative medical treatment for patients in need. 2. There are no educational barriers to physicians to make recommendations and that medical cannabis is treated as any other medicine that physicians use to treat patients. 3. There is a high priority on quality control and there is emphasis on requiring testing by an independent lab-insuring safety and purity of medicine for our patients. There are many other positive changes that will take too much time to mention. However, they will be submitted in writing to the Commission. I want to thank you for this opportunity to speak and congratulate you on an excellent work product. Additional comments not mentioned during the meeting that I would like to acknowledge as positive: the micro-managing of the grower, processor, and dispensary owners has been replaced by deferring to the licensee to create their own standard operating procedures. The initial growing license is now for a four year term. It is no longer mandatory that the director of a dispensary be a licensed physician, pharmacist or nurse. The 30-day supply of non-flower cannabis medicine uses THC as the maximum gm dosage and doesn't limit other non-psychoactive cannabinoids. Not limiting medical cannabis candidates to Maryland residents. I would like to thank you for the opportunity to speak, and again thank the Commission for their work.”

Chairman Davies thanked Debra for her comments.

7. Hunter Holliman, Chief of Staff, Americans for Safe Access (ASA)

“Good Afternoon. Americans for Safe Access is extremely pleased by the changes in this new set of draft regulations. I sincerely applaud the Commission for the work they've accomplished in redrafting these regulations over the last few weeks. To think how far the program has come since this Commission started meeting is astounding, and although no set of regulations or statutes may ever be perfect, I feel that these regulations will result in a functional medical cannabis program that suits the patients, the business side, and balances all other interests fairly. Thank you Commissioners for

your thoughtful reevaluation of the program. I would also like to acknowledge Delegates Morhaim, Glenn and Young for their leadership in the Assembly. They were able to recognize the faults in the current statute that were holding back the regulations and drafted emergency legislation to resolve the issues in a timely fashion. ASA is especially happy to see the physician registration scaled back so heavily and the reporting and education requirements removed. The focus on product safety as a theme throughout the regulations is also laudable, placing reasonable standards on the production of concentrates and medical-infused products through licensing, as well as creating a space for independent testing labs. Finally, ASA is having our 3rd Annual Medical Cannabis Unity Conference this weekend in DC from Saturday through Tuesday. In addition to panels on federal policy, the latest research, and political strategy, there will be a skills building workshop on Monday as well as an accredited CME on the Endocannabinoid System hosed by Dr. Stephen Corn of Harvard Medical School. I encourage everyone to attend. Once again, ASA would like to thank the Commissioners for their dedication in getting this program working effectively.”

Chairman Davies went on to thank Paula Hollinger for attending and for her work on the Program, and also thanked the public for attending, thanked the speakers and the Commissioners and the staff for their work. Ms. Byron mentioned that due to technical difficulties with the streaming, a meeting transcript or summary would be available as soon as possible on the website. Dr. Davies then asked for a motion to adjourn the meeting, which was introduced and seconded, and the meeting adjourned at 2:53 pm.