

# **lowa Department of Public Health Protecting and Improving the Health of Iowans**

Kim Reynolds Governor Adam Gregg Lt. Governor

DRAFT Notes
Iowa Medical Cannabidiol
Board November 1, 2019
10:00 a.m.
Iowa Laboratory Facility – DMACC
Campus 2240 DMACC Blvd.
Ankeny, IA

1. Call to Order

Mike McKelvey, Chair

The November 1, 2019, Iowa Medical Cannabidiol Board meeting was officially called to order at 10:00 a.m.

2. Roll Call

Mike McKelvey, Chair

Members Present	Members Absent
Dr. Ken Cheyne – Pediatrician	Vacant – Gastroenterologist
Dr. Jill Leisveld – Psychiatrist	Vacant - Neurologist
Capt. Mike McKelvey – Law Enforcement	Dr. Bob Shreck - Oncology
Dr. Lonny Miller – Family Medicine – via conference	
call	
Dr. Stephen Richards – Pharmacist	
Dr. Jacqueline Stoken – Pain Management	
Staff	
Sarah Reisetter – Deputy Director	
Owen Parker – Program Manager	
Jennifer Caskey – Recording Officer	

# 3. Approval of Minutes

Mike McKelvey, Chair

a. August 2, 2019 Medical Cannabidiol Board Meeting

Dr. Cheney made a motion to approve the August 2, 2019 meeting minutes, with a second by Dr. Miller.

A verbal vote was taken. Motion carried unanimously.

#### 4. Public Comment Period

Mike McKelvey, Chair

• David Barnette, Program Patient – Mr. Barnette spoke in support of adding PTSD as an eligible condition and adding vaporizable flower as a medical treatment. He expressed he would like the Board to factor in compassionate use as part of the Board's decision making process. He also said the Board should allow patients to purchase the amount of THC they need, listen to patients about what they need, and approve conditions that have been approved in other states.

- John Forbes, Iowa House of Representatives (40<sup>th</sup> District) Rep. Forbes noted he approved of many of the board's prior recommendations, but was concerned with the recommendation to limit THC purchases to 4.5 grams/ 90 days. He noted that the legislature overwhelmingly approved a 25 gram/ 90 day THC purchase limit and discussed the legislature's work to develop HF 732. He spoke of personal experience with a patient in his pharmacy who was prescribed large amounts of opioids prior to participation in the medical cannabidiol program. Rep. Forbes indicated the patient has been able to reduce opiate use through participation in the program, and a 4.5 gram/ 90 day THC purchase limit would be a reduction in the amount of THC needed by this particular patient.
- Connie Brooks Ms. Brooks is a parent of a child diagnosed with Intellectual Disability with Aggression, and shared her personal experience with daughter. She noted the extensive list of psychotropic medications her daughter has had to take, as well as their side effects, and expressed support for access to medical cannabidiol for patients diagnosed with Intellectual Disability with Aggression.
- Jen Simmering, Systems Unlimited Ms. Simmering spoke about Systems Unlimited's 24-hour group homes that serve clients with autism and other intellectual disabilities who are diagnosed with self-injurious or aggressive behavior. She shared that a number of their clients may benefit from the use of medical cannabidiol. She noted group homes are concerned that although medical cannabidiol is legal in lowa, facilities that receive federal funds may jeopardize that funding by storing or administering medical cannabidiol products in their facilities. She also expressed concerns about the lack of recognition for organizations such as Systems Unlimited in the statutory framework for patients and primary caregivers.
- Courtney Rife, Holistic Serives Ms. Rife shared she has PTSD and has sought treatment through
  counseling and other therapies. She spoke about the cost of the PTSD medications she is currently taking, in
  addition to the cost of over-the-counter CBD products. She noted patients who don't have access to
  medical cannabidiol products are using unsafe or illicit products obtained online or on the street. She
  asked the Board for compassion in recommending approval of PTSD, so citizens that need assistance can
  receive it.
- **Sally Gaer** Ms. Gaer recommended adding patients and caregivers to the Board, expressing the importance of their perspectives in the decision making process.
- Peter Komendowski, Partnership for A Healthy Iowa Mr. Komendowski shared his opinion that the Board is in place to keep Iowans safe, and that medical professionals such as themselves need to make the decisions the Board is making. He spoke in support of the 4.5 gram/ 90 day THC purchase limit, as well as limiting THC in general, referencing recent vaping illnesses.
- Erin Bollman, Parent of Patient Ms. Bollman shared a handout of some data showing improvements her child has made since using CBD and THC. Her son has autism, epileptic seizures, self-harm and aggression. She shared his history of injuries to himself and others. She noted that her child's school is keeping records of his behavior, and improvements in his behavioral skills and interaction with his peers have been documented following the initiation of his participation in the program.
- **Kim Phillips, PTSD Patient** Ms. Phillips shared her experience of having a friend that was also a PTSD patient, but who lost her battle with PTSD suddenly. Ms. Phillips noted traditional pharmaceuticals and therapies did not help her friend. She stated many veterans need this as a medication option.

# a. PTSD

Rebecca Lucas, of MedPharm Iowa, was the petitioner for the condition and addressed the Board. She shared highlights of the supporting documents that she provided with the petition, noting that data captured by the Minnesota medical cannabis program on MN's PTSD patients showed that medical cannabis is helping many PTSD patients, and many had seen significant improvements following the use of medical cannabis.

Deputy Director Reisetter explained that a petition subcommittee had been assigned to review the petitions to add new conditions, including the literature included with and referenced within the petitions. The subcommittee has also done independent research for additional literature regarding the use of medical cannabidiol to treat the petitioned conditions, and was tasked with making recommendations to the full Board related to a decision on the petition. Drs. Shreck, Liesveld, and Richards all agreed to serve on this subcommittee for the petitions considered during this meeting.

Dr. Liesveld explained that review of the petition, the materials and literature submitted with the petition, and the subcommittee's independent search for medical literature related to PTSD and cannabis yielded very little information that would support the use of medical cannabidiol in the treatment of PTSD. Dr. Liesveld explained that there are human studies currently underway, but conclusive results are not yet available. Due to the lack of available medical literature, the subcommittee recommended denial of the petition to add PTSD. Dr. Richards said there is no medical literature providing information on safe use of medical cannabidiol for PTSD. He expressed that CBD is not shown to be a harmful, but determining safe levels of THC are the issue that the Board struggles with.

Dr. Miller thanked the subcommittee for reviewing the large amount of research and information provided, and said that although definitive effectiveness and safety research may not be available, the Board should also consider the effects PTSD when untreated in making its decision. Dr. Miller referred to his personal experience as well as his experience as a medical examiner. He said there are veterans who benefit from traditional PTSD treatments but there are others that may benefit from the use of medical cannabidiol. Dr. Miller stated his support for recommending the addition of the condition based on the "right to try." Dr. Richards asked the legislature to be cautious related to THC purchase limits.

A motion was made by Dr. Miller, with a second by Dr. Richards to approve the addition of PTSD as an approved qualifying condition. Dr. Stoken expressed that the provided studies do not support the addition of PTSD. A verbal vote was taken:

Cheyne – aye Liesveld – aye Miller – aye Richards - aye Stoken – oppose Mcklevey- oppose

Motion carried.

PTSD will be forwarded to the Board of Medicine for consideration.

### b. Intellectual Disability (ID) with Aggression and/or Self-Injury

Ann Brownsberger and Mary Roberts presented on behalf of their petition, sharing personal experience with these issues within the organization for which they work, as well as within their own families. Examples of self-injury as well as aggression were shared. Ms. Roberts shared her family experience and described how CBD has greatly reduced the amount of pharmaceutical medications her daughter requires, and consequently, the harmful side effects of those medications. Dr. Richards noted the similarities of this petition to the previously approved autism petition, and provided feedback from a report which explained that additional research is needed to determine the effectiveness of treating this condition with medical cannabidiol. Dr. Liesveld also noted the similarities between this petition and the autism petition and said that medical cannabidiol may be helpful in the treatment of this condition as well. She said she reluctantly supported the autism petition, and will also support this one. Dr. Miller shared his first-hand experience with an autistic pediatric patient, who was non-verbal and exhibited self-injurious behavior prior to participation in the program. Dr. Miller expressed how this patient's condition has shown profound improvement with the use of medical cannabidiol. A motion was made by Dr. Cheyne seconded by Dr. Miller to add Intellectual Disability (ID) with Aggression and/or Self-Injury as an approved qualifying condition. A verbal vote was taken:

Cheyne – aye Liesveld – aye Miller – aye Richards – aye Stoken – aye McKelvey – oppose

Motion carried.

Intellectual Disability (ID) with Aggression and/or Self-Injury will be forwarded to the Board of Medicine for consideration.

# c. Opioid dependency, Tolerance, & Use Disorder

Rebecca Lucas, of MedPharm lowa, was the petitioner for the condition and addressed the Board. She expressed that the benefits of adding this condition included reduced symptoms of opioid withdrawal, provided for tapering down of opioid medications, helped patient retention in MAT programs, and decreased the likelihood of relapse. Rebecca shared information and opinions shared by the state of New Jersey in the course of approving the use of medical marijuana to treat this disorder in NJ.

Dr. Liesveld expressed that a PubMed search for treatment of this condition with medical cannabis yielded no new convincing research. Dr. Liesveld noted the references provided by petitioner were mostly studies on animals, and do not show support for approving this condition. As a psychiatrist, Dr. Liesveld expressed concern that medical cannabidiol use may be harmful if patients attempted to use medical cannabidiol products in place of MAT treatment, and that the petition subcommittee's recommendation is to deny the petition. Ms. Lucas noted that the New Jersey Board found that medical cannabidiol in conjunction with MAT therapy improved retention rates in MAT programs.

A motion was made by Dr. Richards, and seconded by Dr. Miller to deny Opioid Dependency, Tolerance & Use Disorder as a qualifying condition. A verbal vote was taken:

Cheyne – aye Liesveld – aye Miller - aye Richards - aye Stoken – aye McKelvey – aye

Motion carried unanimously.

#### d. Alzheimer's Disease

Rebecca Lucas, of MedPharm Iowa, was the petitioner for the condition and addressed the Board. Ms. Lucas noted that the contents of the petition are identical to the petition that was approved in the state of Minnesota to add Alzheimer's Disease as a qualifying condition.

Dr. Richards said the subcommittee recommended denial of the petition, as the documentation included with the petition cited a single report. Dr. Richards noted the report showed slowing of the progression of the disease, but did not stop it. He also said the studies cited were ongoing, but not completed, and additional research is needed. Dr. Miller said adding this condition would be of little assistance, as many patients with this condition reside in facilities, where the dispensing of the product is problematic or limited.

A motion was made by Dr. Miller, and seconded by Dr. Stoken to deny the addition of Alzeimer's Disease as a qualifying condition. A verbal vote was taken:

Cheyne - aye Liesveld - aye Miller - aye Richards - aye Stoken - aye McKelvey – aye

Motion carried unanimously.

# 6. Petition for Add Vaporized Flower as a Medical Treatment

Michelle Servadio

Michelle Servadio spoke on behalf of petitioner Angela Kerr for the addition of vaporized flower as a medical treatment. Ms. Servadio shared information about how vaporizing flower works, as well as the benefits and cost-savings that patients would receive. Dr. Miller asked what would stop a patient from smoking the flower when they got home. Ms. Servadio noted that dry vaping is a more effective than many available product forms. Deputy Director Reisetter said this petition is request better suited to be addressed by the legislature, as vaporizable flower could also be smoked, which is currently prohibited by the statute.

A motion was made by Dr. Richards, to deny the addition of vaporized flower as a new medical treatment, and was seconded by Dr. Cheyne. A verbal vote was counted:

Cheyne – aye Liesveld – aye Miller – aye Richards - aye Stoken – aye McKelvey – aye

Motion carried unanimously.

# 7. Manufacturer & Dispensary Updates

### a. Rebecca Lucas, MedPharm Iowa

Rebecca Lucas provided an update on behalf of MedPharm Iowa. She explained how their build out is totally complete, and they are continuing their legislative work to expand patient access by adding more types of certifiers. She described the consultation process a patient goes through when visiting a MedPharm dispensary, as well as their intake form and patient journal. Dr. Miller asked what happens if a patient indicates complicating conditions or are contraindicated medications. Ms. Lucas explained that patients and MedPharm staff discuss all possible options and side effects.

### b. Sagar Patel, Iowa Relief

Sagar Patel, Plant Manager, and Mike Bailey, Security Manager, addressed the board to provide an update on lowa Relief's progress. Sagar described the team training process, and how many team members share roles. Iowa Relief's first product, a tincture, went on sale in August. Iowa Relief also just had a harvest, and their next products to be released are another tincture and a balm. Photos of current and future products were shared with the group.

#### 8. Program Update and Review of Data

Owen Parker, Program Manager

Owen Parker, Program Manager for the Office of Medical Cannabidiol provided a review of data from the first year of program sales. Data shared included: application approvals and card issuances, physician adoption, certifications by age and condition, dispensary transactions, rates of patients who make multiple purchases, as well as which products patients are purchasing for the allowed conditions.

#### 9. Draft: Annual Report Recommendations Review

mCBD Board Members

Deputy Director Reisetter led the board through a draft version of their annual report and recommendations. The annual report is required by the law and used to communicate annual activities as well as provide medical cannabidiol program recommendations to the General Assembly. After edits are made following this meeting, a subcommittee will review and approve final edits before report submission.

# 1. Removal of the 3% THC cap, and establish a purchase limit of "4.5g THC over 90 days"

The Board affirmed its support for removing the 3% THC cap on medical cannabidiol products, instead replacing it with a 4.5 g THC purchase limit over a 90 day period. Dr. Richards stated the purchase limit should not apply for patients who are certified to be terminally ill. Dr. Miller and Dr. Cheyne also supported the waiving of purchase limits for terminally ill patients, and agreed that certifying health care providers should be able to certify all other patients for a higher THC purchase limit if, after participating in the program

under the 4.5 g THC purchase limit, the patient and certifying health care provider agree that 4.5 g of THC over 90 days is not a sufficient amount of THC to treat the patient's debilitating medical condition. Dr. Stoken said patients try to manipulate doctors and shared an experience with one of her patients who she did certify for participation in the program, but who did not follow her recommendations to revisit her for a follow-up after three months, and said she will not recertify this patient.

# a. 4.5 g THC over 90 day purchase limit should not apply to terminally ill patients – no mCBD Board approval necessary

There was Board consensus that the 4.5 g THC over 90 day purchase limit should not apply to patients certified for a terminally ill condition, without the need for Board approval of waivers as was proposed by 2019 Iowa Acts, HF 732.

# b. Purchase limit can be increased by the certifying healthcare practitioner – no mCBD Board approval necessary

There was Board consensus that certifying health care providers should be able to certify all other patients for a higher THC purchase limit if, after participating in the program under the 4.5 g THC purchase limit, the patient and certifying health care provider agree that 4.5 g of THC over 90 days is not a sufficient amount of THC to treat the patient's debilitating medical condition. Dr. Stoken expressed opposition to this concept.

### 2. Removal of the felony disqualifier for patients and caregivers

There was Board consensus to recommend removal of the felony disqualifier for program participation for patients and primary caregivers. The Board has repeatedly discussed that withholding medical treatment on the basis of criminal conviction status is a violation of medical ethics.

3. Addition of PAs, ARNPs, and Podiatrists to the definition of healthcare practitioners —
There was Board consensus to add PAs, ARNPs, and podiatrists to the definition of
healthcare practitioners so the pool of health care providers eligible to certify patients for
participation in the program is expanded. Dr. Miller expressed concern about podiatrists
certifying patients beyond their scope of practice.

# 4. Require pharmacists or pharmacy techs in dispensaries

There was Board consensus that pharmacists should be required in dispensaries to provide titration advice to patients. Pharmacy techs are required to be supervised by licensed pharmacists, and Board members did not feel that pharmacy tech presence in the dispensary is sufficient to address the Board's concerns.

#### 5. Provide physician access to the patient registry

There was Board consensus to provide physician access to the patient registry, which would provide a certifying practitioner access to the patient's medical cannabidiol product purchase history. Board members expressed concern about patients who do not return for a follow-up visit to their physician to discuss the use of medical cannabidiol products. Providing physician access to the patient registry was discussed as an alternative to a merger of patient purchase data with the PMP managed by the lowa Board of Pharmacy, which would require extensive resources.

# 6. Address concerns about the use and storage of medical cannabidiol products in long-term care, acute care, and school facilities

There was Board consensus to develop language to address concerns about the use and storage of medical cannabidiol products in long-term care, acute care, and school facilities. These concerns include putting federal funding received by these facilities at risk by allowing patients, clients or students in those facilities to use medical cannabidiol products, as well as an alternative for the current primary caregiver statutory framework that does not work in facilities caring for multiple patients.

# 7. Require Department research (observational study)

There was Board consensus to require ongoing observational study, and a request for resources from the legislature to support the work.

- 8. Renaming of the program to reflect the comprehensive nature of the program

  There was Board consensus to rename Chapter 124E to the "lowa Medical Cannabis Act."
- 9. Movement to Total THC for the calculation of potency, to take THCa into account There was Board consensus to use a "Total THC" calculation for determining THC potency in final medical cannabidiol products. Total THC = THC + (0.88 THCa).
- 10. Remove the DOT from the registration process, and allow IDPH to issue registration cards

  There was Board consensus to remove the requirement for a patient or caregiver to go to
  the DOT to obtain a patient or caregiver registration card. The Board recommends removal
  of the requirement for the registration card to contain the patient or caregiver photo, and
  allowing the Department of Public Health to issue registration cards instead. The
  requirement to go to the DOT is a barrier for participation for the program's most seriously
  ill or disabled patients. The interaction with the DOT ART system would remain intact, so law
  enforcement could still determine if the patient or caregiver was approved for participation
  in the program by querying the patient or caregiver in the DOT ART system.

#### 11. Number of Board Meeting

There was Board consensus remove the meeting restriction in the law, which currently limits the Board to only four meetings each year.

10. IA: Physician Attitudes, Knowledge and Experiences with Medical Cannabis Brian Kaskie & Kanika Arora Dr. Brian Kaskie and Dr. Kanika Arora, from the University of Iowa, College of Public Health, provided a presentation of the results of a survey they conducted with Iowa physicians regarding the use of medical cannabis in older persons. They covered key data from their analysis.

#### 11. Future Meetings

Mike McKelvey, Chair

a. Friday, February 14, 2020

12. Adjourn Mike McKelvey, Chair

A motion was made by Dr. Cheyne, and seconded by Dr. Miller, to adjourn the meeting.

A verbal vote was taken to adjourn the meeting. Motion carried unanimously. The meeting officially adjourned at 1:50 p.m.