

DRAFT Minutes
Iowa Medical Cannabidiol Board
June 19, 2020
10:00 a.m.
Virtual Meeting Hosted via WebEx
Dial-in: 1-408-418-9388
Access Code: 146-389-2555

1. **Call to Order** **Mike McKelvey, Chair**
The June 19, 2020, 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
Capt. Mike McKelvey – Law Enforcement	Vacant – Gastroenterologist
Dr. Jill Leisveld – Psychiatrist	Vacant - Neurologist
Dr. Lonny Miller – Family Medicine	
Dr. Bob Shreck – Oncology	
Dr. Jacqueline Stoken – Pain Mgmt.	
Dr. Ken Cheyne – Pediatrician	
Dr. Stephen Richards – Pharmacist	
Staff	
Dr. Jeffrey Kerber – Division Director, Behavioral Health	
Randy Mayer – Director	
Owen Parker – Program Manager	
Joseph Husak – Compliance Analyst (Recording Officer)	

3. **Approval of Minutes** **Mike McKelvey, Chair**
 a. **February 14, 2020 Medical Cannabidiol Board Meeting**
 Dr. Cheyne made a motion to approve the February 14, 2020, minutes, with a second by Dr. Richards.

 A verbal vote was taken. Motion carried unanimously.

4. **Public Comment Period (3 minutes each)** **Mike McKelvey, Chair**
- **Carl Olsen, Program Advocate**
 - Carl used his time to comment on HF2589, which at the time had passed the Iowa House and Senate and was awaiting signature by Gov. Reynolds. Carl specifically made comment on Section 31, which charged IDPH with making a request to the federal government to not withhold funding to educational and long-term care facilities that implemented policies allowing patients to possess medical cannabidiol on the grounds of the facilities consistent with Iowa Code chapter 124E, or allowing facility staff to administer medical cannabidiol to a patient. Carl noted that the Board had instead recommended that IDPH seek a federal exemption from the DEA for cannabis as a Schedule I substance in Iowa in its 2019 annual report to the legislature. Carl noted this has been done successfully in multiple other states, and he hoped that the IDPH did not move forward with Section 31 as written in HF2589.

- **Carol Berry, Program Advocate**
 - Carol advocated for the addition of Generalized Anxiety Disorder to list of qualifying conditions, expressing that it could be used to limit her use of other pharmaceutical medications which have adverse side effects. Carol also advocated for the addition of PTSD as a qualifying condition for the use of medical cannabidiol in Iowa.
- **Shelly Servadio, Program Patient**
 - Shelly petitioned the Board to refrain from implementing the term ‘refractory’ into any of the conditions when they vote to add a condition to the list of qualifying conditions. As a veteran, Shelly advocated for PTSD to be added to the list of qualifying conditions, as well for those certified for PTSD to be exempt from the 4.5g THC per 90-day purchase limit prescribed in HF2589.
- **John Fenner, Program Patient**
 - John thanked the Board for their recommendations included in HF2589, but noted that the 4.5g THC per 90-day purchase limit was insufficient to treat the symptoms of his condition. John expressed that he had talked with multiple physicians who were not willing to sign the waiver to allow for THC above the 4.5g allowance per 90 days. John noted the purchase limits allowed in other medical cannabis programs.
- **Peter Komendowski, Partnership for a Healthy Iowa**
 - Peter commended the Board for their work on HF2589, but noted that the Board should proceed with caution in regards to access to THC for PTSD. He noted that some may find benefit, but it may harm some as well.
- **Dr. Kurt Gold, NE & IA Physician**
 - Dr. Gold noted that he believes he has patients who are alive today specifically because of Iowa’s medical cannabidiol program. Dr. Gold noted that his research shows that ¼ of pain patients would not tolerate the conventionally high doses of THC in other programs, and advocated for lower THC products like Iowa’s program provides. He expressed that if high doses of THC and the associated toxicity can be mitigated, medical cannabis products can help many people. Dr. Gold expressed the desire to be able to conduct legal clinical trials with his patients, but is still unable to do so.
- **Jason Karimi, Program Advocate**
 - Jason provided background on his work as a grassroots organizer for medical cannabis advocacy in Iowa. Jason expressed his frustration with access to medical cannabis for patients in Iowa, noting the difficult business climate.

5. Petitions to Add Qualifying Conditions

Owen Parker, Program Manager

a. *PTSD, Refractory to Standard Treatment

Owen noted that HF2589 included the addition of *PTSD* to the list of qualifying conditions. In knowing that statutory changes will take precedence over administrative rule, the Department decided to defer action on this petition until Gov. Reynolds made a decision in regards to HF2589.

b. *Severe, Intractable Autism with Intractable Irritability and aggression, Refractory to Acceptable Standard Treatment

Owen noted that HF2589 included the addition of *Severe, Intractable Autism with Intractable Irritability and Aggression* to the list of qualifying conditions. In knowing that statutory changes will take precedence over administrative rule, the Department decided to defer action on this petition until Gov. Reynolds made a decision in regards to HF2589.

c. **Generalized Anxiety Disorder**

The petitioner was not present to speak for the petition. Dr. Liesveld spoke on behalf of the petition, and explained that in review of the petition, there was no new or compelling information that supported its addition to the list of qualifying conditions. Dr. Liesveld noted that the Board had reviewed this petition twice previously. She mentioned that some preliminary studies have noted CBD or THC's benefit for the treatment of this condition, but those studies determined that additional studies were necessary. Dr. Liesveld explained that the Petition Subcommittee voted unanimously to deny the petition.

A motion was made by Dr. Richards, with a second by Dr. Miller to deny the addition of *Generalized Anxiety Disorder* as an approved qualifying condition. A roll call vote was taken:

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

Motion to deny carried unanimously.

d. **Any rare condition or disease that affects less than 200,000 individuals in the U.S., as defined in federal law, refractory to conventional treatment**

Rebecca Lucas was present to speak on behalf of her petition. Rebecca noted that this condition is a qualifying condition in Utah's medical cannabis program, explaining that it provides a "right to try" opportunity to some patients without having to get the specific condition added through traditional means. Dr. Shreck spoke on behalf of the Petition Subcommittee, and noted that the laws put in place for this scenario were initially designed to make it economically beneficial for pharmaceutical companies to develop medications for rare conditions. He noted that the law does not make the medications exempt from standard FDA procedures and process. Dr. Shreck explained that the Petition Subcommittee voted unanimously to deny the petition.

A motion was made by Dr. Shreck, with a second by Dr. Stoken to deny the addition of *any rare condition or disease that affects less than 200,000 individuals in the U.S., as defined in federal law, refractory to conventional treatment* as an approved qualifying condition. A roll call vote was taken:

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

Motion to deny carried unanimously.

e. Tourette Syndrome

The petitioner was not present to speak, but spoke at the Petition Subcommittee meeting. Dr. Shreck spoke on behalf of the Petition Subcommittee, and noted how Tourette Syndrome is difficult to treat, and that there are limited treatments available. Dr. Shreck noted that although there have been studies conducted on the treatment of Tourette Syndrome with medical cannabis, and noted two randomized, placebo-controlled studies, the studies have limited patient populations and are inconclusive or incomplete. Dr. Shreck noted how the petitioner appealed to a Tourette Association of America website, and that the website noted the lack of studies sufficient to support the use of medical marijuana for the treatment Tourette, particularly in children. Dr. Shreck explained the Petition Subcommittee voted 3-0 to deny the petition.

A motion was made by Dr. Shreck, with a second by Dr. Miller to deny the addition of *Tourette Syndrome* as an approved qualifying condition. A roll call vote was taken:

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

Motion to deny carried unanimously.

6. Manufacturer & Dispensary Updates

IA's Licensees

a. Rebecca Lucas, MedPharm Iowa

Rebecca used MedPharm's time to ask Board members if there were any questions that they had for MedPharm in general, or in relation to implementing HF2589. Dr. Shreck thanked MedPharm for their continued service to Iowa and providing this option for patients. Dr. Shrek noted that the current 3% cap allowed patients to purchase as much as they would like, but that it limited certain forms of product. He commented how the movement to grams/90-day purchase limit would allow additional forms of products to be manufactured. He explained that there is still insufficient clinical evidence to support the doses being taken by patients in other medical cannabis programs, including Minnesota's program, which is often cited as a model for comparison. Dr. Shreck also made reference that HF2589 includes a waiver of the THC purchase limit for the terminally ill, or if the patient's certifying practitioner certified them for additional THC per 90-days.

Rebecca noted that the Board recommended that pharmacists or pharmacy technicians be involved in dosing at dispensaries as is done in Minnesota, and was implemented in HF2589. Rebecca noted that although the Board does not condone the doses of THC taken by some of patients in Minnesota, those doses are recommended by pharmacists. Dr. Shreck explained that pharmacists do not recommend dosing in medicine as it is traditionally practiced, it is only the physician who provides the dose of medication.

7. Program Updates Owen Parker, Program Manager

a. Dispensary & Manufacturing Closures

Owen explained that on March 30, 2020, the Have a Heart dispensaries located in Council Bluffs and Davenport permanently closed, and Have a Heart formally relinquished their dispensary licenses on April 17, 2020. Owen also noted that on April 2, 2020, Iowa Relief temporarily ceased operations at the Cedar Rapids Iowa manufacturing facility. Iowa Relief notified the Department on June 2, 2020, that they did not intend to renew their manufacturing license for the next licensing period, and formally

relinquished their manufacturing license on June 3, 2020.

b. Dispensary & Manufacturing RFP Update

Owen explained that in response to the aforementioned dispensary closures, the Department released an RFP on April 17, 2020, to license two new dispensaries as quickly as possible. Upon the passage of HF2589, and the notification of Iowa Relief's intention to relinquish their manufacturing license, the Department rescinded that RFP on June 5 in order to update the RFP and reference those changes. The Department relaunched that RFP on June 9, with the intention to post a notice of intent to license for those two dispensaries on September 7, 2020. Owen explained that the Department was still considering when to launch an RFP for a new manufacturer, and would provide further details when available.

c. Legislative Update - HF2589

Owen explained that HF2589 does contain the majority of the recommendations made by the Board in their 2019 Annual Report to the Legislature. Owen noted specific highlights of the bill, including:

- Removal of the 3% THC, and replacement with a 4.5g THC per 90-day purchase limit, with exceptions for the terminally ill or if the patient's certifying practitioner certified them for additional THC.
 - Owen explained that the Department was making updates to the Department's Secure Sales and Inventory Tracking System to allow dispensaries to enforce that 4.5g THC per 90-day limit. He also made note of creating the waiver process that healthcare practitioners will use to certify patients for additional THC if appropriate.
- Dispensaries will be required to employ either a pharmacist or pharmacy technician.
- Adds Chronic Pain, PTSD, and severe, intractable autism with self-injurious or aggressive behaviors to the list of qualifying conditions.
- Adds Physician Assistants (PAs), Advanced Registered Nurse Practitioners (ARNPs), and Podiatrists (DPM) to the definition of healthcare practitioners.
- Removes the felony disqualifier for patients and caregivers
- Removes the limit on the number of Board meetings each year

Owen noted that HF2589 includes other provisions, but that these were of particular interest to the Board. He explained that the Department would be communicated these changes to the necessary stakeholders once there was a definitive decision on HF2589.

Cpt. McKelvey noted that they had received comments that these changes may reduce patient participation in Iowa's program, and would be interested in the data showing whether patient participation increased or decreased with these changes. Cpt. McKelvey also inquired whether the two dispensary closures led to increased sales at the remaining three dispensaries in Iowa, as well as if COVID-19 had any impact on dispensary sales and new patient registrations.

Owen confirmed that many states did see increases in dispensary sales leading up to broadly implemented stay-at-home orders, and that Iowa was one of these states. Owen also noted that while patient registrations initially were steady, they began to decrease due to lack of access to health care practitioners to have their condition certified or renewed. Owen explained that DOT closures created some barriers to patients receiving their registration card, but that the Department worked with the Iowa Department of Transportation to mail patients their card for renewals, and also to schedule specific visits for the printing of new cards. The Department also allowed for curbside delivery at dispensaries to allow for socially distanced transactions, as well as facilitated telemedicine with certain providers.

8. Future Meetings

Mike McKelvey, Chair

- a. **September 4, 2020**
- b. **November 13, 2020**

9. Adjourn

Mike McKelvey, Chair

A motion to adjourn the meeting was made by Dr. Shreck, seconded by Dr. Miller. A verbal vote was taken:

Motion carried unanimously. The meeting officially adjourned at **11:12** a.m.

DRAFT