DRAFT Minutes

Iowa Medical Cannabidiol Advisory Board
October 27, 2017
9:00 a.m. – 4:00 p.m.

Iowa Laboratory Facility – DMACC Campus
2240 DMACC Blvd., Ankeny, IA

1. **Call to Order**
   The meeting was officially called to order at 9:04 a.m.

2. **Roll Call –** Mike McKelvey, Chairperson

Present	Absent
Ken Cheyne	Stephen Richards
Jill Liesveld	Archanda Verma
Mike McKelvey	
Lonny Miller	
Bob Shreck	
Jacqueline Stoken (at 1:00 p.m. via telephone)	
Wendy Zadeh	
Staff	
Heather Adams – Assistant Attorney General	
Sarah Reisetter - Deputy Director	
Jen Caskey – Executive Officer	

3. **Approval of Minutes**
   a. **Sept. 22, 2017, Medical CBD Advisory Board Mtg.**
      A motion to approve the minutes of the September 22, 2017, meeting was made by Ken Cheyne, seconded by Bob Shreck.

      A verbal vote was taken. Motion carried unanimously.

4. **Department Update –** Sarah Reisetter, Deputy Director, IDPH
   Sarah Reisetter, Deputy Director of the Iowa Dept. of Public Health, provided an update to the board on the recent activity in the department related to the Office of Medical Cannabidiol. Highlights include:

   - The Governor's Office has appointed the final member of the Medical Cannabidiol Advisory Board, representing the field of gastroenterology. Dr. Archanda Verma. Dr. Verma is not able to be present at the meeting today but the department has made contact with Dr. Verma.
   - A special meeting of the State Board of Health was held on Oct. 4, 2017. During the meeting staff answered questions regarding the changes proposed for 641 Iowa Administrative Code Ch. 154 related to medical cannabidiol manufacturing and dispensing. The proposed rules were filed with the Administrative Rules Review Committee and published in the Administrative Bulletin on October 25, 2017. This action initiated the formal rulemaking process where legislative oversight will occur.
   - The manufacturing RFP has been released and the department received nine letters of intent to apply. IDPH staff have assigned a seven member review team, including a representative from IDPH, representatives from other state agencies, as well as persons from other state medical cannabis programs. Applications for manufacturer licensure are due Oct. 30, 2017, with the posting of intent to award scheduled for Dec. 1, 2017.
   - Department staff continue to work on the laboratory rules with the hopes that a reviewable format will be ready for the Dec. 1, 2017, meeting.

5. **Review Statutory Directive – re: Form and Quantity – Heather Adams, Assistant Attorney General**
   Heather Adams, Assistant Attorney General provided a review of the statutory directives regarding form and quantity for medical cannabidiol. Heather talked through select provisions within HF 524.
   - Provisions in definitions state that dosage has to be delivered in a form recommend by the medical cannabidiol board, approved by the board of medicine and adopted by the department by rule.
   - Duties of the Medical Cannabidiol Advisory board are found in section 8. One duty of the board is to make recommendations regarding form and quantity of medical cannabidiol to be manufactured and available in the state.
   - Recommendations made by the medical cannabidiol board pursuant to Iowa Code section 124E.4A(3), paragraphs "b" and "e", shall be made to the board of medicine for consideration, and if approved, shall be adopted by the board of medicine by rule.
   - HF524 section 8, subsection 6 currently limits the allowable level of tetrahydrocannabidiol (THC) to no more than 3%. The Medical Cannabidiol Advisory Board can review this recommendation and determine whether to recommend a change to this statutory provision. Any recommended change would require legislative action to be effective.
   - HF524, section 10 specifies that a medical cannabidiol manufacturer shall not manufacture edible products.
   - It is outlined in HF524, section 12 that dispensaries are limited to distributing medical cannabidiol in form and quantity allowed by the department pursuant to rule.

- HF524, section 14 outlines the duties of the department, to include adopting rules to administer the chapter, and establish form and quantity based on board recommendations.
- HF524, section 20 states that patients shall not smoke medical cannabidiol.
- Quantity limits currently in place in the department rule 641 Iowa Administrative Code 154.14 were held over from the 2014 Medical Cannabidiol Act. A patient or primary caregiver with a registration card cannot possess more than 32 oz. of medical cannabidiol. This current limitation is subject to review and consideration by the this medical cannabidiol advisory board.
- Other points to clarify include that board members are welcome to engage in conversations with other persons, legislators and their community about their work on this board. Members are cautioned to limit conversations with anyone intending to bid during any RFP process as this could be detrimental to interested parties. Members are also cautioned regarding lobbying either for or against any particular parts of a bill related to medical cannabidiol. This activity should be left to the department's lobbyist. If the board has not taken a position, it is fine to convey that the board has not taken a position. Board members are free to share personal opinions, please be clear when comments represent an individual board member's personal opinions. Board members are free to discuss with legislators other topics, unrelated to medical cannabidiol as desired.

6. **Report On Medical Use of CBD –** Dr. Bob Wallace, MD, MSc. University of Iowa, College of Public Health

   Dr. Bob Wallace, University of Iowa, College of Public Health, joined the meeting via conference call. Dr. Wallace pulled together some information for the board regarding the medical use of CBD. Dr. Wallace, along with graduate students from the university did some quick research on this subject. Dr. Wallace has conducted some research in the past regarding the effects of cannabis, however the focus of this research was consumption via smoking marijuana. The report provided to the board accompanies the literature reviewed by Dr. Wallace and his group. Dr. Wallace noted that currently there is not much information available regarding the medical use of cannabidiol and that there is very little evidence of the analgesic effects. Most information indicates that use is not very anabolic for some patients, and that there is extremely limited information for some of the other conditions allowed currently under Iowa's law.

   Several questions asked regarding the research and information available. It was shared that a great deal of the information available comes from patients with seizure disorders. Much of this information includes evidence based medications, clinical trials, random trials, etc. Dr. Wallace stated that blinded controlled clinical trials are needed to make sure there are actual beneficial effects of the use of medical CBD. Dr. Wallace also stated that he feels that additional smoking trials are also necessary.

   Dr. Zedah, board member representing neurology stated that she is not surprised about the lack of adequate clinical trials, that it was expected. Dr. Zedah indicated the use of medical cannabidiol is as an alternative for compassionate use. It was questioned if additional information may be available concerning safety with a focus on driving. Dr. Wallace stated that he is not aware of studies related to CBD and driving. There is information on smoking cannabis and driving. It was stated that for some compassionate indications, it is believed many patients

are not driving. It was shared that the state of Minnesota is using extracts of CBD and has a registry of adverse effects. Staff from IDPH will contact Minnesota's program and request that they share their information on adverse effects.

Dr. Shreck, board member representing oncology, noted that many Iowa physicians rely on sending patients to the Mayo Clinic in Rochester, MN. Dr. Shreck noted he would be interested in the clinics position on marijuana. Dr. Shreck stated the Mayo Clinic lists 18 medical conditions and grades the evidence of use for these conditions. Most conditions are in the middle and receive positive reports. Pain and Multiple Sclerosis both receive a B, all others are a C, indicating there is unclear scientific evidence. The Mayo Clinic, like most entities doing evidence based work, are conservative. Evidence in most of the trials are with children with uncontrolled seizures who engage in the trials after other medications do not work**.**

A question was asked about whether Dr. Wallace's review of the literature includes Epidiolex or other pharmaceutical company drugs that are being reviewed and used. Dr. Wallace indicated that only peer reviewed literature was used for this report. Dr. Wallace noted that companies that are enlisted in clinic trials are listed in a national registry, www.clinical trials.gov.

7. **Review: Other State's CBD Form & Quantity Rules –** Randy Mayer, Director, Office of Medical Cannabidiol

   Randy Mayer, Director for the Office of Medical Cannabidiol researched the other states that have CBD-focused medical cannabidiol laws and what CBD products they have available. It was found that other state's laws are changing quickly and their summaries were not always up to date. Very few states have lists of products available. Through comparative research, it was learned that many states do have a minimum amount of CBD that is required to be in the product, with the most common percentages being 5, 10, or 15 percent CBD. During the review, it was noted that two states have limits on the amount of product that can be in a patient's possession. One state listed its possession limits in ounces, the other as being limited to 30 day supply. The state of Virginia has allows for the use of THC–A, at 15%. It was opined by Mr. Mayer that the state of Minnesota is the most developed in terms of products available.

   A question was asked about whether any states have central registries of patients receiving CBD, as physicians may have an interest in knowing whether their patients are purchasing or receiving CBD products. The department is aware of one state that provides this type of access to physicians. Additional research to determine if any other states have similar registries is needed. IDPH currently has a patient registry in the form of spreadsheet that does collect some information on patients who apply for a medical cannabidiol registration card. As the statute is currently written, the department is prohibited from sharing this information with certifying or other physicians.

   Form and Quantity Discussion:

   Discussion focused on the possible considerations for the board in making form and quantity recommendations for medical cannabidiol products in Iowa. Documents from the state of Minnesota listing the various products they have available were shared for a point of reference. Dialogue included concerns that some forms, specifically chewable tablets designed for children may taste like candy or appear too "yummy", although making products palatable, especially

for young patients or those with appetite or swallowing issues were noted. Various ways of consumption, including vaporizer cartridge vs. bulk vaporizer oil were also discussed. Board members inquired if information regarding the number of Merinol prescriptions in Iowa was available. Merinol, a synthetic form of THC, is often prescribed to treat or prevent nausea and vomiting caused by cancer medications when other medications do not work. In addition, it is sometimes prescribed to AIDS patients to increase appetites. Information from Iowa's Prescription Monitoring Program (PMP) was shared with the board. A bar graph outlining the number of patients broken down by debilitating medical conditions was also included in the board's information.

The board moved on to a discussion about quantity recommendations. This discussion included reviewing how to calculate currently allowed 3% THC, in mg/ML. Reference materials containing product forms and quantities available in Minnesota were again discussed. Board members referenced a past Epidiolex study conducted by Dr. Joshi, former pediatric neurologist from the University of Iowa, noting that this study may contain helpful information. Discussion centered on concerns about the limited information available related to what forms and dosages work best for the various conditions allowed in Iowa, concerns about setting quantity limits, and concerns regarding a limited number of dispensaries, affecting patient access and supply and demand.

Other items to note throughout the board's discussion included potential concerns and apprehension by certifying physicians about making dosage recommendations, adequate information available to make educated recommendations related to THC levels, concerns with training and education of dispensary staff who will be working with patients, and concerns with current laws prohibiting pharmacists to work in dispensaries.

8. **Medical Cannabis: An Introduction - Dr. Frank Caligiuri, Phar.D., BCPS, CCMS, Drake University, College of Pharmacy and Health Sciences**

   Dr. Frank Caligiuri from the Drake University College of Pharmacy and Health Services provided a presentation on medical cannabis based on his personal education and research. The presentation included information on Iowa's current statute and qualifying conditions, information on other states that allow some form of medical cannabis use, a brief historical review of the use of medical cannabis, botany and pharmacology information, as well as additional educational information. The board was very appreciative of the information provided and asked a number of questions.

9. **Public Comment Period on Form & Quantity**

   A number of attendees registered to address the board and provided comments regarding form and quantity,. A total of five persons provided comments to the board:

   Carl Olsen - citizen

   - Provided a document (get copy from Sarah)
   - Expressed concerns with Dr. Wallace's National Academy of Sciences 2017 report; specifically regarding toxicity and adverse effects in illicit users as being irrelevant to the subject of the use of medical cannabidiol.

Roxanne Cogil – Epilepsy Foundation

- Responded to questions regarding the Epidiolex trials at University of Iowa, provided the name of the new principle investigator name (Dr. Ciliburto) and noted his trials, suggesting the board utilize his expertise.

Chaney Yeast – Blank Children's Hospital

- Encouraged the board to have more discussion on transdermal patches – info about transdermal patches, noting the importance of educating potential users of proper disposal and use, noting the danger of use around children (access to used patches, chewing on them, etc.)

Threase Harms – Multiple Sclerosis Society

- Requested the ability to have general public comment at future meetings
- Suggested the department look for information from other medical. cannabidiol states besides Minnesota. Patient advocates request this due to issues MN is seeing. Please don't limit research to MN.
- Urged the department to look at other studies since clinical trials not available.
- Noted that Iowa needs to have a variety as different forms work for different conditions and patients.
- Suggested that a tincture is the same thing as an oil.
- When discussing dosing, suggested that perhaps this is best left for the patient to determine with their physician.

Sally Gaer – Epilepsy Patient Caregiver

- Adult daughter has Dravet Syndrome, currently takes four medication, plus the Charlotte's Web strain of marijuana.
- Since beginning the use of Charlotte's Web, her daughter has been able to decrease the use of one of her epilepsy medications.
- Ms. Gaer provided information about the medications her daughter currently takes, noting that some that are shipped to her from other states (Charlotte's Web). Ms. Gaer's daughter takes 250 mg CBD daily.
- Ms. Gaer stated that Charlotte's Web is legal to purchase in Iowa, and is available locally, however the quantity of CBD needed for Ms. Gaer's daughter is not currently available for purchase in Iowa.

10. Next Steps and Future Meetings

a. Friday Dec. 1, 2017; 9:00 a.m. – 4:00 p.m.
b. Friday Jan. 19, 2018; 9:00 a.m. – 4:00 p.m.

11. **Adjourn**

A motion to adjourn the meeting was made by Ken Cheyne, seconded by Wendy Zedah.

A verbal vote was taken. Motion carried unanimously.

Chairperson Mike McKelvey officially adjourned the meeting at 2:45 p.m.