

# Iowa Medical Cannabidiol Board - Annual Report to the Iowa General Assembly

Submitted January 1, 2018, by the Iowa Department of Public Health, Office of Medical Cannabidiol



January, 2018

Iowa Medical Cannabidiol Board – Annual Report to the Iowa General Assembly

#### Suggested Citation:

Iowa Department of Public Health. Division of Behavioral Health, Office of Medical Cannabidiol. *Iowa Medical Cannabidiol Board – Annual Report to the Iowa General Assembly.* Des Moines: Iowa Dept. of Public Health, 2018. Web. URL. Access date – day month year.

Governor: Kim Reynolds

Lieutenant Governor: Adam Gregg IDPH Director: Gerd W. Clabaugh

Report Contact Information: Randy Mayer, Director, Office of Medical Cannabidiol randall.mayer@idph.iowa.gov 515-242-5150 https://idph.iowa.gov/mcarcp

### Acknowledgements:

Iowa Medical Cannabidiol Board Members – Cpt. Mike McKelvey, Chair, Dr. Ken Cheyne, Dr. Jill Liesveld, Dr. Lonny Miller, Dr. Stephen Richards, Dr. Robert Shreck, Dr. Jacqueline Stoken, Dr. Archana Verma, and Dr. Wendy Zadeh.

# **Table of Contents**

E	xecutive Summary	1
R	eport on Activities of the Board2	
	Board Meetings	2
	Accepting and Reviewing Petitions	2
	Making Recommendations for Adding/ Removing Medical Conditions	3
	Working with the Department on Licensure Requirements	3
	Advising the Department as to the Location of Manufacturers and Dispensaries	3
	Recommendations Relating to the Form and Quantity of Allowable Uses of Medical Cannabidiol	3
Other Recommendations of the Board		3
	Definition of Medical Cannabidiol Tetrahydrocannabinol (THC) Level Recommendation	3
	Financial Sustainability of Program	3
	Number of Board Meetings	4
	Background Checks for Patients	4
	Adding Midlevel Providers to the List of Those Allowed to Certify Debilitating Medical Conditions	4
	Qualifications of Dispensary Employees	4
	Physician Access to the Patient Registry	4

### **Executive Summary**

Iowa Code chapter 124E was enacted on May 12, 2017. This new code chapter established the Medical Cannabidiol Board (Board). The Board is tasked with the following responsibilities<sup>1</sup>:

- Accepting and reviewing petitions to add medical conditions, medical treatments or debilitating diseases to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial under this chapter.
- 2. Making recommendations relating to the removal or addition of debilitating medical conditions to the list of allowable debilitating medical conditions for which the medical use of cannabidiol under this chapter would be medically beneficial.
- Working with the department regarding the requirements for the licensure of medical cannabidiol manufacturers and medical cannabidiol dispensaries, including licensure procedures.
- 4. Advising the department regarding the location of medical cannabidiol manufacturers and medical cannabidiol dispensaries throughout the state.
- 5. Making recommendations relating to the form and quantity of allowable medical uses of cannabidiol.

The Board also has the authority to make a recommendation for a statutory revision to the definition of medical cannabidiol to increase the allowable tetrahydrocannabinol (THC) level in medical cannabidiol products manufactured and sold in the state of lowa<sup>2</sup>.

This report summarizes the Board's activities in each of these areas during calendar year 2017.

<sup>&</sup>lt;sup>1</sup> Iowa Code section 124E.4A(3)

<sup>&</sup>lt;sup>2</sup> Iowa Code section 124E.4A(6)

## Report on Activities of the Board<sup>3</sup>

### Board Meetings<sup>4</sup>

Board members were appointed by Governor Reynolds on August 30, 2017. The Board held its initial meeting on September 6, 2017, during which the Board received an overview of the new Iowa Code chapter 124E as well as a briefing on the Iowa Attorney General's guidance for members of Iowa boards and commissions. The Board also received an update on the Department of Public Health's (Department) implementation work and proposed future Board meeting calendar.

A second Board meeting was held on September 22, 2017. At this meeting, the Board reviewed proposed administrative rules for regulating manufacturing, dispensing and Board operations. The Board recommended moving the proposed rules forward to the State Board of Health for consideration. The Board also heard a presentation from the state of Minnesota medical cannabis program staff and had an opportunity to ask questions about the successes and challenges experienced by the Minnesota program. An opportunity for public comment on the manufacturing, dispensing and Board operation rules was provided.

A third Board meeting was held on October 27, 2017, during which the Board began discussing form and quantity recommendations. As requested by Board members during the September 22, 2017, Board meeting, the Board heard a presentation from Dr. Bob Wallace, M.D., MSc, with the University of Iowa College of Public Health regarding evidence based research on the use of medical cannabidiol. Board members also received a presentation from Dr. Frank Caliguiri, PharmD, on medical cannabidiol and its history of use. An opportunity for public comment on form and quantity of medical cannabidiol was provided.

A fourth Board meeting was held on December 1, 2017. At this meeting, Board members received information about a bill proposing technical changes to chapter 124E that the Department intends to have introduced during the 2018 legislative session. The Board also heard a presentation from MedPharm Iowa LLC, Iowa's first licensed medical cannabidiol manufacturer about the forms and quantities of products MedPharm Iowa has proposed for production in the state of Iowa. The Board had an opportunity to hear from a representative of the Rhode Island medical marijuana program, held an open public comment period, discussed a draft form and quantity rule and reviewed a draft version of this annual report.

#### Accepting and Reviewing Petitions<sup>5</sup>

The Board recommended adoption of administrative rules governing the process for accepting and reviewing petitions to add medical conditions, medical treatments or debilitating diseases to the list of debilitating medical conditions for which medical cannabidiol registration cards may be obtained under chapter 124E. The petition process rules were published in the lowa Administrative Bulletin on October 25, 2017, as <u>ARC 3420C</u>. The rules are anticipated to be adopted by the State Board of Health in January 2018, with an effective date in early March 2018.

<sup>&</sup>lt;sup>3</sup> Iowa Code section 124E.4A(5)

<sup>&</sup>lt;sup>4</sup> Iowa Code section 124E.4A(2)

<sup>&</sup>lt;sup>5</sup> Iowa Code section 124E.4A(3)(a)

### Making Recommendations for Adding/Removing Medical Conditions<sup>6</sup>

The Board did not receive a petition to add a medical condition, medical treatment or debilitating disease to the list of debilitating medical conditions for which the medical use would be medically beneficial under chapter 124E during 2017.

### Working with the Department on Licensure Requirements<sup>7</sup>

Board members received a draft copy of proposed manufacturing and dispensing rules, including rules for licensure and license renewals on September 8, 2017. At its meeting on September 22, 2017, the Board reviewed the proposed rules in their entirety, had an opportunity for input, and took action to recommend moving the rules forward to the State Board of Health for adoption as presented and amended during the discussion.

### Advising the Department as to the Location of Manufacturers and Dispensaries<sup>8</sup>

At its meeting on September 22, 2017, the Board was provided an opportunity to advise the Department as to considerations for the location of manufacturers during the medical cannabidiol manufacturer procurement process. Further discussion between the Board and the Department on the location of dispensaries is anticipated in early 2018.

Recommendations Relating to the Form and Quantity of Allowable Uses of Medical Cannabidiol<sup>9</sup>
The Board began discussions about forms and quantities of allowable uses of medical cannabidiol at its meeting on October 27, 2017. At its meeting on December 1, 2017, the Board heard a presentation from MedPharm Iowa, LLC about the forms and quantities of products the licensed manufacturer is proposing to manufacture in the state. The Board also reviewed a draft form and quantity rule, requested amendments to the draft and will consider the amended rule at its next board meeting.

#### Other Recommendations of the Board

Definition of Medical Cannabidiol Tetrahydrocannabinol (THC) Level Recommendation<sup>10</sup> The Board did not make a recommendation about the level of tetrahydrocannabinol to be allowed in medical cannabidiol products in 2017.

#### Financial Sustainability of Program

The Board supports the Department's proposal to allow for fee retention by the Department to cover program operation costs as required by chapter 124E. The Board also supports authority for the Department to set fees for patient and primary caregiver cards to ensure sufficient funding is available. In addition, the Board encourages an appropriation of funding to the Department for the purpose of acquiring the patient registry and seed to sale tracking system required by chapter 124E.

<sup>&</sup>lt;sup>6</sup> Iowa Code section 124E.4A(3)(b)

<sup>&</sup>lt;sup>7</sup> Iowa Code section 124E.4A(3)(c)

<sup>8</sup> Iowa Code section 124E.4A(3)(d)

<sup>9</sup> Iowa Code section 124E.4A(3)(e)

<sup>&</sup>lt;sup>10</sup> Iowa Code section 124E.4(6)vi

### **Number of Board Meetings**

The Board supports the Department's proposal to remove the limitation on the number of Board meetings that can be held in a year. The current limit of four meetings a year is too limiting, especially during the period of program implementation.

#### **Background Checks for Patients**

Currently, chapter 124E disqualifies patients with certain criminal violations from obtaining patient registration cards. The Board recommends removing this provision for patients, as withholding medical treatment on the basis of criminal conviction violates the medical code of ethics.

Adding Midlevel Providers to the List of Those Allowed to Certify Debilitating Medical Conditions Chapter 124E permits only licensed physicians to certify a patient's debilitating medical condition for purposes of obtaining a patient or primary caregiver registration card. To ensure access to registration cards for a greater number of patients, the Board recommends allowing midlevel providers, including physician assistants and advanced registered nurse practitioners to certify a patient's debilitating medical condition for the purpose of obtaining a medical cannabidiol registration card.

### Qualifications of Dispensary Employees

The Board recommends that the Department be authorized to establish training requirements or specific required qualifications for dispensary employees. The Board makes this recommendation to ensure patient safety. At least two other states, Connecticut and Minnesota, require a licensed pharmacist to work at each dispensary. Other states have adopted minimum training requirements for dispensary employees.

### Physician Access to the Patient Registry

The Board recommends an exception to the confidentiality provisions for the patient registry established by Chapter 124E for licensed medical providers. This would allow providers to determine whether patients have been approved for medical cannabidiol registration cards by providers other than themselves. Ideally, this would be a function built into the existing Prescription Monitoring Program administered by the Iowa Board of Pharmacy, so providers would not need to access an additional system.