

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

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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, and Dr. Wendy Zadeh.

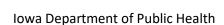


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Executive Summary

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 responsibilities¹:

- 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 lowa².

This report summarizes the Board's activities in each of these areas during calendar year 2018 and concludes with other Board recommendations regarding Iowa's Medical Cannabidiol Program.

¹ Iowa Code section 124E.5(3)

² Iowa Code section 124E.5(6)

Report on Activities of the Board³

Board Meetings⁴

The Board held 4 meetings during 2018 as allowed by Iowa Code chapter 124E.

- 1. August 3, 2018
- 2. November 2, 2018

January 19, 2018

At its January meeting, the Board approved form and quantity recommendations that were subsequently forwarded to the Iowa Board of Medicine for approval as required by law. The form recommendations made by the Board included oral forms, topical forms, inhaled forms and rectal/vaginal forms. The Board recommended allowing patients to purchase up to a 90-day supply of each product. Each of the Board's recommendations was approved by the Iowa Board of Medicine, with the exception of allowing patients to access a vaporizable form of medical cannabidiol.

After being approved and amended by the Board of Medicine, the form and quantity administrative rules were forwarded to the State Board of Health for adoption and became effective in July of 2018. The Board also reviewed proposed regulations for laboratory testing, advised the department about locations for dispensaries and received educational information about cannabis pharmacology during its January meeting.

May 4, 2018

At its May meeting, the Board reviewed the process for considering petitions to add medical conditions, received presentations from the 3 companies licensed to operate dispensaries, received an update from MedPharm Iowa, LLC on the status of the manufacturing operation and received a presentation from Dr. Michael Ciliberto from the University of Iowa Hospitals and Clinics about the use of medical cannabidiol in patients with epilepsy.

August 3, 2018

In August, Board members received information about the statutory protections for physicians participating in certification of debilitating medical conditions for patients, listened to a presentation from Dr. Jolene Smith on the use of medical cannabidiol in treating patients, and considered petitions to add medical conditions to the list of those for which patients may be certified for participation in lowa's medical cannabidiol patient registration program. The petitions considered at its August meeting included:

1. Trigeminal Neuralgia. The Board determined that patients with this condition are already eligible for participation in Iowa's medical cannabidiol patient registry because the condition causes a

³ Iowa Code section 124E.5(5)

⁴ Iowa Code section 124E.5(2)

- patient to experience untreatable pain, which is a qualifying condition enumerated in Iowa Code section 124E.2.
- 2. PTSD/ Bipolar Disorder. The Board requested to address these two conditions as separate agenda items at its November, 2018 meeting.
- 3. Ulcerative Colitis. The Board recommended that this condition be added to the list of debilitating medical conditions for which a patient is eligible to be added to the patient registry. The Board's recommendation was forwarded to the Iowa Board of Medicine as required by law, and considered by the Board of Medicine at its meeting on September 14, 2018. The Board of Medicine concurred with the Board's recommendation to add Ulcerative Colitis as a debilitating medical condition, and will consider administrative rules to effectuate the concurrence at a future Board of Medicine meeting.

Accepting and Reviewing Petitions⁵

As detailed above, the Board considered petitions to add 7 new qualifying debilitating medical conditions during 2018.

- 1. Trigeminal Neuralgia
- 2. PTSD
- 3. Bipolar Disorder
- 4. Ulcerative Colitis
- 5. Autism
- 6. ADHD
- 7. Glioblastoma

Making Recommendations for Adding/Removing Medical Conditions⁶

The Board recommended adding the following debilitating medical conditions in 2018:

- 1. Ulcerative Colitis
- 2.

Working with the Department on Licensure Requirements⁷

No additional action was taken on this duty in 2018 as the regulations were reviewed by the Board in 2017.

Advising the Department as to the Location of Manufacturers and Dispensaries⁸

At its meeting on January 19, 2018, the Board was provided an opportunity to advise the Department as to considerations for the location of dispensaries during the medical cannabidiol dispensary procurement process.

Recommendations Relating to the Form and Quantity of Allowable Uses of Medical Cannabidiol⁹ At its January meeting, the Board approved form and quantity recommendations that were subsequently forwarded to the Iowa Board of Medicine for approval as required by law. The form

⁵ Iowa Code section 124E.5(3)(a)

⁶ Iowa Code section 124E.5(3)(b)

⁷ Iowa Code section 124E.5(3)(c)

⁸ Iowa Code section 124E.5(3)(d)

⁹ Iowa Code section 124E.5(3)(e)

recommendations made by the Board included oral forms, topical forms, inhaled forms and rectal/vaginal forms. The Board recommended allowing patients to purchase up to a 90-day supply of each product. Each of the Board's recommendations was approved by the Iowa Board of Medicine, with the exception of allowing patients to access a vaporizable form of medical cannabidiol. After being approved and amended by the Board of Medicine, the form and quantity administrative rules were forwarded to the State Board of Health for adoption and became effective in July of 2018.

Other Recommendations of the Board

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

Felony Disqualifiers

Currently, chapter 124E disqualifies patients with certain felony convictions 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. [SR1]

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. [SR2]

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. [SR3]

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. [SR4]

VA Patient Access[SR5]

¹⁰ Iowa Code section 124E.5(6)