

Iowa Department of Public Health



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

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Division of Behavioral Health, Office of Medical Cannabidiol

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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:

1. 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.
3. 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 Iowa².

This report summarizes the Board's activities in each of these areas during calendar year 2018 and concludes with recommendations from the Board regarding statutory changes that should be made to improve 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.

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 three 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 Iowa'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 may already be eligible for participation in Iowa's medical cannabidiol patient registry because the petition focused on pain caused by Trigeminal Neuralgia and untreatable pain is already a qualifying condition enumerated in Iowa Code section 124E.2.
2. Post-Traumatic Stress Disorder (PTSD)/Bipolar Disorder. The Board received a single petition for both conditions and requested to address these two conditions as separate agenda items at its November, 2018 meeting.

³ Iowa Code section 124E.5(5)

⁴ Iowa Code section 124E.5(2)

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 participate in the patient registry. The Board considered that Crohn's disease is one of the debilitating medical conditions included by the Legislature in Iowa Code section 124E.2, and discussed the similarity of symptoms and medical treatments used to treat Crohn's disease and Ulcerative Colitis. Due to the similarity of symptoms and recommended treatment for these two conditions, the Board recommended addition of Ulcerative Colitis. 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 adopted a rule to add Ulcerative Colitis, which is anticipated to become effective February 20, 2019.

November 2, 2018

In November, Board members considered petitions to add the following debilitating medical conditions:

1. Post-Traumatic Stress Disorder (PTSD). The Board had a discussion about the lack of scientific evidence supporting the addition of PTSD as a qualifying debilitating medical condition. It was noted that the Veterans Administration had studied cannabis use for PTSD on two occasions, most recently in 2017. Their conclusion was that evidence of benefit that exceeds harm is lacking and recommended withholding use awaiting further research. Board members also commented on the lack of scientific evidence supporting inclusion of the conditions enumerated by the Legislature in Iowa Code section 124E.2 and encouraged colleagues to defer to compassionate care principles by voting to recommend addition of this condition on that basis. A motion to add the condition failed.
2. Bipolar Disorder. The Board discussed the lack of scientific evidence supporting the addition of bipolar disorder as a qualifying debilitating medical condition. A motion to deny the petition was approved.
3. Autism Spectrum Disorder. The Board discussed autism spectrum disorder, and its wide range of symptoms and severity of those symptoms. Concerns about deleterious effects of *Cannabis*, specifically THC, on the developing brain were raised. Board members opined that concerns about negative effects on the developing brain were not necessarily applicable to pediatric patients with the most severe forms of autism. A motion to recommend the addition of severe, intractable pediatric autism with self-injurious or aggressive behavior was approved.
4. Attention Deficit Hyperactivity Disorder (ADHD). The Board discussed the lack of scientific evidence supporting the addition of ADHD as a qualifying debilitating medical condition. Concerns about deleterious effects of *Cannabis*, specifically THC, on the developing brain were raised. A motion to deny the petition was approved.
5. Ganglioglioma. The Board could find no evidence in the medical literature that cannabis would treat this benign brain tumor. The Board determined that patients with this condition may already be eligible for participation in Iowa's medical cannabidiol patient registry because the petition focused on pain caused by Ganglioglioma and untreatable pain is already a qualifying condition enumerated in Iowa Code section 124E.2.

Also at its November meeting, the Board reviewed a draft of this annual report, and recommended the addition of an inhaled, vaporizable form of medical cannabidiol to the list of forms that may be

manufactured and distributed. 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 December 14, 2018. The Board of Medicine concurred with the Board’s recommendation to add an inhaled, vaporizable form of medical cannabidiol to the list of forms that may be manufactured and distributed. The recommendation will go before the State Board of Health as a notice of intended action at its meeting January 9, 2019.

The Board discussed the 3% THC cap specified in Iowa Code section 124E.2. Board members noted an existing capsule form contains 20 mg of THC, is compliant with the 3% THC cap, and is currently manufactured and available for distribution in licensed medical cannabidiol dispensaries. This 20 mg dose is well into the range considered psychoactive; i.e., creating a “high” for most persons. It also covers the majority of indications documented in the medical literature for which THC has been found to be beneficial. 20 mg of THC is twice the amount of THC in the largest dose of dronabinol, a synthetic THC preparation available only by prescription by a licensed medical provider. Following this discussion, the Board recommended the THC cap on medical cannabidiol products in Iowa remain at 3%.

The Board received updates from licensed dispensaries and manufacturers as well.

Accepting and Reviewing Petitions⁵

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

1. Trigeminal Neuralgia - Denied
2. Ulcerative Colitis – Recommended Addition
3. Post-Traumatic Stress Disorder (PTSD) - Denied
4. Bipolar Disorder - Denied
5. Autism – Recommended Addition of Severe, Intractable Pediatric Autism with Self-Injurious or Aggressive Behaviors
6. Attention Deficit Hyperactivity Disorder (ADHD) - Denied
7. Ganglioglioma - Denied

Making Recommendations for Adding/Removing Medical Conditions⁶

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

1. Ulcerative Colitis
2. Severe, Intractable Pediatric Autism with Self-Injurious or Aggressive Behaviors

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.

⁵ Iowa Code section 124E.5(3)(a)

⁶ Iowa Code section 124E.5(3)(b)

⁷ Iowa Code section 124E.5(3)(c)

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 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.

At its November 2018 meeting, the Board discussed and voted to renew its recommendation to the Board of Medicine to approve manufacturing of a vaporizable product. A majority of board members agreed that a vaporizable form is more easily titrated and faster acting than an ingestible form, less likely to be inadvertently overdosed than an ingestible form, and may be easier for some patients to use, especially patients who experience difficulty swallowing.

Other Recommendations of the Board

Definition of Medical Cannabidiol Tetrahydrocannabinol (THC) Level Recommendation¹⁰

At its November meeting, the Board voted to recommend leaving the THC cap on medical cannabidiol products manufactured in Iowa at 3%.

Felony Disqualifiers

Currently, chapter 124E disqualifies patients and primary caregivers with certain felony convictions from obtaining patient registration cards. The Board recommends removing this provision for patients and primary caregivers, as withholding medical treatment on the basis of criminal conviction violates the American Medical Association Code of Ethics¹¹. In no other area of medicine is there discrimination based on criminal or legal status.

Recommendation - Amend Iowa Code section 124E.4(1)"f" and Iowa Code section 124E.4(3)"c" as follows: **124E.4 Medical cannabidiol registration card.**

1. Issuance to patient. Subject to subsection 7, the department may approve the issuance of a medical cannabidiol registration card by the department of transportation to a patient who:
 - a. Is at least eighteen years of age.

⁸ Iowa Code section 124E.5(3)(d)

⁹ Iowa Code section 124E.5(3)(e)

¹⁰ Iowa Code section 124E.5(6)

¹¹ American Medical Association Code of Ethics 2015, Chapter 2.065, "...a court does not have the ability to make a medical diagnosis or to determine the type of treatment that will be administered. In accordance with ethical practice, physicians should treat patients based on sound medical diagnoses, not court-defined behaviors."

- b. Is a permanent resident of this state.
- c. Submits a written certification to the department signed by the patient's health care practitioner that the patient is suffering from a debilitating medical condition.
- d. Submits an application to the department, on a form created by the department, in consultation with the department of transportation, that contains all of the following:
 - (1) The patient's full name, Iowa residence address, date of birth, and telephone number.
 - (2) A copy of the patient's valid photograph identification.
 - (3) Full name, address, and telephone number of the patient's health care practitioner.
 - (4) Full name, residence address, date of birth, and telephone number of each primary caregiver of the patient, if any.
 - (5) Any other information required by rule.
- e. Submits a medical cannabidiol registration card fee of one hundred dollars to the department. If the patient attests to receiving social security disability benefits, supplemental security insurance payments, or being enrolled in the medical assistance program, the fee shall be twenty-five dollars.
- ~~f. Has not been convicted of a disqualifying felony offense.~~

3. Issuance to primary caregiver. For a patient in a primary caregiver's care, subject to subsection 7, the department may approve the issuance of a medical cannabidiol registration card by the department of transportation to the primary caregiver who:

- a. Submits a written certification to the department signed by the patient's health care practitioner that the patient in the primary caregiver's care is suffering from a debilitating medical condition.
- b. Submits an application to the department, on a form created by the department, in consultation with the department of transportation, that contains all of the following:
 - (1) The primary caregiver's full name, residence address, date of birth, and telephone number.
 - (2) The patient's full name.
 - (3) A copy of the primary caregiver's valid photograph identification.
 - (4) Full name, address, and telephone number of the patient's health care practitioner.
 - (5) Any other information required by rule.
- ~~c. Has not been convicted of a disqualifying felony offense.~~
- d. Submits a medical cannabidiol registration card fee of twenty-five dollars to the department.

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. Physician assistants (PAs) and advanced registered nurse practitioners (ARNPs) have been instrumental in extending access to health care in Iowa. In many group practices these midlevel providers outnumber physicians, and in many rural areas, are the only primary care practitioners available. To ensure access to registration cards for a greater number of patients, the Board recommends allowing midlevel providers, including physician assistants (PAs) and advanced registered nurse practitioners (ARNPs) to certify a patient’s debilitating medical condition for the purpose of obtaining a medical cannabidiol registration card.

Recommendation – Amend Iowa Code section 124E.2(5) as follows:

“Health care practitioner,” means an individual licensed under chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, or a physician assistant licensed under chapter 148C, or an advanced registered nurse practitioner licensed under chapter 152 or 152E, who is a patient’s primary care provider. ~~“Health care practitioner” shall not include a physician assistant licensed under chapter 148C or an advanced registered nurse practitioner licensed pursuant to chapter 152 or 152E.~~

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, the Board would like to see 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.

Address the Use of Medical Cannabidiol Products in Long-Term, Acute Care and School Settings

The Board recommends the Legislature address the use of medical cannabidiol products in long-term and acute care settings, as well as in schools.

Call to Research

The Board has discussed the lack of existing medical literature on benefits and adverse effects of the use of medical cannabidiol products at multiple meetings. The lack of medical research related to petitions to add additional qualifying medical conditions has been a recurring theme. Current information consists, with rare exceptions, of anecdotal reports, study products of uncertain nature, small study populations, short observation times, incomplete results and very few prospectively-randomized, placebo-controlled, double-blinded design studies. The new availability in Iowa of pharmaceutical-grade,

lab-tested products of precise CBD:THC content opens an opportunity for modern clinical research on the benefits and adverse effects of medical cannabidiol. Multiple organizations in Iowa are engaged in rigorous medical research studies that are Institutional Review Board approved and federally compliant. The Board recommends removing statutory obstacles to clinical medical cannabidiol research.