

MEDICINE BOARD[653]

Notice of Intended Action

Proposing rule making related to medical cannabidiol standards of practice and providing an opportunity for public comment

The Board of Medicine hereby proposes to amend Chapter 13, “Standards of Practice and Principles of Medical Ethics,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, 2017 Iowa Acts, House File 524, and Iowa Code chapters 124E, 147, 148, and 272C.

Purpose and Summary

The purpose of Chapter 13 is to establish standards of practice and principles of medical ethics for administrative medicine physicians, medical physicians and surgeons, and osteopathic physicians and surgeons. The proposed rule relates to the use of medical cannabidiol for patients with a qualifying illness. This rule establishes the process by which the Board of Medicine receives recommendations from the Medical Cannabidiol Board concerning amendments for the list of debilitating medical conditions that could be treated with medical cannabidiol and the form and quantity of the medical cannabidiol. This rule also provides grounds for discipline for physicians who violate the rule.

The Board approved this Notice of Intended Action during a regularly scheduled meeting on February 16, 2018.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 653—Chapter 3.

Public Comment

Any interested person may submit written or oral comments concerning this proposed rule making. Written or oral comments in response to this rule making must be received by the Board no later than 4:30 p.m. on April 4, 2018. Comments should be directed to:

Mark Bowden, Executive Director
Board of Medicine
RiverPoint Office Park
400 S.W. Eighth Street, Suite C
Des Moines, Iowa 50309
Fax: 515.242.5908
Phone: 515.242.3268
Email: mark.bowden@iowa.gov

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

April 4, 2018
8:30 a.m.

Board Office, Suite C
400 S.W. Eighth Street
Des Moines, Iowa

Persons who wish to make oral comments at the public hearing may be asked to state their names for the record and to confine their remarks to the subject of this proposed rule making.

Any persons who intend to attend a public hearing and have special requirements, such as those related to hearing or mobility impairments, should contact the Board and advise of specific needs.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Adopt the following **new** rule 653—13.15(124E,147,148,272C):

653—13.15(124E,147,148,272C) Standards of practice—medical cannabidiol.

13.15(1) Definitions. For purposes of this rule:

“*Board of medicine*” means the board established pursuant to Iowa Code chapters 147 and 148.

“*Bordering state*” means the same as defined in Iowa Code section 331.910.

“*Debilitating medical condition*” means any of the following:

1. Cancer, if the underlying condition or treatment produces one or more of the following:
 - Severe or chronic pain.
 - Nausea or severe vomiting.
 - Cachexia or severe wasting.
2. Multiple sclerosis with severe and persistent muscle spasms.
3. Seizures, including those characteristic of epilepsy.
4. AIDS or HIV as defined in Iowa Code section 141A.1.
5. Crohn’s disease.
6. Amyotrophic lateral sclerosis.
7. Any terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:
 - Severe or chronic pain.

- Nausea or severe vomiting.
- Cachexia or severe wasting.
- 8. Parkinson’s disease.
- 9. Untreatable pain.

“*Department*” means the Iowa department of public health.

“*Form and quantity*” means the types and amounts of medical cannabidiol allowed to be dispensed to a patient or primary caregiver as approved by the department subject to recommendation by the medical cannabidiol board and approval by the board of medicine.

“*Medical cannabidiol*” means any pharmaceutical grade cannabinoid found in the plant *Cannabis sativa* L. or *Cannabis indica* or any other preparation thereof that has a tetrahydrocannabinol level of no more than 3 percent and that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and adopted by the department pursuant to rule.

“*Medical cannabidiol board*” means the board established pursuant to Iowa Code section 124E.5.

“*Primary caregiver*” means a person who is a resident of this state or a bordering state, including but not limited to a parent or legal guardian, at least 18 years of age, who has been designated by a patient’s health care practitioner as a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol pursuant to the provisions of this chapter.

“*Untreatable pain*” means any pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for the patient has been used without adequate result or with intolerable side effects.

“*Written certification*” means a document signed by a physician licensed pursuant to Iowa Code chapter 148 with whom the patient has established a patient-physician relationship and who is the patient’s primary care provider which states that the patient has a debilitating medical condition and identifies that condition and provides any other relevant information.

13.15(2) *Written certification.* A physician who is a patient’s primary care provider may provide the patient a written certification of diagnosis if, after examining and treating the patient, the physician determines, in the physician’s medical judgment, that the patient suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E.

a. The physician shall provide explanatory information as provided by the department to the patient about the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment.

b. Subsequently, the physician shall do the following:

(1) Determine, on an annual basis, if the patient continues to suffer from a debilitating medical condition and, if so, may issue the patient a new written certification of that diagnosis.

(2) Otherwise comply with all requirements established by the department pursuant to rule.

c. A physician may provide, but has no duty to provide, a written certification pursuant to this rule.

13.15(3) *Adding or removing debilitating medical conditions and amending form and quantity of medical cannabidiol.* Recommendations made by the medical cannabidiol board pursuant to Iowa Code section 124E.5 relating to the addition or removal of allowable debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial or to the amendment of the form and quantity of allowable medical uses of cannabidiol shall be made to the board of medicine for consideration. The medical cannabidiol board shall submit a written recommendation, a copy of the petition and all other information received during consideration of the petition. The board of medicine shall consider the information received from the medical cannabidiol board and may seek information from other sources if it is deemed relevant by the board of medicine. The decision regarding a recommendation by the medical cannabidiol board is at the sole discretion of the board of medicine. The board of medicine shall make its decision within 180 days of receipt of the recommendation from the medical cannabidiol board. If the recommendation is approved by the board of medicine, it shall be adopted by rule.

13.15(4) *Financial interests.* A physician shall not share office space with, accept referrals from, or have any financial relationship with a medical cannabidiol manufacturer or dispensary.

13.15(5) *Criminal prosecution.* A physician, including any authorized agent or employee thereof, shall not be subject to prosecution for the unlawful certification, possession, or administration of marijuana under the laws of this state for activities arising directly out of or directly related to the certification or use of medical cannabidiol in the treatment of a patient diagnosed with a debilitating medical condition as authorized by Iowa Code chapter 124E.

13.15(6) *Civil or disciplinary penalties.* A physician, including any authorized agent or employee thereof, shall not be subject to any civil or disciplinary penalties by the board of medicine or any business, occupational, or professional licensing board or entity, solely for activities conducted relating to a patient's possession or use of medical cannabidiol as authorized by Iowa Code chapter 124E. Nothing in this rule prevents the board of medicine from taking action in response to violations of any other sections of law or rule.

13.15(7) *Grounds for discipline.* A physician may be subject to disciplinary action for violation of these rules or the rules found in 653—Chapter 23. Grounds for discipline include, but are not limited to, the following:

a. The physician provides an individual a written certification without establishing a patient-physician relationship, including examining and treating the individual, or without being the individual's primary care provider.

b. The physician provides a patient a written certification without determining, in the physician's medical judgment, that the patient suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E.

c. The physician provides a patient a written certification without providing explanatory information as provided by the department to the patient about the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment.

d. The physician provides an individual a new written certification without determining, on an annual basis, that the patient continues to suffer from a debilitating medical condition.

e. The physician shares office space with, accepts referrals from, or has a financial relationship with a medical cannabidiol manufacturer or dispensary.

This rule is intended to implement Iowa Code chapters 124E, 147, 148 and 272C.