House File 2384 - Introduced

HOUSE FILE 2384
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HSB 607)

A BILL FOR

1 An Act relating to the medical cannabidiol Act, making
2 related modifications, and providing for civil and criminal
3 penalties and fees.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
Section 1. Section 124D.2, Code 2016, is amended by striking the section and inserting in lieu thereof the following:

**124D.2 Definitions.**

As used in this chapter:

1. "Cannabidiol" means a nonpsychoactive cannabinoid found in the plant Cannabis sativa L. or Cannabis indica or any other preparation thereof that is essentially free from plant material, and has a tetrahydrocannabinol level of no more than three percent.

2. "Debilitating medical condition" means any of the following:
   a. Intractable epilepsy.
   b. Multiple sclerosis.
   c. Cancer, if a health care practitioner has determined a prognosis for a patient of less than twelve months of life.

3. "Department" means the department of public health.

4. "Health care practitioner" means an individual licensed under chapter 148 to practice medicine and surgery or osteopathic medicine and surgery who provides specialty care for a resident of this state for one or more debilitating medical conditions.

5. "Intractable epilepsy" means an epileptic seizure disorder for which standard medical treatment does not prevent or significantly ameliorate recurring, uncontrolled seizures or for which standard medical treatment results in harmful side effects.

6. "Medical cannabidiol manufacturer" means an entity located in this state and licensed by the department to manufacture and to possess, cultivate, harvest, package, process, transport, supply, and dispense cannabidiol pursuant to the provisions of this chapter.

7. "Primary caregiver" means a person, at least eighteen years of age, who has been designated by a patient's health care practitioner or by a person having custody of a patient, as being necessary to take responsibility for managing the...
well-being of the patient with respect to the medical use of cannabidiol pursuant to the provisions of this chapter.

Sec. 2. Section 124D.3, Code 2016, is amended to read as follows:

124D.3 Neurologist health care practitioner recommendation — medical use of cannabidiol.

A neurologist health care practitioner who has examined and treated a patient suffering from intractable epilepsy a debilitating medical condition may provide but has no duty to provide a written recommendation for the patient’s medical use of cannabidiol to treat or alleviate symptoms of intractable epilepsy the debilitating medical condition if no other satisfactory alternative treatment options exist for the patient and all of the following conditions apply:

1. The patient is a permanent resident of this state.
2. A neurologist health care practitioner has treated the patient for intractable epilepsy a debilitating medical condition for at least six months. For purposes of this treatment period, and notwithstanding section 124D.2, subsection 4, treatment provided by a neurologist health care practitioner may include treatment by an out-of-state licensed neurologist health care practitioner in good standing.
3. The neurologist health care practitioner has tried alternative treatment options that have not alleviated the patient’s symptoms.
4. The neurologist health care practitioner determines the risks of recommending the medical use of cannabidiol are reasonable in light of the potential benefit for the patient.
5. The neurologist health care practitioner maintains a patient treatment plan.

Sec. 3. Section 124D.4, subsection 1, paragraph c, Code 2016, is amended to read as follows:

c. Requests the patient’s neurologist health care practitioner to submit a written recommendation to the department signed by the neurologist health care practitioner
that the patient may benefit from the medical use of
2 cannabidiol pursuant to section 124D.3.
3 Sec. 4. Section 124D.4, subsection 1, paragraph d,
4 subsection (3), Code 2016, is amended to read as follows:
5 (3) Full name, address, and telephone number of the
6 patient’s health care practitioner.
7 Sec. 5. Section 124D.4, subsection 1, Code 2016, is amended
8 by adding the following new paragraph:
9 NEW PARAGRAPH. e. Submits a cannabidiol registration card
10 fee of one hundred dollars to the department. If the patient
11 attests to receiving social security disability benefits,
12 supplemental security insurance benefits, or being enrolled in
13 the medical assistance program, the fee shall be twenty-five
14 dollars.
15 Sec. 6. Section 124D.4, subsection 3, paragraph b, Code
16 2016, is amended to read as follows:
17 b. Requests a patient’s health care practitioner
18 to submit a written recommendation to the department signed by
19 the health care practitioner that a patient in the
20 primary caregiver’s care may benefit from the medical use of
21 cannabidiol pursuant to section 124D.3.
22 Sec. 7. Section 124D.4, subsection 3, paragraph c,
23 subparagraph (4), Code 2016, is amended to read as follows:
24 (4) Full name, address, and telephone number of the
25 patient’s health care practitioner.
26 Sec. 8. Section 124D.5, subsection 1, paragraph b,
27 subparagraph (1), Code 2016, is amended by adding the following
28 new subparagraph division:
29 NEW SUBPARAGRAPH (c) To authorized employees of
30 a medical cannabidiol manufacturer, but only for the purpose
31 of verifying that a person is lawfully in possession of a
32 cannabidiol registration card issued pursuant to this chapter.
33 Sec. 9. Section 124D.5, subsection 2, Code 2016, is amended
34 by striking the subsection and inserting in lieu thereof the
35 following:
The department shall adopt rules pursuant to chapter 17A to administer this chapter which shall include but not be limited to rules to do all of the following:

a. Govern the manner in which the department shall consider applications for new and renewal cannabidiol registration cards.

b. Establish requirements for the suspension and revocation of a cannabidiol registration card and a medical cannabidiol manufacturer license.

c. Establish requirements for the licensure of medical cannabidiol manufacturers and set forth procedures for medical cannabidiol manufacturers to obtain licenses.

d. Develop a dispensing system for medical cannabidiol manufacturers to dispense cannabidiol within this state that provides for all of the following:

1. Medical cannabidiol manufacturers within this state housed on secured grounds.

2. The dispensing of cannabidiol to patients and their primary caregivers in person to occur at medical cannabidiol manufacturer locations designated by the department.

e. Establish and collect annual fees from medical cannabidiol manufacturers to cover the costs associated with regulating and inspecting medical cannabidiol manufacturers.

f. Specify and implement procedures that address public safety including security procedures and product quality including measures to ensure contaminant-free cultivation of cannabidiol, safety, and appropriate labeling.

g. Establish and implement a real-time, statewide cannabidiol registry management sale tracking system that is available to medical cannabidiol manufacturers on a twenty-four-hour-day, seven-day-a-week basis for the purpose of verifying that a person is lawfully in possession of a cannabidiol registration card issued pursuant to this chapter and for tracking the date of the sale and quantity of cannabidiol purchased by a patient or a primary caregiver.
h. Establish and implement a cannabidiol inventory and delivery tracking system to track cannabidiol from production by a medical cannabidiol manufacturer through dispensing by a medical cannabidiol manufacturer.

Sec. 10. Section 124D.6, subsections 1 and 2, Code 2016, are amended to read as follows:

1. a. A recommendation for the possession or use of cannabidiol as authorized by this chapter shall be provided exclusively by a neurologist health care practitioner for a patient who has been diagnosed with intractable epilepsy a debilitating medical condition.

b. Cannabidiol provided exclusively pursuant to the recommendation of a neurologist shall be obtained from an out-of-state source and health care practitioner shall only be recommended for oral or transdermal administration.

c. A neurologist health care practitioner shall be the sole authorized recommender as part of the treatment plan by the neurologist health care practitioner of a patient diagnosed with intractable epilepsy a debilitating medical condition.

A neurologist health care practitioner shall have the sole authority to recommend the use or amount of cannabidiol, if any, in the treatment plan of a patient diagnosed with intractable epilepsy a debilitating medical condition.

2. A neurologist health care practitioner, including any authorized agent thereof, shall not be subject to prosecution for the unlawful recommendation, possession, or administration of marijuana under the laws of this state for activities arising directly out of or directly related to the recommendation or use of cannabidiol in the treatment of a patient diagnosed with intractable epilepsy a debilitating medical condition.

Sec. 11. Section 124D.6, Code 2016, is amended by adding the following new subsection:

NEW SUBSECTION. 2A. A medical cannabidiol manufacturer, including any authorized agent or employee thereof, shall
not be subject to prosecution for manufacturing, possessing, cultivating, harvesting, packaging, processing, transporting, supplying, or dispensing cannabidiol pursuant to this chapter.

Sec. 12. Section 124D.6, subsection 3, paragraphs a and b, Code 2016, are amended to read as follows:

a. In a prosecution for the unlawful possession of marijuana under the laws of this state, including but not limited to chapters 124 and 453B, it is an affirmative and complete defense to the prosecution that the patient has been diagnosed with intractable epilepsy a debilitating medical condition, used or possessed cannabidiol pursuant to a recommendation by a neurologist health care practitioner as authorized under this chapter, and, for a patient eighteen years of age or older, is in possession of a valid cannabidiol registration card.

b. In a prosecution for the unlawful possession of marijuana under the laws of this state, including but not limited to chapters 124 and 453B, it is an affirmative and complete defense to the prosecution that the person possessed cannabidiol because the person is a primary caregiver of a patient who has been diagnosed with intractable epilepsy a debilitating medical condition and is in possession of a valid cannabidiol registration card, and where the primary caregiver's possession of the cannabidiol is on behalf of the patient and for the patient's use only as authorized under this chapter.

Sec. 13. NEW SECTION. 124D.9 Medical cannabidiol manufacturer licensure.

1. The department shall license two medical cannabidiol manufacturers by December 1, 2016, to manufacture and dispense cannabidiol within this state consistent with the provisions of this chapter. The department shall relicense the existing medical cannabidiol manufacturers by December 1 of each year.

2. As a condition for licensure, a medical cannabidiol manufacturer must agree to begin supplying and dispensing cannabidiol to patients in this state by July 1, 2017.
3. The department shall consider the following factors in determining whether to license a medical cannabidiol manufacturer:
   a. The technical expertise of the medical cannabidiol manufacturer in cannabidiol.
   b. The qualifications of the medical cannabidiol manufacturer's employees.
   c. The long-term financial stability of the medical cannabidiol manufacturer.
   d. The ability to provide appropriate security measures on the premises of the medical cannabidiol manufacturer.
   e. The medical cannabidiol manufacturer's projection of and ongoing assessment of fees on patients with debilitating medical conditions.

4. The department shall require each medical cannabidiol manufacturer to contract with the state hygienic laboratory at the university of Iowa in Iowa City to test the cannabidiol produced by the medical cannabidiol manufacturer as to content, contamination, and consistency. The department shall require that the laboratory report testing results to the medical cannabidiol manufacturer in a manner determined by the department pursuant to rule.

5. Each entity submitting an application for licensure as a medical cannabidiol manufacturer shall pay a nonrefundable application fee of ten thousand dollars to the department.

Sec. 14. NEW SECTION. 124D.10 Medical cannabidiol manufacturers.

1. A medical cannabidiol manufacturer shall pay the cost of all laboratory testing.

2. The operating documents of a medical cannabidiol manufacturer shall include all of the following:
   a. Procedures for the oversight of the medical cannabidiol manufacturer and procedures to ensure accurate recordkeeping.
   b. Procedures for the implementation of appropriate security measures to deter and prevent the theft of cannabidiol and
H.F. 2384

1 unauthorized entrance into areas containing cannabidiol.
2 3. A medical cannabidiol manufacturer shall implement
3 security requirements, including requirements for protection
4 of each location by a fully operational security alarm system,
5 facility access controls, perimeter intrusion detection
6 systems, and a personnel identification system.
7 4. A medical cannabidiol manufacturer shall not share
8 office space with, refer patients to, or have any financial
9 relationship with a health care practitioner.
10 5. A medical cannabidiol manufacturer shall not permit any
11 person to consume cannabidiol on the property of the medical
12 cannabidiol manufacturer.
13 6. A medical cannabidiol manufacturer is subject to
14 reasonable inspection by the department.
15 7. A medical cannabidiol manufacturer shall not employ a
16 person who is under twenty-one years of age or who has been
17 convicted of a disqualifying felony offense. An employee
18 of a medical cannabidiol manufacturer shall be subject to a
19 background investigation conducted by the division of criminal
20 investigation of the department of public safety and a national
21 criminal history background check.
22 8. A medical cannabidiol manufacturer shall comply with
23 reasonable restrictions set by the department relating to
24 signage, marketing, display, and advertising of cannabidiol.
25 9. a. All manufacturing, cultivating, harvesting,
26 packaging, and processing of cannabidiol shall take place in an
27 enclosed, locked facility at a physical address provided to the
28 department during the licensure process.
29 b. A medical cannabidiol manufacturer shall manufacture
30 a reliable and ongoing supply of cannabidiol to treat every
31 debilitating medical condition listed in this chapter.
32 c. A medical cannabidiol manufacturer shall not, within
33 a thirty-day period, dispense more than thirty-two ounces of
34 cannabidiol to a patient or a primary caregiver.
35 10. A medical cannabidiol manufacturer shall pay an
1 annual fee determined by the department equal to the cost of
2 regulating and inspecting the medical cannabidiol manufacturer
3 during that year.
4
5 Sec. 15. NEW SECTION. 124D.11 Fees.
6 Cannabidiol registration card fees and medical cannabidiol
7 manufacturer application and annual fees collected by the
8 department pursuant to this chapter shall be retained by
9 the department, shall be considered repayment receipts as
10 defined in section 8.2, and shall be used for the purpose of
11 regulating medical cannabidiol manufacturers and for other
12 expenses necessary for the administration of this chapter.
13 Notwithstanding section 8.33, moneys that remain unencumbered
14 or unobligated at the end of the fiscal year shall not revert
15 to the general fund of the state.
16
17 Sec. 16. NEW SECTION. 124D.12 Use of cannabidiol — smoking
18 and vaping prohibited.
19 A patient shall not consume cannabidiol possessed or used as
20 authorized by this chapter by smoking or vaping cannabidiol.
21
22 Sec. 17. NEW SECTION. 124D.13 Penalties.
23 1. A person who knowingly or intentionally possesses or uses
24 cannabidiol in violation of the requirements of this chapter is
25 subject to the penalties provided under chapters 124 and 453B.
26 2. A medical cannabidiol manufacturer shall be assessed
27 a civil penalty of up to one thousand dollars per violation
28 for any violation of this chapter in addition to any other
29 applicable penalties.
30
31 Sec. 18. REPEAL. Sections 124D.7 and 124D.8, Code 2016,
32 are repealed.
33
34 EXPLANATION
35 The inclusion of this explanation does not constitute agreement with
36 the explanation’s substance by the members of the general assembly.
37
38 This bill relates to the medical cannabidiol Act, makes
39 related modifications, and provides for civil and criminal
40 penalties and fees.
41 MEDICAL CANNABIDIOL ACT — OVERVIEW. Iowa Code chapter
1. The medical cannabidiol Act, currently allows an Iowa licensed neurologist who has examined and treated a patient suffering from intractable epilepsy to provide a written recommendation for the patient's medical use of cannabidiol to treat or alleviate symptoms of intractable epilepsy if no other satisfactory alternative treatment options exist and if certain conditions apply. A patient who receives a written recommendation from the patient's neurologist or the patient's primary caregiver is required to have a valid cannabidiol registration card to use or possess cannabidiol for medical purposes. The cannabidiol must be obtained from an out-of-state source. The department of public health is required to maintain a confidential file of the names of each patient and primary caregiver to or for whom the department issues a cannabidiol registration card and to keep such information confidential except as otherwise allowed.

The medical cannabidiol Act provides affirmative defenses to a neurologist, a patient, and a primary caregiver from prosecution. A person who knowingly or intentionally possesses or uses cannabidiol in violation of the medical cannabidiol Act is subject to the penalties provided under Code chapters 124 (controlled substances) and 453B (excise taxes on unlawful dealing in certain substances).

DEBILITATING MEDICAL CONDITIONS — HEALTH CARE PRACTITIONER.

The bill amends the medical cannabidiol Act to include multiple sclerosis and terminal cancer, in addition to intractable epilepsy, as additional debilitating medical conditions for which a patient may receive a written recommendation from a health care practitioner for the patient's medical use of cannabidiol. "Health care practitioner" is defined to mean any Iowa licensed physician who provides specialty care for one or more debilitating medical conditions.

CANNABIDIOL REGISTRATION CARD FEE. The bill requires a patient to submit a cannabidiol registration card fee of $100 or $25 to the department, depending on whether a patient is the
1 recipient of certain public assistance.
2 CONFIDENTIALITY. The bill provides that confidential
3 patient and primary caregiver cannabidiol registration card
4 information maintained by the department may be disclosed to
5 authorized employees of a medical cannabidiol manufacturer
6 under certain circumstances.
7 MEDICAL CANNABIDIOL MANUFACTURER — LICENSURE. The bill
8 requires the department to license by December 1, 2016,
9 two medical cannabidiol manufacturers to manufacture and
10 dispense cannabidiol within this state. As a condition for
11 licensure, a medical cannabidiol manufacturer must agree to
12 begin supplying and dispensing cannabidiol to patients in
13 this state by July 1, 2017. The department is directed to
14 consider several factors in determining whether to license a
15 medical cannabidiol manufacturer. Each medical cannabidiol
16 manufacturer is required to contract with the state hygienic
17 laboratory at the university of Iowa to test the cannabidiol
18 produced by the manufacturer and to report testing results to
19 the medical cannabidiol manufacturer, and is required to pay a
20 nonrefundable application fee of $10,000.
21 MEDICAL CANNABIDIOL MANUFACTURER — ADDITIONAL REQUIREMENTS.
22 The bill provides that certain requirements must be included in
23 the operating documents of a medical cannabidiol manufacturer.
24 A medical cannabidiol manufacturer is prohibited from engaging
25 in certain activities and is subject to reasonable inspection
26 and reasonable restrictions by the department.
27 A medical cannabidiol manufacturer is required to provide
28 a reliable and ongoing supply of cannabidiol to treat every
29 debilitating medical condition pursuant to the provisions of
30 the bill and shall manufacture, cultivate, harvest, package,
31 and process cannabidiol in an enclosed, locked facility at
32 a physical address provided to the department during the
33 licensure process.
34 FEES. Cannabidiol registration card fees and medical
35 cannabidiol manufacturer application and annual fees collected
by the department shall be retained by the department, and
shall be used for the purpose of regulating medical cannabidiol
manufacturers and for other expenses necessary for the
administration of the bill.

ADDITIONAL DEPARTMENT DUTIES — RULES. The bill requires
the department to adopt rules relating to cannabidiol
registration cards and medical cannabidiol manufacturer
licenses, requirements for the licensure of medical cannabidiol
manufacturers, a dispensing system for medical cannabidiol
manufacturers to dispense cannabidiol within this state
that follows certain requirements, annual fees from medical
cannabidiol manufacturers, public safety procedures, and the
establishment and implementation of a statewide cannabidiol
registry management sale tracking system.

USE OF CANNABIDIOL — SMOKING AND VAPING PROHIBITED. The
bill provides that a patient, including an out-of-state patient
who is in Iowa, shall not consume the cannabidiol by smoking or
vaping the cannabidiol.

USE OF MEDICAL CANNABIDIOL — AFFIRMATIVE DEFENSES.
The bill provides prosecution immunity for a health care
practitioner and a medical cannabidiol manufacturer
including any authorized agents or employees of the health
care practitioner or medical cannabidiol manufacturer, for
activities undertaken by the health care practitioner or
medical cannabidiol manufacturer, pursuant to the provisions
of the bill.

PENALTIES. The bill provides that a medical cannabidiol
manufacturer shall be assessed a civil penalty of up to $1,000
per violation for any violation of the bill in addition to any
other applicable penalties.

REPEAL. The bill repeals Code sections 124D.7 (penalties)