

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

The Public Health Department hereby proposes to amend Chapter 154, “Medical Cannabidiol Program,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code chapter 124E and 2020 Iowa Acts House File 2589.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 124E and 2020 Iowa Acts House File 2589.

Purpose and Summary

The proposed amendments implement needed updates to the rules per the requirements of 2020 Iowa Acts House File 2589. Updates include:

- Removes the 3% THC cap on products, and replaces it with a 4.5g THC/ 90-day purchase limit. Establishes exceptions to the 4.5g THC/ 90-day purchase limit for the terminally ill, or if the patient’s Healthcare Practitioner certifies them for additional THC
- Dispensaries will be required to employ either a pharmacist or a pharmacy tech
- Amends "untreatable pain" to "chronic pain," adds PTSD, and adds severe, intractable autism with self-injurious or aggressive behaviors.
- Adds PAs, ARNPs, APRNs, and podiatrists to the list of health care practitioners that can certify patients for participation in the program
- Provides a new definition for total THC
- Makes the IDPH responsible for issuance of registration cards, instead of the DOT

- Removes the felony disqualifiers for patients and primary caregivers
- Removes the limit on the number of board meetings allowed each year, requires the board to meet at least twice
- Removes the requirement for manufacturers to contract specifically with SHL, instead they must contract with a "laboratory"
- Provides access to the patient registry for health care practitioners for the purposes of determining whether patients have received a certification from another health care provider

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 Department for a waiver of the discretionary provisions, if any, pursuant to the Department's waiver and variance provisions contained in 641—Chapter 178.

Public Comment

Any interested person may submit comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on August 4, 2020. Comments should be directed to:

Owen Parker

Department of Public Health

Lucas State Office Building

321 East 12th Street

Des Moines, Iowa 50319

Email: owen.parker@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1) “b,” an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

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 proposed:

ITEM 1. Amend rule **641—154.1(124E)**, definition of “*Date of issuance*,” “*Debilitating medical condition*,” “*Health care practitioner*,” “*Laboratory*,” and “*Medical cannabidiol*,” as follows:

“*Date of issuance*” means the date of issuance of the medical cannabidiol registration card by the department of ~~transportation~~.

“*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~~ Chronic pain.
 10. Severe, intractable autism with self-injurious or aggressive behaviors.
 11. Post-traumatic stress disorder.

~~40~~12. Any medical condition that is recommended by the medical cannabidiol board and adopted by the board of medicine by rule pursuant to Iowa Code section 124E.5 and that is listed in 653—subrule 13.15(1).

“Health care practitioner” means an individual licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, a physician assistant licensed under Iowa Code chapter 148C, an advanced registered nurse practitioner licensed under Iowa

Code chapter 152, or an advanced practice registered nurse under Iowa Code chapter 152E who is a patient’s primary care provider or a podiatrist licensed pursuant to Iowa Code chapter 149. ~~“Health care practitioner” shall not include a physician assistant licensed under Iowa Code chapter 148C or an advanced registered nurse practitioner licensed pursuant to Iowa Code chapter 152 or 152E.~~

“*Laboratory*” means the state hygienic laboratory at the University of Iowa or any other independent medical cannabidiol testing facility accredited to Standard ISO/IEC 17025 by an ISO-approved international organization for standards-approved accrediting body, with a controlled substance registration certificate from the Drug Enforcement Administration of the U.S. Department of Justice and a certificate of registration from the Iowa board of pharmacy, and approved by the department to examine, analyze, or test samples of medical cannabidiol or any substance used in the manufacture of medical cannabidiol. For the purposes of these rules, an independent laboratory is a laboratory operated by an entity that has no equity ownership in a medical cannabidiol manufacturer.

“*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 designated in this chapter.

ITEM 2. Adopt the following **new** definition of “*Total tetrahydrocannabinol*” in rule **641—154.1(124E)**:

“*Total tetrahydrocannabinol*” means eighty-seven and seven-tenths percent of the amount of tetrahydrocannabinolic acid plus the amount of tetrahydrocannabinol.

ITEM 3. Rescind the definitions of “Department of transportation” and “Untreatable pain” in rule **641—154.1(124E)**.

ITEM 4. Amend paragraph **154.2(1)“a”** as follows:

a. Determine, in the health care practitioner’s medical judgment, whether the patient whom the health care practitioner has examined and treated suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol as defined by this chapter, and if so determined, provide the patient with a written certification of that diagnosis by completing the health care practitioner section of the application form provided for this purpose on the department’s website (www.idph.iowa.gov).

(1) If the health care practitioner provides written certification that a patient’s qualifying debilitating medical condition is a terminal illness with a life expectancy of less than one year, the health care practitioner shall determine an appropriate total tetrahydrocannabinol cap. The health care practitioner shall indicate the total tetrahydrocannabinol cap on the written certification.

(2) If the health care practitioner determines that four and one-half grams of total tetrahydrocannabinol in a ninety-day period is insufficient to treat a patient’s qualifying debilitating medical condition, and the patient has participated in the medical cannabidiol program, the health care practitioner may recommend a higher total tetrahydrocannabinol cap. The health care practitioner shall indicate the higher total tetrahydrocannabinol cap on the written certification.

ITEM 5. Amend rules 641—154.3(124E) to 641—154.4(124E) as follows:

641—154.3(124E) Medical cannabidiol registration card—application and issuance to patient.

154.3(1) Subject to subrule 154.3(7), the department ~~may approve the issuance of~~ issue a

medical cannabidiol registration card ~~by the department of transportation~~ to a patient who:

- a.* Is at least 18 years of age.
- b.* Is a permanent resident of Iowa.
- c.* Submits a written certification to the department, provided to the patient pursuant to rule 641—154.2(124E) and signed by the patient’s health care practitioner certifying 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~~ and available at the department’s website (www.idph.iowa.gov), that contains all of the following:

(1) The patient’s full legal name, Iowa residence address, mailing address (if different from the patient’s residence address), telephone number, date of birth, and sex designation. The patient shall not provide as a mailing address an address for which a forwarding order is in place.

(2) A copy of the patient’s valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver’s license,
2. A valid Iowa nonoperator’s identification card, or
3. An alternative form of valid photo identification. A patient who possesses or is eligible for an Iowa driver’s license or an Iowa nonoperator’s identification card shall present such document as valid photo identification. A patient who is ineligible to obtain an Iowa driver’s license or an Iowa nonoperator’s identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A patient who applies for an exemption is subject to verification of the patient’s identity through a process established by the department ~~and the department of transportation~~ to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(3) Full name, address, and telephone number of the patient's health care practitioner.

(4) Full legal name, residence address, date of birth, and telephone number of each primary caregiver of the patient, if any.

(5) An attestation as to the truthfulness and accuracy of the information provided by the patient on the application.

e. ~~Has not been convicted of a disqualifying felony offense.~~

f. Submits the required fee, as described in subrule 154.12(1).

154.3(2) Upon the completion, verification, and approval of the patient's application and the receipt of the required fee, the department shall ~~issue~~ notify the department of transportation that the patient may be issued a medical cannabidiol registration card to the patient.

154.3(3) A medical cannabidiol registration card issued to a patient by the department ~~of transportation~~ shall contain all of the following:

a. The patient's full legal name, Iowa residence address, date of birth, and sex designation, as shown on the patient's Iowa driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1) "d"(2)"3." If the patient's name, Iowa residence address, date of birth, or sex designation has changed since the issuance of the patient's Iowa driver's license, nonoperator's identification card, or alternative form of valid photo identification, the patient shall first update the patient's Iowa driver's license or nonoperator's identification card to reflect the current information, according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321), or shall update the alternative form of valid photo identification in accordance with the process of the issuing agency.

b. The date of issuance and the date of expiration, which shall be one year from the date of

issuance.

c. A distinguishing registration number that is not the patient's social security number.

~~*d.* The patient's signature. The signature shall be without qualification and shall contain only the patient's usual signature without any other titles, characters, or symbols. The patient's signature certifies, under penalty of perjury and pursuant to the laws of the state of Iowa, that the statements made and information provided in the patient's application for a medical cannabidiol registration card are true and correct. The patient's signature shall be captured electronically.~~

e. A color photograph of the patient.

~~*f.d.* A statement that the medical cannabidiol registration card is not valid for identification purposes.~~

154.3(4) Every patient 18 years of age or older must obtain a valid medical cannabidiol registration card to use medical cannabidiol in Iowa. ~~The department may waive this requirement for a patient who is unable to obtain a card because of health, mobility, or other issues, but only when the patient:~~

~~— *a.* Has submitted an application for a medical cannabidiol registration card;~~

~~— *b.* Has had the application approved by the department;~~

~~— *c.* Has been assigned a patient registration number;~~

~~— *d.* Has designated a primary caregiver whose application has been approved and whose medical cannabidiol registration card has been issued; and~~

~~— *e.* Complies with all provisions of Iowa Code chapter 124E.~~

154.3(5) An authorization to use medical cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E or these rules for the issuance of a medical cannabidiol registration card.

154.3(6) A valid medical cannabidiol registration card, or its equivalent, issued under the laws of another state that allow an out-of-state patient to possess or use medical cannabidiol in the jurisdiction of issuance shall have the same force and effect as a valid medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E, except that an out-of-state patient in Iowa shall not obtain medical cannabidiol from a medical cannabidiol dispensary in Iowa.

154.3(7) The department shall not ~~issue~~ ~~approve the issuance of~~ a medical cannabidiol registration card for a patient who is enrolled in a federally approved clinical trial for the treatment of a debilitating medical condition with medical cannabidiol.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 4489C**, IAB 6/5/19, effective 7/10/19]

641—154.4(124E) Medical cannabidiol registration card—application and issuance to primary caregiver.

154.4(1) For a patient in a primary caregiver’s care, the department may ~~approve the issuance of~~ ~~issue~~ a medical cannabidiol registration card ~~by the department of transportation~~ to a primary caregiver who:

- a. Is at least 18 years of age.
- b. Submits a written certification to the department, provided to the patient pursuant to rule 641—154.2(124E) and signed by the patient’s health care practitioner certifying that the patient is suffering from a debilitating medical condition.
- c. Submits an application as a primary caregiver for each patient for whom the person is the primary caregiver. The primary caregiver application must be on a form created by the department ~~in consultation with the department of transportation~~ and available at the department’s website (www.idph.iowa.gov) that contains all of the following:

(1) The primary caregiver's full legal name, residence address, mailing address (if different from the primary caregiver's residence address), telephone number, date of birth, and sex designation. The primary caregiver shall not provide as a mailing address an address for which a forwarding order is in place.

(2) The patient's full legal name, date of birth, and parent or legal guardian's name if the patient is under the age of 18.

(3) A copy of the primary caregiver's valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. If the primary caregiver is not a resident of the state of Iowa, a valid state-issued driver's license or nonoperator's identification card issued by a state other than Iowa, or
4. An alternative form of valid photo identification. A primary caregiver who possesses or is eligible for a driver's license or a nonoperator's identification card shall present such document as valid photo identification. A primary caregiver who is ineligible to obtain a driver's license or a nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A primary caregiver who applies for an exemption is subject to verification of the primary caregiver's identity through a process established by the department and the department of transportation to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(4) Full name, address, and telephone number of the patient's health care practitioner.

(5) An attestation as to the truthfulness and accuracy of the information provided by the primary caregiver on the application.

~~*d.* Has not been convicted of a disqualifying felony offense.~~

ed. Submits the required fee, as described in subrule 154.12(2).

154.4(2) Upon the completion, verification, and approval of the primary caregiver's application, the department shall ~~notify the department of transportation that the primary caregiver may be issued~~ issue a medical cannabidiol registration card to the primary caregiver.

154.4(3) A medical cannabidiol registration card issued to a primary caregiver ~~by the department of transportation~~ shall contain all of the following:

a. The primary caregiver's full legal name, current residence address, date of birth, and sex designation, as shown on the primary caregiver's state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.4(1) "*c*"(3)"4." If the primary caregiver's name, current residence address, date of birth, or sex designation has changed since issuance of the primary caregiver's Iowa-issued driver's license, nonoperator's identification card, or other form of valid photo identification, the primary caregiver shall first update the primary caregiver's Iowa-issued driver's license or nonoperator's identification card according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321) or update the alternative form of valid photo identification in accordance with the process of the issuing agency.

b. The date of issuance and the date of expiration, which shall be one year from the date of issuance.

c. A distinguishing registration number that is not the primary caregiver's social security number.

d. The medical cannabidiol registration number for each patient in the primary caregiver's care. This number shall not be the primary caregiver's or patient's social security number. If the

patient in the primary caregiver's care is under the age of 18, the full name of the patient's parent or legal guardian shall be printed on the primary caregiver's registration card in lieu of the patient's medical cannabidiol registration number.

~~e. The primary caregiver's signature. The signature shall be without qualification and shall contain only the primary caregiver's usual signature without any other titles, characters, or symbols. The primary caregiver's signature certifies, under penalty of perjury and pursuant to the laws of the state of Iowa, that the statements made and information provided in the primary caregiver's application for a medical cannabidiol registration card are true and correct. The primary caregiver's signature shall be captured electronically.~~

~~f. A color photograph of the primary caregiver.~~

~~g. A statement that the medical cannabidiol registration card is not valid for identification purposes.~~

~~h. A statement distinguishing the medical cannabidiol registration cardholder as a primary caregiver.~~

154.4(4) A patient who is 18 years of age or older must have an approved application and a distinguishing medical cannabidiol registration number that is not the patient's social security number prior to the issuance of a medical cannabidiol registration card to the patient's primary caregiver.

154.4(5) An authorization to use, or to act as a primary caregiver for a patient authorized to use, cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E or these rules for the issuance of a medical cannabidiol registration card.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

~~641—154.5(124E) Tamperproofing.~~ The department of transportation shall issue a medical cannabidiol registration card by a method or process which prevents as nearly as possible the alteration, reproduction, or superimposition of a photograph on the cannabidiol registration card without ready detection.

~~[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]~~

641—154.6(124E) Denial and cancellation. The department may deny an application for a medical cannabidiol registration card, or may cancel ~~or direct the department of transportation to cancel~~ a medical cannabidiol registration card, for any of the following reasons:

1. Information contained in the application is illegible, incomplete, falsified, misleading, deceptive, or untrue.
2. The department ~~or the department of transportation~~ is unable to verify the identity of the applicant from the photo identification or other documentation presented pursuant to paragraph 154.3(1) “d”(2)“3” or 154.4(1) “c”(3)“4.”
3. The applicant violates or fails to satisfy any of the provisions of Iowa Code chapter 124E or these rules.
4. A patient, the patient’s legal guardian, or other person with durable power of attorney requests in writing that the department cancel the patient’s medical cannabidiol registration card. The department shall notify a primary caregiver in writing when the registration card of the primary caregiver’s patient has been canceled.
5. A primary caregiver requests in writing that the department cancel the primary caregiver’s medical cannabidiol registration card. The department shall notify a patient in writing when the registration card of the patient’s primary caregiver has been canceled.
6. The department becomes aware of the death of a patient or primary caregiver.

ITEM 6. Amend rule 641—154.8(124E) as follows:

641—154.8(124E) Duplicate card.

154.8(1) *Lost, stolen, or destroyed card.* To replace a medical cannabidiol registration card that is lost, stolen, or destroyed, a cardholder shall present to the department of transportation the cardholder's valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1) "d"(2)"3" or 154.4(1) "c"(3)"4."

154.8(2) *Change in card information and voluntary replacement.*

a. To replace a medical cannabidiol registration card that is damaged, the cardholder shall surrender to the department of transportation the card to be replaced and present the cardholder's valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1) "d"(2)"3" or 154.4(1) "c"(3)"4."

b. A patient or primary caregiver to whom a medical cannabidiol registration card is issued shall notify the department of a change in current residence address, name, or sex designation listed on the card, within ten calendar days of the change. To replace a medical cannabidiol registration card to change the current residence address, name, or sex designation listed on the card, the cardholder shall surrender to the department of transportation the card to be replaced and present a valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1) "d"(2)"3" or 154.4(1) "c"(3)"4" that has been updated according to the procedures established by the state or agency of issuance to reflect the requested residence address, name, or sex designation.

c. To replace a medical cannabidiol registration card held by a primary caregiver to change, add, or remove a patient's medical cannabidiol registration number or the name of a patient's

parent or legal guardian listed on the primary caregiver's card, the primary caregiver shall submit a new application to the department pursuant to rule 641—154.4(124E). A medical cannabidiol registration card issued pursuant to this paragraph shall not be considered a duplicate card.

154.8(3) Expiration date. A duplicate medical cannabidiol registration card shall have the same expiration date as the medical cannabidiol registration card being replaced, changed, or amended.

ITEM 7. Amend rule 641—154.10(124E) as follows:

641—154.10(124E) Confidentiality. The department shall maintain a confidential file of the names of each patient to or for whom the department ~~issues~~ approves the issuance of a medical cannabidiol registration card and the name of each primary caregiver to whom the department issues a medical cannabidiol registration card under Iowa Code section 124E.4.

154.10(1) Personally identifiable information of patients and primary caregivers shall be maintained as confidential and is not accessible to the public. The department ~~and the department of transportation~~ shall release aggregate and statistical information regarding the medical cannabidiol act registration card program in a manner which prevents the identification of any patient or primary caregiver.

154.10(2) Personally identifiable information of patients and primary caregivers may be disclosed under the following limited circumstances:

a. To authorized employees or agents of the department ~~and the department of transportation~~ as necessary to perform the duties of the department ~~and the department of transportation~~ pursuant to Iowa Code chapter 124E and these rules.

b. To authorized employees of state or local law enforcement agencies located in Iowa, solely for the purpose of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E and these rules.

c. To a patient, primary caregiver, or health care practitioner, upon written authorization of the patient or primary caregiver.

d. To a health care practitioner for the purpose of determining whether a patient seeking a written certification pursuant to Iowa Code section 124E.3 and these rules has already received a written certification from another health care practitioner.

e. To authorized employees of a medical cannabidiol dispensary, but only for the purposes of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E and these rules and that a person has not purchased total tetrahydrocannabinol in excess of the amount authorized by Iowa Code chapter 124E and these rules.

ITEM 8. Rescind and reserve rule **641—154.11(124E)**.

ITEM 9. Amend rule 641—154.14(124E) as follows:

641—154.14(124E) Allowable Form forms and quantity of medical cannabidiol. ~~The forms and quantity of medical cannabidiol authorized in this rule may be modified pursuant to recommendations by the medical cannabidiol board, subsequent approval of the recommendations by the board of medicine and adoption of the recommendations by the department by rule.~~

154.14(1) Modification of allowable forms. Quantity. ~~A 90-day supply is the maximum amount of each product that shall be dispensed by a dispensary at one time.~~ The allowable forms of medical cannabidiol authorized in this rule may be modified pursuant to recommendations by the medical cannabidiol board, subsequent approval of the recommendations by the board of medicine and adoption of the recommendations by the department by rule.

154.14(2) Allowable Form Forms.

a. A manufacturer may only manufacture medical cannabidiol in the following forms:

(1) Oral forms, including but not limited to:

1. Tablet.
2. Capsule.
3. Liquid.
4. Tincture.
5. Sublingual.

(2) Topical forms, including but not limited to:

1. Gel.
2. Ointment, cream or lotion.
3. Transdermal patch.

(3) Inhaled forms, limited to:

1. Nebulizable.
2. Vaporizable.

(4) Rectal/vaginal forms, including but not limited to suppository.

b. A manufacturer may not produce medical cannabidiol in any form that may be smoked.

c. A manufacturer may not produce medical cannabidiol in an edible form as defined in rule

641—154.1(124E).

ITEM 10. Amend subrule 154.40(4) as follows:

154.40(4) *Establishment and maintenance of a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available 24 hours a day, seven days a week to track:

- a.* Inventory of medical cannabidiol and waste material;
- b.* Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

c. Total tetrahydrocannabinol purchased in the last ninety days by a patient and the patient's primary caregiver.

ITEM 11. Amend rule 641—154.41(124E) as follows:

641—154.41(124E) Dispensary operations.

154.41(1) Operating documents. The operating documents of a dispensary shall include all of the following:

a. Procedures for the oversight of the dispensary, including descriptions of operational and management practices regarding:

(1) The forms and quantities of medical cannabidiol products that will be stored and dispensed at the dispensary;

(2) The estimated forms and quantities of medical cannabidiol waste to be generated or collected;

(3) The disposal methods for all waste materials;

(4) Employee training methods for the dispensary employees;

(5) Strategies for identifying and reconciling discrepancies in inventory of medical cannabidiol;

(6) Procedures to ensure the dispensary does not dispense more than a patient's certified cap of total tetrahydrocannabinol to a patient and the patient's primary caregiver(s) in a ninety-day period.

~~(7)~~ Medical cannabidiol labeling procedures;

~~(8)~~ Procedures for recall or market withdrawal of medical cannabidiol;

~~(9)~~ Plans for responding to a security breach at the dispensary facility;

~~(10)~~ A business continuity plan; and

~~(114)~~ Other information requested by the department.

b. Procedures to ensure accurate record keeping.

c. Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas of the dispensary facility containing medical cannabidiol.

154.41(2) Prohibited activities.

a. A person or entity shall not own or operate a dispensary unless the person or entity is licensed by the department pursuant to Iowa Code chapter 124E and these rules.

b. A dispensary shall not:

(1) Dispense medical cannabidiol in any location except in those areas approved by the department;

(2) Sell, receive, transport, or distribute medical cannabidiol from any location except its dispensary;

(3) Sell, receive, or distribute medical cannabidiol from any entity other than a manufacturer licensed by the department;

(4) Sell or distribute medical cannabidiol to any person other than an approved patient or primary caregiver;

(5) Sell or distribute more than four and one-half grams of total tetrahydrocannabinol to a patient and the patient's primary caregiver(s) in a ninety-day period, unless the patient's health care practitioner has certified a higher total tetrahydrocannabinol cap.

~~(56)~~ Transport or deliver medical cannabidiol to any location, unless approved by the department;

~~(67)~~ Sell medical cannabidiol that is not packaged and labeled in accordance with rules 641—

154.21(124E) and 641—154.46(124E);

(~~78~~) Repackage medical cannabidiol or remove the manufacturer's label;

(~~89~~) Sell medical cannabidiol in any form or quantity other than a form or quantity approved by the department and adopted by rule;

(~~910~~) Permit any person to consume medical cannabidiol on the property of the dispensary;

(~~1011~~) Employ a person who is under 18 years of age or who has been convicted of a disqualifying felony offense.

154.41(3) *Criminal background checks.*

a. An owner of a dispensary shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

b. An employee of a dispensary shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

c. An applicant or licensed dispensary shall respond within 30 days to a request from the department or the department of public safety for more information to complete a background investigation and national criminal history background check on an owner, investor, or employee.

154.41(4) *Relationship to health care practitioners.* A dispensary shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.

154.41(5) *Employment of a pharmacist or pharmacy technician.* A medical cannabidiol dispensary shall employ a pharmacist or pharmacy technician licensed or registered pursuant to Iowa Code chapter 155A for the purpose of making dosing recommendations.

ITEM 12. Amend rule 641—154.46(124E) as follows:

641—154.46(124E) Dispensing.

154.46(1) *Access to all forms of product.* A dispensary shall provide access to all medical cannabidiol forms produced by each licensed manufacturer.

154.46(2) *Dispensing to a patient.*

a. Prior to dispensing any medical cannabidiol to a patient, a dispensary shall do all of the following:

(1) Verify the patient's identity; using a valid photo ID. Acceptable photo identification includes:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. U.S. Passport,
4. U.S. Military ID or Veteran ID,
5. Tribal ID Card/Document.

(2) Verify that the patient is registered and listed in the secure sales and inventory tracking system and has a valid medical registration card;

(3) Check the secure sales and inventory tracking system for the patient's total tetrahydrocannabinol ninety-day purchase cap and the amount of total tetrahydrocannabinol that the patient and the patient's caregiver(s) have purchased on behalf of the patient in the past ninety days to ensure that the amount of total tetrahydrocannabinol sold by the dispensary to the patient does not exceed the patient's cap.

(~~3~~4) Assign a tracking number to any medical cannabidiol that is to be dispensed to the patient;

(~~4~~5) Issue a label that contains the following information:

1. The medical cannabidiol tracking number; and

2. The patient registration number;

(56) Ensure the following information, which may be printed on a secondary label or package insert, is issued with dispensed medical cannabidiol:

1. The date and time the medical cannabidiol is dispensed;
2. The name and address of the dispensary;
3. Any specific instructions for use based upon manufacturer guidelines or department rules.

Text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

b. The dispensary shall record the patient name, the amount dispensed, the price, the medical cannabidiol tracking number, the time and date, and other information required by the department in the secure sales and inventory tracking system within one business day.

154.46(3) *Dispensing to a primary caregiver.*

a. Prior to dispensing any medical cannabidiol to a primary caregiver, a dispensary shall do all of the following:

(1) Verify the primary caregiver's identity; using a valid photo ID. Acceptable photo identification includes:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. U.S. Passport,
4. U.S. Military ID or Veteran ID,
5. Tribal ID Card/Document.

(2) Verify that the patient and the primary caregiver are registered and listed in the secure sales and inventory tracking system and have valid medical registration cards;

(3) Check the secure sales and inventory tracking system for the associated patient's total tetrahydrocannabinol ninety-day purchase cap and the amount of total tetrahydrocannabinol that the patient and patient's caregiver(s) have purchased on behalf of the patient in the past ninety days to ensure that the amount of total tetrahydrocannabinol sold by the dispensary to the caregiver does not exceed the patient's cap.

(34) Assign a medical cannabidiol tracking number to any medical cannabidiol that is to be dispensed to the primary caregiver;

(45) Issue a label that contains the following information:

1. The medical cannabidiol tracking number; and
2. The patient registration number;

(56) Ensure the following information, which may be printed on a secondary label or package insert, is issued with dispensed medical cannabidiol:

1. The date and time the medical cannabidiol is dispensed;
2. The name and address of the dispensary;
3. Any specific instructions for use based upon manufacturer guidelines or department rules.

Text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

b. The dispensary shall record the names of the patient and primary caregiver, the amount dispensed, the price, the medical cannabidiol tracking number, the time and date, and other information required by the department in the secure sales and inventory tracking system within one business day.

ITEM 13. Amend subrule 154.60(2) as follows:

154.60(2) Responsibilities of the board include but are not limited to:

a. 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 Iowa Code chapter 124E.

b. Making recommendations to the board of medicine 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 Iowa Code chapter 124E would be medically beneficial.

c. Working with the department regarding the requirements for the licensure of manufacturers and dispensaries, including licensure procedures.

d. Advising the department regarding the location of manufacturers and dispensaries throughout the state.

e. Making recommendations to the board of medicine relating to the form and quantity of allowable medical uses of cannabidiol.

~~f. Considering recommendations to the general assembly for statutory revisions to the definition of medical cannabidiol to increase the tetrahydrocannabinol (THC) level to more than 3 percent.~~

~~g.~~ Submitting an annual report to the general assembly detailing the activities of the board no later than January 1.

ITEM 14. Amend subrule 154.61(4) as follows:

154.61(4) Board meetings.

a. The board shall convene at least twice ~~but no more than four times a~~ per year.

b. Board meetings shall be conducted in accordance with the open meetings requirements of Iowa Code chapter 21.

c. The department's office of medical cannabidiol shall schedule the time, date and location

of meetings.

d. A majority of the members shall constitute a quorum for conducting business of the board.

e. An affirmative vote of a majority of the board members present at a meeting is required for a motion to pass.

