

**PUBLIC HEALTH DEPARTMENT[641]**

**Adopted and Filed**

**Rule making related to the medical cannabidiol program**

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

*Legal Authority for Rule Making*

This rule making is adopted under the authority provided in Iowa Code chapter 124E.11.

*State or Federal Law Implemented*

This rule making implements, in whole or in part, Iowa Code sections 124E.2, 124E.4 and 124E.11.

*Purpose and Summary*

These amendments implement necessary updates to the rules regarding the medical cannabidiol program to formalize waivers currently in effect, reduce compliance burden for licensees and the Department, reduce barriers for veteran participation, and provide additional authority to certifying practitioners. Updates include:

- Providing certifying practitioners the authority to request cancellation of a patient’s medical cannabidiol registration card for reasons including, but not limited to, suspected abuse or fraud and violation of health network standard operating procedures;
- Clarifying registration card application language based on program evaluation;
- Formalizing administrative rule waivers that are currently in effect, including for waste disposal processes;
- Striking the real-time requirement for transmission of manufacturing data to the Department to allow for the implementation of a simpler, more cost-effective solution;
- Removing certain low-value waste tracking requirements because of unnecessary difficulties with tracking for licensees and enforcement for the Department;
- Allowing veterans to be eligible for the reduced application fee option when enrolling in the program when confirming documentation is provided.

*Public Comment and Changes to Rule Making*

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on January 26, 2022, as **ARC 6159C**.

The Department received one comment requesting the inclusion of a grace period between the date the written request for card cancellation is received and the effective date of the card cancellation. After discussion about the potential impacts of cancellations for the reasons set forth in rule 641—154.6(124E), the Department determined a 30-day grace period is necessary in some situations for the patient or primary care giver to receive sufficient notice of the card cancellation following the Department’s receipt of the request to cancel the registration card. Consequently, a new Item 5 has been added to amend rule 641—154.7(124E) to include a 30-day grace period when cancellation of the card is due to receipt of a request for cancellation by a third party. Card cancellations requested by cardholders themselves and upon the Department’s receipt of notification that the cardholder is deceased will be effective as soon as the request is received. The subsequent original Items 5 through 14 have been renumbered as 6 through 15. These refinements are the only changes from the Notice.

*Adoption of Rule Making*

This rule making was adopted by the State Board of Health on May 11, 2022.

*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 provisions contained in 641—Chapter 178.

*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).

*Effective Date*

This rule making will become effective on July 20, 2022.

The following rule-making actions are adopted:

ITEM 1. Renumber subrule **154.2(4)** as **154.2(5)**.

ITEM 2. Adopt the following **new** subrule 154.2(4):

**154.2(4)** A health care practitioner may make a written request to the department to rescind a written certification the practitioner provided to a patient or caregiver, based on reasons deemed appropriate by the health care practitioner.

ITEM 3. Amend subparagraph **154.3(1)“d”(2)** as follows:

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

1. and 2. No change.

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 or unable 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 to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

ITEM 4. Amend rule 641—154.6(124E) as follows:

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

1. to 6. No change.

7. A health care practitioner requests in writing that the department rescind the written certification the practitioner provided to a patient or caregiver.

8. A patient requests in writing that the department cancel the patient's primary caregiver's medical cannabidiol registration card.

ITEM 5. Amend rule 641—154.7(124E) as follows:

**641—154.7(124E) Appeal.**

**154.7(1)** *Written notice of denial or cancellation.* If the department denies an application for or cancels a medical cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation, ~~and~~ state the reasons for the denial or cancellation in writing, ~~and~~ state the effective date of the denial or cancellation. If the department cancels a card upon request from a patient or primary care giver, or the department becomes aware of the death of a patient or primary caregiver, the cancellation is effective immediately upon issuance of the written notice of cancellation. If the department cancels a card upon any other ground listed in rule 641—154.6(124E), the cancellation shall become effective 30 days following issuance of the written notice of cancellation.

**154.7(2)** *Effect of written notice of cancellation on use and possession of medical cannabidiol.* A cardholder is authorized to purchase, possess, and use medical cannabidiol up to and including the effective date of the cancellation. For purposes of the affirmative defenses in Iowa Code section 124E.12, a patient or primary caregiver shall be deemed to be in possession of a valid medical cannabidiol registration card up to and including the effective date of the cancellation.

**154.7(3)** *Request for appeal.* An applicant or cardholder may appeal the denial or cancellation of a medical cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department's address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173. In the event of a timely appeal of a cancellation of a medical cannabidiol registration card, cancellation of the card shall be deemed to be suspended pending the outcome of the contested case proceeding. If the cancellation is affirmed following the contested case proceeding, the card cancellation shall become effective 30 days following issuance of the department's final agency action.

ITEM 6. Amend subrule 154.9(1) as follows:

**154.9(1)** A cardholder seeking renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department ~~at least 60 days prior to the date of expiration.~~

a. and b. No change.

ITEM 7. Amend subrule 154.12(1) as follows:

**154.12(1)** *Patient medical cannabidiol registration card fee.*

a. Each application fee is \$100 unless the patient qualifies for a reduced fee as described in paragraph 154.12(1) "b."

b. Each reduced application fee is \$25 if the patient attests to receiving social security disability benefits, supplemental security income payments, proof of veteran status, or is enrolled in the medical assistance program as defined in rule 641—154.1(124E).

~~c. Each renewal fee is the same as the initial card application fee.~~

ITEM 8. Amend subrule 154.16(4) as follows:

**154.16(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 plant material, and medical cannabidiol, ~~and waste material;~~

b. to e. No change.

ITEM 9. Amend subparagraph **154.17(1)“b”(1)** as follows:

(1) Procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:

1. to 3. No change.
4. ~~The estimated types and amounts of medical cannabidiol waste and plant material waste to be generated;~~
5. 4. The disposal methods for all waste materials;
6. 5. Employee training methods for the specific phases of production. A manufacturer may make operating documents for these procedures available on site only;
7. 6. Biosecurity measures and standard operating procedures used in the production and manufacturing of medical cannabidiol. A manufacturer may make operating documents for these procedures available on site only;
8. 7. Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;
9. 8. Sampling strategy and quality testing for labeling purposes. A manufacturer may make operating documents for these procedures available on site only;
10. 9. Medical cannabidiol packaging and labeling procedures;
11. 10. Procedures for recall and market withdrawal of medical cannabidiol;
12. 11. Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary. A manufacturer may make operating documents for these procedures available on site only;
13. 12. A business continuity plan. A manufacturer may make this operating document available on site only;
14. 13. Records relating to all transport activities; and
15. 14. Other information requested by the department.

ITEM 10. Amend paragraph **154.17(2)“e”** as follows:

*e.* Sell or distribute medical cannabidiol to any person or business other than a dispensary or manufacturer licensed by the department under Iowa Code chapter 124E;

ITEM 11. Amend rule 641—154.22(124E) as follows:

**641—154.22(124E) Transportation of medical cannabidiol and plant material.**

**154.22(1)** *Transport of medical cannabidiol.* A manufacturer is authorized to transport medical cannabidiol to and from:

- a.* to *c.* No change.
- d.* A manufacturer licensed by the department under Iowa Code chapter 124E;
- ~~*e.*~~ Other sites only with departmental approval.

**154.22(2)** *Transport of plant material.* A manufacturer is authorized to transport cannabis plant material from its manufacturing facility to:

- a.* A waste disposal site;
- b.* A manufacturer licensed by the department under Iowa Code chapter 124E;
- ~~*c.*~~ Other sites only with departmental approval.

**154.22(3)** *Chain-of-custody tracking system.*

- a.* No change.
- b.* Before transporting medical cannabidiol, a manufacturer shall:
  - (1) Record in the secure sales and inventory tracking system or on the manifest information about the material to be transported; and
  - (2) Notify the dispensary, laboratory, manufacturer licensed by the department under Iowa Code chapter 124E, or waste facility, as applicable, of the expected arrival time and transmit a copy of the manifest to the dispensary, laboratory, manufacturer, or waste facility, if applicable.
- c.* to *e.* No change.

**154.22(4)** No change.

ITEM 12. Amend rule 641—154.23(124E) as follows:

**641—154.23(124E) Disposal of medical cannabidiol and plant material.**

**154.23(1)** No change.

**154.23(2)** *Medical cannabidiol and plant material waste.* A manufacturer shall store, secure, and manage medical cannabidiol waste and plant material waste in accordance with all applicable federal, state, and local regulations.

*a. and b.* No change.

*c.* Before transport of plant material waste, the manufacturer shall render the plant material waste unusable and unrecognizable, ~~by grinding and incorporating the waste with a greater quantity of noneconsumable, solid wastes including:~~

~~(1) Paper waste;~~

~~(2) Cardboard waste;~~

~~(3) Food waste;~~

~~(4) Yard waste;~~

~~(5) Vegetative wastes generated from industrial or manufacturing processes that prepare food for human consumption;~~

~~(6) Soil; or~~

~~(7) Other waste approved by the department.~~

**154.23(3)** No change.

**154.23(4)** *Waste-tracking requirements.* A manufacturer shall ~~use forms approved by the department to maintain accurate and comprehensive records regarding waste material. The records shall account for, reconcile, and evidence all waste activity related to the disposal of medical cannabidiol waste and plant material waste.~~

ITEM 13. Amend subparagraph **154.24(3)“c”(4)** as follows:

(4) Inventory records, ~~including disposal of waste.~~

ITEM 14. Amend subrule 154.24(4) as follows:

**154.24(4)** *Entry into the department’s secure sales and inventory tracking system.* Unless otherwise provided in these rules, a manufacturer shall adhere to the following schedule for entering data into the department’s secure sales and inventory tracking system.

*a.* A manufacturer shall enter data in real time for data related to:

(1) Transport of medical cannabidiol, plant material, waste material, and laboratory samples; and

(2) Sales of medical cannabidiol to dispensaries.

*b.* A manufacturer shall enter data on changes to inventory of plant material, and medical cannabidiol, ~~and waste material~~ by the end of the business day in which the changes occurred.

*c.* No change.

ITEM 15. Amend subrule 154.27(3) as follows:

**154.27(3)** ~~*Real-time inventory*~~ *Inventory tracking required.* A manufacturer shall use the department-approved secure sales and inventory tracking system to track medical cannabidiol production from seed or plant cutting through distribution of medical cannabidiol to a dispensary. The manufacturer shall use the system to maintain a ~~real-time~~ record of the manufacturer’s inventory of plant material and medical cannabidiol to include:

*a.* The quantity and form of medical cannabidiol maintained by the manufacturer at the manufacturing facility on a daily basis;

*b.* The amount of plants being grown at the manufacturing facility on a daily basis; and

~~*c.* The names of the employees or employee conducting the inventory; and~~

~~*d. c.*~~ *c.* Other information deemed necessary and requested by the department.

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 6/15/22.