ARC 6159C

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Proposing rule making related to the medical cannabidiol program and providing an opportunity for public comment

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.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

The proposed 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.

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.

Public Comment

Any interested person may submit written 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 February 15, 2022. 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 actions are proposed:

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 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 6. 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 7. 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 8. 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 9. 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 10. 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;

~~*d.*~~ *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;

~~*b.*~~ *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 11. 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 nonconsumable, 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 12. Amend subparagraph **154.24(3)"c"(4)** as follows:

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

ITEM 13. 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 14. 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.* Other information deemed necessary and requested by the department.