ARC 4928C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Rule making related to 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 section 124E.11.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 124E.

Purpose and Summary

These amendments are primarily intended to address concerns raised by MedPharm Iowa, LLC (MPI) and the Administrative Rules Review Committee (ARRC) at the July 2019 ARRC meeting regarding **ARC 4489C** where a session delay was imposed by the ARRC for Items 1, 4, 7, 10, 11, 12, 13, 15, 21, 22, and 24 in **ARC 4489C**. The Department met with representatives from MPI to understand the details of the concerns raised and appeared at the ARRC meeting in October as requested for a special review of this rule making. These amendments are intended to address the concerns raised by MPI and the ARRC. All session-delayed items are addressed in this rule making with the exception of **ARC 4489C**, Item 4, which relates to health care practitioner certification, duties and prohibitions.

In addition to the aforementioned, these amendments clarify that while manufacturers must continue to track all cannabis plants at all times, plants can be assigned to a "batch" for tracking at the time of harvest instead of at the time of planting. Additional amendments include:

- Revisions to the definitions of "batch" and "batch number" to accomplish the objective described above;
- Revisions to allow a manufacturer to designate a single employee for the transport of medical cannabidiol to dispensaries;
- Revisions to allow a manufacturer to use product samples returned from a laboratory for research and development or to conduct stability studies;
- Revisions to the processes for product recalls to allow for a more thorough investigation prior to recall; and
- Revisions to simplify a manufacturer's data disclosures in relation to crop inputs and plant batches.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on November 20, 2019, as **ARC 4772C**. No public comments were received.

In its Notice of Intended Action, **ARC 4772C**, published in the November 20, 2019, Iowa Administrative Bulletin, the Department proposed removing the specific restriction on advertising that was previously session-delayed. The Department agreed to remove the specific restriction on advertising based on existing rules of the Board of Medicine. At its meeting on January 8, 2020, the State Board of Health expressed concerns with removing the advertising restriction and voted to approve these amendments with the exception of Item 2 as proposed in **ARC 4772C**. Item 2 of the Notice was not adopted, and the remaining items have been renumbered accordingly.

Adoption of Rule Making

This rule making was adopted by the State Board of Health on January 8, 2020.

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.

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 March 18, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend rule **641—154.1(124E)**, definitions of "batch" and "batch number," as follows:

"Batch" means a ~~set of cannabis plants that are grown, harvested, and processed together, such that they are exposed to substantially similar conditions throughout cultivation and processing~~ specifically identified quantity of dried flower and other cannabis plant matter that is uniform in strain or cultivar, harvested at the same time, and cultivated using the same pesticides and other crop inputs.

"Batch number" means a unique numeric or alphanumeric identifier assigned to a batch of cannabis plants by a manufacturer when the batch is ~~first planted~~ harvested. The batch number shall contain the manufacturer's number and a sequence to allow for inventory and traceability.

ITEM 2. Amend subrule 154.16(7) as follows:

154.16(7) *Recall of medical cannabidiol products.* ~~The department may require a manufacturer to recall medical cannabidiol from dispensaries when there is potential for serious health consequences from use of the products as determined by the department. Situations that may require a recall include but are not limited to:~~ Medical cannabidiol products may be recalled in the following ways:

~~*a.* After consultation with the department's medical director, it is determined that the distribution, sale, or use of the medical cannabidiol creates or poses an immediate and serious threat to human life or health; and~~

~~*b.* Other procedures available to the department to prevent or remedy a situation would result in an unreasonable delay that may place the health of patients at risk.~~

a. By manufacturer. Recalls may be undertaken voluntarily and at any time by a licensed manufacturer.

b. By department. If the department determines, based on an evaluation of the health hazard presented, that there is a reasonable probability that use of, or exposure to, a violative medical cannabidiol product will cause a serious adverse health consequence or death, the department may

require a manufacturer to recall such violative medical cannabidiol products from dispensaries. An evaluation of the health hazard presented by medical cannabidiol being considered for recall shall be conducted by an ad hoc committee of scientists appointed by the director of the department and shall take into account, but need not be limited to, each of the following factors:

(1) Whether any disease or injuries have already occurred from the use of the medical cannabidiol.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(7) The findings of the department during a directed inspection of the licensed manufacturing facility.

ITEM 3. Amend subrule 154.22(4) as follows:

154.22(4) *Vehicle requirements for transport.*

a. A manufacturer shall ensure that all medical cannabidiol transported on public roadways is:

(1) Packaged in tamper-evident, bulk containers;

(2) Transported so it is not visible or recognizable from outside the vehicle; and

(3) Transported in a vehicle that does not bear any markings to indicate that the vehicle contains medical cannabidiol or bears the name or logo of the manufacturer.

b. When the motor vehicle contains medical cannabidiol, manufacturer employees who are transporting the medical cannabidiol on public roadways shall:

(1) Travel directly to a dispensary or other department-approved locations; and

(2) Document refueling and all other stops in transit, including:

1. The reason for the stop;
2. The duration of the stop; and
3. The location of the stop.

c. If the vehicle must be stopped due to an emergency situation, the employee shall notify 911 and complete an incident report on a form approved by the department.

d. Under no circumstance shall any person other than a designated manufacturer employee have actual physical control of the motor vehicle that is transporting the medical cannabidiol.

e. ~~A manufacturer shall staff all motor vehicles with a minimum of two employees when transporting medical cannabidiol between a manufacturing facility and a dispensary. At least one employee shall remain with the motor vehicle at all times that the motor vehicle contains medical cannabidiol.~~ A single employee may transport medical cannabidiol to the laboratory.

f. ~~Each~~ An employee in a transport motor vehicle shall have telephone or other communication access with the manufacturer's personnel and have the ability to contact law enforcement via telephone or other method at all times that the motor vehicle contains medical cannabidiol.

g. An employee shall carry the employee's identification card at all times when transporting or delivering medical cannabidiol and, upon request, produce the identification card to the department or to a law enforcement officer acting in the course of official duties.

h. A manufacturer shall not leave a vehicle that is transporting medical cannabidiol unattended overnight.

ITEM 4. Amend subrule 154.23(1) as follows:

154.23(1) *Return of medical cannabidiol from dispensaries and laboratory.* ~~A manufacturer shall collect at no charge medical cannabidiol waste from dispensaries and from the laboratory that has tested samples submitted by the manufacturer. A manufacturer shall:~~

a. A manufacturer shall collect at no charge medical cannabidiol waste from dispensaries. A manufacturer shall:

(1) Collect medical cannabidiol waste from each dispensary on a schedule mutually agreed upon by the manufacturer and dispensary;

~~*c.*~~ (2) Dispose of medical cannabidiol waste as provided in subrule 154.23(2); and

~~*d.*~~ (3) Maintain a written record of disposal that includes:

~~(1)~~ 1. The tracking number assigned at the time of the dispensing, if available, or the name of the patient, if the tracking number is unavailable, when the medical cannabidiol was returned to the dispensary from a patient or primary caregiver;

~~(2)~~ 2. The date the medical cannabidiol waste was collected;

~~(3)~~ 3. The quantity of medical cannabidiol waste collected; and

~~(4)~~ 4. The type and lot number of medical cannabidiol waste collected.

b. ~~Collect medical cannabidiol waste from a laboratory on a schedule mutually agreed upon by the manufacturer and laboratory;~~ A manufacturer shall collect at no charge medical cannabidiol and medical cannabidiol waste from a laboratory that has tested samples submitted by the manufacturer. A manufacturer shall:

(1) Collect medical cannabidiol and medical cannabidiol waste from a laboratory on a schedule mutually agreed upon by the manufacturer and laboratory.

(2) Maintain a written record of return that includes:

1. The date the medical cannabidiol and medical cannabidiol waste were collected;

2. The quantity of medical cannabidiol and medical cannabidiol waste collected; and

3. The type and lot number of medical cannabidiol collected.

(3) A manufacturer may use medical cannabidiol returned from a laboratory for research and development or retained samples, but a manufacturer shall not introduce medical cannabidiol returned from a laboratory into lots or products intended for sale.

(4) A manufacturer shall dispose of medical cannabidiol waste returned from a laboratory as provided in subrule 154.23(2).

ITEM 5. Amend subrule 154.25(2) as follows:

154.25(2) *Crop inputs and plant batches.*

~~*a.* All crop inputs used by a manufacturer must be approved by the department prior to the first application of the input. A manufacturer shall email a request for approval of a crop input to the department. The subject line of the email shall read, "RESPONSE REQUIRED – Crop input approval request." The department shall have up to 48 hours to respond with an approval or denial. A manufacturer may proceed with the application if the department does not reply within 48 hours of receiving the request. A crop input will remain approved unless or until the department withdraws the approval because of newly discovered product safety concerns. The department shall give a manufacturer written notification 48 hours before withdrawing an approval of a crop input.~~

~~*b.*~~ *a.* The manufacturer shall use the department's secure sales and inventory tracking system to maintain an electronic record of all crop inputs. The record shall include the following:

(1) The date of input application;

(2) The name of the employee applying the crop input;

(3) The crop input that was applied;

(4) The plants that received the application; and

~~(5) The amount of crop input that was applied; and~~

~~(6)~~ (5) A copy of or electronic link to the safety data sheet for the crop input applied.

~~*c.*~~ *b.* At the time of ~~planting~~ harvesting, all plants shall be tracked in a batch process with a unique batch number that shall remain with the batch through final processing into medical cannabidiol.

~~*d.* A manufacturer shall record any removal of plants from the batch, including the reason for removal, on a record maintained at the manufacturing facility for at least five years.~~

~~*e.*~~ *c.* Each batch or part of a batch of cannabis plants that contributes to a lot of medical cannabidiol shall be recorded in the department's secure sales and inventory tracking system or other manifest system.

ITEM 6. Amend subrule 154.40(7) as follows:

154.40(7) *Recall of medical cannabidiol products.* ~~The department may require a dispensary to recall medical cannabidiol from the dispensary facility and patients when there is potential for serious health consequences from use of the products as determined by the department. Situations that may require a recall include but are not limited to:~~ If the department determines, based on an evaluation of the health hazard presented, that there is a reasonable probability that use of, or exposure to, a violative medical cannabidiol product will cause a serious adverse health consequence or death, the department may require a dispensary to recall such violative medical cannabidiol products from the dispensary facility and from patients. An evaluation of the health hazard presented by medical cannabidiol being considered for recall shall be conducted by an ad hoc committee of scientists appointed by the director of the department and shall take into account, but need not be limited to, each of the following factors:

~~*a.* After consultation with the department's medical director, it is determined that the distribution, sale, or use of the medical cannabidiol creates or poses an immediate and serious threat to human life or health, and~~

~~*b.* Other procedures available to the department to prevent or remedy a situation would result in an unreasonable delay that may place the health of patients at risk.~~

a. Whether any disease or injuries have already occurred from the use of the medical cannabidiol.

b. Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

c. Assessment of hazard to various segments of the population, e.g., children, who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

d. Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

e. Assessment of the likelihood of occurrence of the hazard.

f. Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

g. The findings of the department during a directed inspection of the licensed manufacturing facility.

[Filed 1/21/20, effective 3/18/20]
[Published 2/12/20]
EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 2/12/20.