ARC 4078C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Rule making related to medical cannabidiol

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 sections 17A.3(1)"b," 124E.11(2) and 136.3(9).

State or Federal Law Implemented

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

Purpose and Summary

These amendments revise the laboratory testing procedures for medical cannabidiol products to require that the majority of the testing be conducted at the process lot stage, as opposed to the product lot stage. Testing for product potency and microbial contaminants will still be required at the product lot stage. This change will assist in controlling laboratory testing costs for the regulated community and still meet the goal of ensuring that products are free of contaminants. In addition, the amendments also clarify that the detected concentration of cannabinoids may not vary from the labeled concentration by more than 15 percent. The amendments also clarify that discrepancies discovered during inventory reconciliation processes need to be reported to law enforcement only when it is suspected that product or plant material diversion has occurred. This change will ensure that law enforcement resources are utilized most efficiently, that is, only when the reconciliation process reveals possible diversion. Finally, the amendments require that an action plan be initiated when a reconciliation process differs from the inventory recorded in the state's seed-to-sale tracking system.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on July 18, 2018, as **ARC 3899C**. The Department received three comments on the proposed amendments. The following changes were incorporated in response to the comments. The changes clarify guidance to manufacturers on sampling and laboratory testing procedures.

1. In Item 1, subrule 154.26(2) is amended to add a new paragraph "f."
2. In subparagraph 154.26(3)"b"(2) in Item 1, minor edits have been made to remove the words "and microbiological toxins" from both sentences of the subparagraph.
3. In Item 1, subparagraph 154.26(4)"a"(1) is amended to add the words "and departmental guidance pursuant to subrule 154.69(1)" after the word "criteria."
4. Item 6 contains a new adopted rule that will be the first rule under the heading "Laboratory Testing."
5. Item 7 amends rule 641—154.71(124E) to add new subrules 154.71(3) and 154.71(4).
6. The original Item 6 in the Notice has been renumbered as Item 8.

Adoption of Rule Making

This rule making was adopted by the State Board of Health on September 12, 2018.

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 variance and 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 November 14, 2018.

The following rule-making actions are adopted:

ITEM 1. Amend subrules 154.26(2) to 154.26(4) as follows:

154.26(2) *Sampling protocols.* A manufacturer shall develop and follow written procedures for sampling medical cannabidiol that require the manufacturer to:

a. Conduct sample collection in a manner that provides analytically sound and representative samples;

b. Document every sampling event and provide this documentation to the department upon request;

c. Describe all sampling and testing plans in written procedures that include the sampling method and the number of units per lot to be tested;

d. Ensure that random samples from each lot are:

(1) Taken in an amount necessary to conduct the applicable test;

(2) Labeled with the lot number; and

(3) Submitted for testing; ~~and~~

e. Retain the results from the random samples for at least five years~~.~~; and

f. Notify the department at least two business days prior to sample collection and allow the department or its designees to be present to observe the sampling procedures when the samples are to be sent to a laboratory for testing.

154.26(3) *Sampling and testing.* A manufacturer shall:

a. Work with the department and laboratory personnel to develop acceptance criteria for all potential contaminants based on the levels of metals, microbes, or other contaminants that the manufacturer uses in cultivating and producing medical cannabidiol;

b. Conduct sampling and testing of all medical cannabidiol lots using acceptance criteria that are protective of patient health. ~~At a minimum, testing of lots shall occur after packaging but before transport or sale to a dispensary.~~ The sampling and testing results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol meet allowable health risk limits for contaminants~~;~~. Testing of lots shall occur as follows:

(1) At a minimum, testing of lots for cannabinoid potency and all microbiological impurities except microbiological toxins shall occur after packaging but before transport or sale to a dispensary;

(2) At a minimum, testing of lots for residual solvents and processing chemicals, pesticides, and metals shall occur at the process lot stage. A packaged product that contains medical cannabidiol solely from process lots that passed laboratory testing for residual solvents and processing chemicals, pesticides, and metals does not need to be retested for these analytes provided that solvents and processing chemicals are not used during the processing into the packaged product;

(3) Testing of lots for residual solvents and processing chemicals shall also occur after packaging but before transport or sale to a dispensary if solvents or processing chemicals are used in the production process after the testing of the process lot has occurred;

c. Refrain from packaging or selling medical cannabidiol from a process lot that fails to meet established standards, specifications, and any other relevant quality control criteria. Medical cannabidiol from a process lot that fails quality assurance testing may be remixed and retested;

d. Reject and destroy medical cannabidiol from a lot that fails to meet established standards, specifications, and any other relevant quality control criteria ~~except for potency of CBD and THC. Medical cannabidiol from a lot that fails quality assurance testing based on potency of CBD or THC may be remixed and retested~~ when remixing and retesting are not warranted;

e. Develop and follow a written procedure for responding to results failing to meet established standards, specifications, and any other relevant quality control criteria, including:

(1) Criteria for when remixing and retesting are warranted;

(2) Instructions for destroying contaminated or substandard medical cannabidiol as provided in subrule 154.23(2) when remixing and retesting are not warranted; and

(3) Instructions for determining the source of contamination;

f. Retain documentation of test results, assessment, and destruction of medical cannabidiol for at least five years.

154.26(4) *Stability testing.*

a. The quality assurance program shall include procedures for performing stability testing of each product type produced to determine product expiration dates. The procedures shall describe:

(1) Sample size and test intervals based on statistical criteria and departmental guidance pursuant to subrule 154.69(1) for each attribute examined to ensure valid stability estimates;

(2) Storage conditions for samples retained for testing; and

(3) Reliable and specific test methods.

b. Stability studies shall include:

(1) Medical cannabidiol testing at appropriate intervals; and

(2) Medical cannabidiol testing in the same container-closure system in which the medical cannabidiol is marketed and dispensed.

c. If product-expiration-date studies have not been completed before December 1, 2018, a manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information. A manufacturer shall concurrently conduct stability studies to determine the actual product expiration date.

d. After a manufacturer verifies the tentative product expiration date, or determines the appropriate product expiration date, a manufacturer shall include that product expiration date on each lot of medical cannabidiol.

e. Stability testing shall be repeated if the manufacturing process or the product's chemical composition is changed.

ITEM 2. Amend subrule 154.27(5) as follows:

154.27(5) *Reconciliation.* No less often than every two calendar weeks, a manufacturer shall reconcile its physical inventory with the inventory recorded in the department's secure sales and inventory tracking system. ~~Inconsistencies shall be reported to the department and law enforcement within 72 hours of discovery. Reconciliation shall include:~~

a. ~~Plant material at the manufacturing facility and in transit; and~~ Reconciliation shall include:

(1) Plant material at the manufacturing facility and in transit; and

(2) Medical cannabidiol at the manufacturing facility, at distribution and storage facilities, and in transit.

b. ~~Medical cannabidiol at the manufacturing facility, at distribution and storage facilities, and in transit.~~ Discrepancies between the physical inventory of the manufacturer and the inventory recorded in the department's secure sales and inventory system shall be handled as follows:

(1) A manufacturer shall report suspected diversion of plant material or medical cannabidiol to the department and law enforcement within 72 hours of discovery.

(2) A manufacturer shall have up to 72 hours to reconcile discrepancies in the manufacturer's physical inventory with the inventory recorded in the secure sales and inventory tracking system. If the manufacturer cannot reconcile the manufacturer's physical inventory with the secure sales and inventory tracking system's inventory within 72 hours but diversion of plant material or medical cannabidiol is not suspected, the manufacturer shall immediately contact the department to report the discrepancy and to initiate a compliance action plan pursuant to paragraph 154.28(4)*"b."*

ITEM 3. Amend subrule 154.28(4) as follows:

154.28(4) *Compliance required.* A manufacturer shall ~~pay for and cooperate in a timely manner with the department's requirement that it undergo an independent health and sanitary inspection in accordance with this rule.~~ respond to deficiencies found during inspections or inventory reconciliation as follows:

a. Deficiencies not related to inventory reconciliation.

(1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a manufacturer shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two weeks to accept or require revision of the action plan.

b. Deficiencies related to inventory reconciliation.

(1) Upon notifying the department that the manufacturer cannot reconcile the manufacturer's physical inventory with the inventory recorded in the department's secure sales and inventory tracking system, the manufacturer shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two business days to accept or require revision of the action plan.

c. Failure to complete actions in the action plan within the timelines mutually agreed upon by the manufacturer and the department shall result in assessment of penalties or in suspension or revocation of a manufacturer license as authorized by these rules.

d. At the department's request and in a timely manner, a manufacturer shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.

ITEM 4. Amend subrule 154.51(3) as follows:

154.51(3) *Reconciliation.* At least once a calendar week, a dispensary shall reconcile all medical cannabidiol at the dispensary with the inventory recorded in the department's secure sales and inventory tracking system. ~~Inconsistencies~~ Discrepancies shall be ~~reported to the department and law enforcement within 24 hours of discovery.~~ handled as follows:

a. A dispensary shall report suspected diversion of medical cannabidiol to the department and law enforcement within 24 hours of discovery.

b. A dispensary shall have up to 24 hours to reconcile the dispensary's physical inventory with the inventory recorded in the secure sales and inventory tracking system. If the dispensary cannot reconcile the dispensary's physical inventory with the secure sales and inventory tracking system's inventory within 24 hours but diversion of product is not suspected, the dispensary shall immediately contact the department to report the discrepancy and to initiate a compliance action plan pursuant to paragraph 154.52(4)*"b."*

ITEM 5. Amend subrule 154.52(4) as follows:

154.52(4) *Compliance required.* A dispensary shall ~~pay for and cooperate in a timely manner with the department's requirement that the dispensary undergo an independent health and sanitary inspection~~

~~in accordance with this rule.~~ respond to deficiencies found during inspections or inventory reconciliation as follows:

a. Deficiencies not related to inventory reconciliation.

(1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a dispensary shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two weeks to accept or require revision of the action plan.

b. Deficiencies related to inventory reconciliation.

(1) Upon notifying the department that the dispensary cannot reconcile the dispensary's physical inventory with the inventory recorded in the department's secure sales and inventory tracking system, the dispensary shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two business days to accept or require revision of the action plan.

c. Failure to complete actions in the action plan within the timelines mutually agreed upon by the dispensary and the department shall result in assessment of penalties or in suspension or revocation of a dispensary license as authorized by these rules.

d. At the department's request and in a timely manner, a dispensary shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.

ITEM 6. Adopt the following **new** rule 641—154.69(124E):

641—154.69(124E) Requirements of the department.

154.69(1) *Laboratory testing requirements and acceptance criteria.* The department shall work with manufacturers and laboratories to create and maintain a document describing required sampling methodology, acceptance criteria, stability-testing procedures, and other guidance for manufacturers and laboratories on testing procedures. The document shall:

a. Describe the minimum number of sample units and reserve samples required for testing by the laboratory;

b. Describe an option for manufacturers to reduce the amount of testing conducted by allowing compositing of sample units or other techniques that reduce the number of tests required without compromising the safety of the products once a manufacturer has satisfactorily completed a control study for a specific extraction or production process;

c. Describe the minimum requirements for sample size and testing intervals for stability testing;

d. Be available on the department's website (www.idph.iowa.gov).

154.69(2) *Review and approval of manufacturer sampling protocols.* The department shall have up to two weeks to review and approve or request revisions to a manufacturer's sampling protocols required pursuant to subrules 154.26(2) and 154.26(3).

154.69(3) *Review and approval of manufacturer stability-testing procedures.* The department shall have up to two weeks to review and approve or request revisions to a manufacturer's stability-testing procedures required pursuant to subrule 154.26(4).

ITEM 7. Amend rule 641—154.71(124E) as follows:

641—154.71(124E) Requirements of a manufacturer.

154.71(1) *Assuming costs.* A manufacturer shall assume the costs for all laboratory testing requested by the department or laboratory for medical cannabis goods produced by the manufacturer.

154.71(2) *Sample waste retrieval.* A manufacturer shall retrieve analyzed samples and waste containing medical cannabis goods from the laboratory at a duration and frequency approved by the department.

154.71(3) *Obtaining approval for sampling protocols.* A manufacturer shall obtain approval from the department for the manufacturer's sampling protocols pursuant to subrule 154.26(2) prior to submitting samples for laboratory testing related to content and contamination.

154.71(4) *Obtaining approval for stability-testing procedures.* A manufacturer shall obtain approval from the department for the manufacturer's stability-testing procedures pursuant to subrule 154.26(4) prior to submitting samples for laboratory testing related to stability testing and product-expiration-date studies.

ITEM 8. Amend subrule 154.72(1) as follows:

154.72(1) *Cannabinoids.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall, at minimum, test for and report measurements for the following cannabinoid analytes:

(1) THC;
(2) THCA;
(3) CBD;
(4) CBDA;
(5) CBG; and
(6) CBN.

b. A laboratory shall report that the primary sample passed THC potency testing if the detected concentration of THC does not exceed 3 percent by weight in milligrams per milliliter (mg/ml) for liquids and milligrams per gram (mg/g) for solids and if the detected concentration of THC does not vary from the manufacturer's labeled concentration by more ~~or less~~ than 15 percent by weight in mg/ml for liquids and mg/g for solids. Thus, a solid product labeled as containing a concentration of THC of 10 mg/g shall have a detected concentration of THC that is no more than 11.50 mg/g and no less than 8.50 mg/g.

c. A laboratory shall report that the primary sample failed THC potency testing if the detected concentration of THC exceeds 3 percent by weight in mg/ml for liquids and mg/g for solids or if the detected concentration of THC varies from the labeled concentration of THC by more ~~or less~~ than 15 percent by weight in mg/ml for liquids and mg/g for solids.

d. A laboratory shall report that the primary sample passed CBD potency testing if the detected concentration of CBD does not vary from the manufacturer's labeled concentration by more ~~or less~~ than 15 percent by weight in mg/ml for liquids and mg/g for solids. Thus, a solid product labeled as containing a concentration of CBD of 10 mg/g shall have a detected concentration of CBD that is no more than 11.50 mg/g and no less than 8.50 mg/g.

e. A laboratory shall report that the primary sample failed potency testing if the detected concentration of CBD varies from the labeled concentration of CBD by more ~~or less~~ than 15 percent by weight in mg/ml for liquids and mg/g for solids.

f. For each cannabinoid analyte test, a laboratory shall issue a certificate of analysis that contains the following:

(1) Concentrations of cannabinoid analytes in mg/ml for liquids and mg/g for solids, or other measures approved by the department.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(1)*"b"* and 154.72(1)*"c."*

g. The laboratory may test for and provide test results for additional cannabinoid analytes if asked to do so by a requester.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 10/10/18.