ARC 4489C

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 sections 124E.2, 124E.4 and 124E.11.

Purpose and Summary

These amendments implement needed updates to the rules to provide proper oversight of the program. These amendments are in response to issues that have become apparent since the program was initiated. Updates include:

- A mechanism to update the list of debilitating conditions when new conditions are approved by the Board of Medicine;
- Revisions to the definitions of "debilitating medical condition," "medical cannabidiol waste," "plant material," and "stability" and the addition of definitions for "investor," "medical cannabidiol tracking number," "owner," and "patient registration number";
- Prohibitions for health care practitioners, including self-certifying, advertising certification services, or accepting remuneration beyond a consultation fee for certifying conditions;
- A mechanism to allow patients and primary caregivers to cancel their registration cards;
- Simplification of labeling requirements for manufacturers and dispensaries; and
- Movement of laboratory testing requirements for manufacturers to the laboratory testing requirements and acceptance criteria document where the requirements can be updated as needed.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on March 27, 2019, as **ARC 4363C**. Twenty-three comments were received from MedPharm Iowa, a licensed manufacturer.

Summary of comments: The commenter asked for a definition of "investor" to be added, as well as for clarifications on the definitions of "plant material," "financial backer," and "principal." The commenter also asked for justification for not allowing health care practitioners to advertise that they certify qualifying medical conditions, suggested that a rule banning medical cannabidiol samples was unnecessary, asked the Department to notify patients when their primary caregiver's card has been canceled, asked for further details on when a recall would be issued by the Department, requested that operating documents with sensitive intellectual property be available only on site, asked that the Department of Public Safety be held to a timeline for completing background checks, asked for clarification of real-time data entry for tasks performed at a manufacturing facility that take time to complete, asked for clarification on processes to review changes to the laboratory testing requirements and acceptance criteria document, asked for consistency in language related to medical cannabidiol waste, asked for the removal of the patient's and primary caregiver's names from the secondary label or package insert, and asked for clarification of who pays for laboratory tests requested by the Department.

Summary of changes: An amendment was made to the definition of "medical cannabidiol waste," a small change to the definition of "plant material" was incorporated, and new definitions of "investor,"

"medical cannabidiol tracking number," and "patient registration number" were added to improve the rules. It was clarified that in order to have the requirement to obtain a medical cannabidiol registration card waived by the Department, a patient must be approved for a medical cannabidiol registration card, have been issued a patient registration number, have an approved primary caregiver, and meet all requirements of Iowa Code chapter 124E. The rules were revised to reflect that the Department agrees to notify patients when the registration card of their primary caregiver has been canceled and to notify a primary caregiver when the patient's registration card has been canceled, that the Department will consult with the Department's medical director prior to issuing a recall, and that a manufacturer may make certain sensitive operating documents available to the Department only on site. Language regarding medical cannabidiol waste was made more consistent throughout the rules. The period of time for a manufacturer to enter data related to changes to inventory of plant material, medical cannabidiol, and waste material was extended to the end of the business day in which the changes occurred. The process for requesting approval of crop inputs was added, as was the process for reviewing and commenting on revisions to the laboratory testing requirements and acceptance criteria document. The requirement for the patient's and primary caregiver's names to be included on a secondary label or package insert was removed, and language relating to field samples was amended to reflect that the requirements for a laboratory to prepare and run a duplicate sample will be described in the laboratory testing requirements and acceptance criteria document.

Adoption of Rule Making

This rule making was adopted by the State Board of Health on May 8, 2019.

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 July 10, 2019.

The following rule-making actions are adopted:

ITEM 1. Amend rule **641—154.1(124E)**, definitions of "Debilitating medical condition," "Medical cannabidiol waste," "Plant material" and "Stability," as follows:

"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 pain.
10. 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).

"Medical cannabidiol waste" means medical cannabidiol that is ~~returned,~~ unused, unwanted, damaged, defective, expired, or contaminated and that is returned to a dispensary or manufacturer for disposal.

"Plant material" means any ~~cannabis~~ plant~~, cutting, trimming, or clone that has roots or that is cultivated with the intention of growing roots~~ of *Cannabis sativa* L. or *Cannabis indica*, or any part thereof, including flowers, leaves, trichomes, and tissue.

"Stability" or *"stable"* means that after storage of an unopened package of medical cannabidiol at a licensed manufacturing facility or dispensary facility, the contents shall not vary in concentrations of THC and CBD by more ~~or less than 15 percent by weight in milligrams per milliliter (mg/ml) for liquids and milligrams per gram (mg/g) for solids from the concentration indicated on the package label~~ than an amount determined by the department and listed in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1). ~~Thus, after storage, a solid product labeled as containing a concentration of CBD of 10 milligrams per gram shall have a detected concentration of CBD that is no more than 11.50 milligrams per gram and no less than 8.50 milligrams per gram.~~

ITEM 2. Adopt the following **new** definitions of "Investor," "Medical cannabidiol tracking number," "Owner" and "Patient registration number" in rule **641—154.1(124E)**:

"Investor" means a person making a cash investment of at least 5 percent interest in an applicant or licensed manufacturer or dispensary with the expectation of receiving financial returns.

"Medical cannabidiol tracking number" means the sales identification number assigned by a dispensary to a transaction at the time of the sale of a medical cannabidiol product.

"Owner" means a person with a 5 percent or greater ownership interest in an applicant or licensed manufacturer or dispensary.

"Patient registration number" means the unique identification number issued to a patient by the department of transportation upon approval of a patient's application by the department as described in these rules.

ITEM 3. Amend rule 641—154.2(124E), catchwords, as follows:

641—154.2(124E) Health care practitioner certification—duties and prohibitions.

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

154.2(4) Health care practitioner prohibitions.

a. A health care practitioner shall not accept, solicit, or offer any form of remuneration from or to any individual, including but not limited to a patient, a primary caregiver, or an employee, investor, or owner of a medical cannabidiol manufacturer or dispensary, to certify a patient's condition, other than

accepting a fee for a patient consultation to determine if the patient should be issued a certification of a qualifying debilitating medical condition.

b. A health care practitioner shall not accept, solicit, or offer any form of remuneration from or to any individual, including but not limited to a patient, a primary caregiver, or an employee, investor, or owner of a medical cannabidiol manufacturer or dispensary, to certify an individual as a primary caregiver for a patient with respect to the use of medical cannabidiol, other than accepting a fee for a consultation to determine if the individual is a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol.

c. A health care practitioner shall not advertise certifying a qualifying debilitating medical condition as one of the health care practitioner's services.

d. A health care practitioner shall not certify a qualifying debilitating medical condition for a patient who is the health care practitioner or a family or household member of the health care practitioner.

e. A health care practitioner shall not be designated to act as a primary caregiver for a patient for whom the health care practitioner has certified a qualifying debilitating medical condition.

f. A health care practitioner shall not receive or provide medical cannabidiol product samples.

ITEM 5. Amend subrule 154.3(4) as follows:

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.

ITEM 6. 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 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 7. Adopt the following **new** subrule 154.16(7):

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:

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.

ITEM 8. Amend rule 641—154.17(124E) as follows:

641—154.17(124E) Manufacturer operations.

154.17(1) *Operating documents.* ~~The operating documents of a manufacturer shall include all of the following:~~

a. A manufacturer shall maintain operating documents that accurately reflect the manufacturer's standard operating procedures. Unless otherwise noted, a manufacturer shall make the operating documents available to the department upon request through secure electronic mail, an electronic file-sharing service, or other secure means.

~~*a.*~~ *b.* The operating documents of a manufacturer shall include all of the following:

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

~~(1)~~ 1. The forms and quantities of medical cannabidiol products that are produced at the manufacturing facility;

~~(2)~~ 2. The methods of planting, harvesting, drying, and storing cannabis. A manufacturer may make operating documents for these procedures available on site only;

~~(3)~~ 3. The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;

~~(4)~~ 4. The estimated types and amounts of medical cannabidiol waste and plant material waste to be generated;

~~(5)~~ 5. The disposal methods for all waste materials;

~~(6)~~ 6. Employee training methods for the specific phases of production. A manufacturer may make operating documents for these procedures available on site only;

~~(7)~~ 7. 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)~~ 8. Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;

~~(9)~~ 9. Sampling strategy and quality testing for labeling purposes. A manufacturer may make operating documents for these procedures available on site only;

~~(10)~~ 10. Medical cannabidiol packaging and labeling procedures;

~~(11)~~ 11. Procedures for recall and market withdrawal of medical cannabidiol;

~~(12)~~ 12. 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)~~ 13. A business continuity plan. A manufacturer may make this operating document available on site only;

~~(14)~~ 14. Records relating to all transport activities; and

~~(15)~~ 15. Other information requested by the department.

~~*b.*~~ (2) Procedures to ensure accurate record keeping.

~~*c.*~~ (3) Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas containing medical cannabidiol. A manufacturer may make operating documents for these procedures available on site only.

c. Operating documents may be trade secrets if designated as such by a manufacturer and shall be considered confidential records pursuant to Iowa Code section 22.7(3).

154.17(2) No change.

154.17(3) *Criminal background investigations.*

a. A manufacturer 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 record check.

b. An employee of a manufacturer 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 manufacturer 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.

154.17(4) No change.

ITEM 9. Amend subrule 154.21(3) as follows:

154.21(3) *Package labeling.*

a. A manufacturer shall ensure that all medical cannabidiol packaging is labeled with the following information:

(1) The name ~~and address~~ of the manufacturer ~~where the medical cannabidiol was manufactured~~;

(2) The medical cannabidiol's primary active ingredients, including concentrations of tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid. Concentrations of tetrahydrocannabinolic acid and cannabidiolic acid may be omitted if the manufacturer uses chemical decarboxylation or other means to substantially remove the acids from the product prior to testing;

~~(3) Directions for use of the product, including recommended and maximum amount by age and weight, if applicable;~~

~~(4)~~ (3) All ingredients of the product shown with common or usual names, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight;

~~(5)~~ (4) Instructions for storage, including light and temperature requirements, if any;

~~(6)~~ (5) Product expiration date;

~~(7)~~ (6) The date of manufacture and lot number;

~~(8)~~ (7) A notice with the statement, including capitalization: "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.";

~~(9)~~ (8) The universal warning symbol provided by the department; and

~~(10)~~ (9) A notice with the statement: "This medical cannabidiol is for therapeutic use only. Use of this product by a person other than the patient listed on the label is unlawful and may result in the cancellation of the patient's medical cannabidiol registration card. Return unused medical cannabidiol to a dispensary for disposal."

b. Labeling text shall not include any false or misleading statements.

c. A package may contain multiple labels if the information required by this rule is not obstructed.

d. ~~Labeling text font size shall be no smaller than 6 point~~ A manufacturer shall ensure that directions for use of the product, including recommended and maximum amount by age and weight, if applicable, are included with the product.

ITEM 10. 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 ~~unused, excess, or expired~~ medical cannabidiol waste from dispensaries~~, including medical cannabidiol that was returned to a dispensary from a patient or primary caregiver,~~ and from the laboratory that has tested samples submitted by the manufacturer. A manufacturer shall:

a. Collect ~~waste~~ medical cannabidiol waste from each dispensary on a schedule mutually agreed upon by the manufacturer and dispensary;

b. Collect ~~waste~~ medical cannabidiol waste from a laboratory on a schedule mutually agreed upon by the manufacturer and laboratory;

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

d. Maintain a written record of disposal that includes:

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

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

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

ITEM 11. Adopt the following **new** subrule 154.24(4):

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 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, medical cannabidiol, and waste material by the end of the business day in which the changes occurred.

c. A manufacturer shall enter data within five business days for data related to:

(1) Application and use of crop inputs and other solvents and chemicals; and

(2) Other manufacturing and production records not related to inventory of plant material, medical cannabidiol, and waste material.

ITEM 12. Amend subrule 154.25(2) as follows:

154.25(2) ~~*Record-keeping and tracking requirements*~~ *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.

~~*a.*~~ *b.* The manufacturer shall use the department's secure sales and inventory tracking system to maintain an electronic record of all crop inputs ~~for at least five years~~. 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;

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

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

~~*b.*~~ *c.* At the time of planting, 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.

~~*c.*~~ *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.

~~*d.*~~ *e.* 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 13. Amend paragraph **154.26(3)"b"** as follows:

b. Conduct sampling and testing of ~~all~~ plant material and medical cannabidiol lots using acceptance criteria that are protective of patient health. 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 plant material and lots shall occur as

~~follows:~~ described in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

~~(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;~~

ITEM 14. Amend paragraph **154.30(1)"j"** as follows:

j. Failure of a manufacturer's business owner or investors to have a satisfactory result in a background investigation or national criminal history background check conducted by the department of public safety and as determined by the department.

ITEM 15. Adopt the following **new** subrule 154.40(7):

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:

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.

ITEM 16. Adopt the following **new** paragraph **154.41(3)"c"**:

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.

ITEM 17. Amend subparagraph **154.46(2)"a"(4)** as follows:

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

1. The medical cannabidiol tracking number; and
2. The ~~date and time the medication is being dispensed~~ patient registration number;
3. ~~The name and address of the dispensary;~~
4. ~~The patient's registry identification number, name, and date of birth;~~
5. ~~The patient's address; and~~
6. ~~Any specific instructions for use based upon manufacturer or departmental guidelines. Labeling text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.~~

ITEM 18. Adopt the following **new** subparagraph **154.46(2)"a"(5)**:

(5) 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.

ITEM 19. Amend subparagraph **154.46(3)"a"(4)** as follows:

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

1. The medical cannabidiol tracking number; and

2. The ~~date and time the medication is being dispensed~~ patient registration number;

~~3. The name and address of the dispensary;~~

~~4. The patient's registry identification number, name, and date of birth;~~

~~5. The primary caregiver's registry identification number, name, and date of birth;~~

~~6. The patient's address; and~~

~~7. Any specific instructions for use based upon manufacturer or departmental guidelines. Labeling text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.~~

ITEM 20. Adopt the following **new** subparagraph **154.46(3)"a"(5)**:

(5) 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.

ITEM 21. Amend paragraph **154.48(2)"a"** as follows:

a. A dispensary shall accept at no charge ~~unused, expired, or unwanted~~ medical cannabidiol waste from any patient or primary caregiver. A dispensary shall provide all medical cannabidiol waste to the manufacturer for disposal.

ITEM 22. Amend subrule 154.69(1) as follows:

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 department shall provide manufacturers and laboratories no less than 14 days in which to comment on proposed revisions to the document, and the department shall provide no less than 30 days' notice before a revision takes effect. 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).

ITEM 23. Adopt the following **new** subrule 154.69(4):

154.69(4) *Establish a laboratory review committee.* The department shall establish a laboratory review committee to assist with the review of applications by laboratories and the establishment of accepted laboratory testing standards and practices.

ITEM 24. 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; and

(4) CBDA~~;~~.

~~(5) CBG; and~~

~~(6) CBN.~~

b. A laboratory shall report that the primary sample passed or failed 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 than 15 percent by weight in mg/ml for liquids and mg/g for solids~~ according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1). ~~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 than 15 percent by weight in mg/ml for liquids and mg/g for solids.~~

~~*d.*~~ *c.* A laboratory shall report that the primary sample passed or failed CBD potency testing ~~if the detected concentration of CBD does not vary from the manufacturer's labeled concentration by more than 15 percent by weight in mg/ml for liquids and mg/g for solids~~ according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1). ~~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 than 15 percent by weight in mg/ml for liquids and mg/g for solids.~~

~~*f.*~~ *d.* 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."*~~ paragraph 154.72(1)*"b."*

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

ITEM 25. Amend paragraph **154.75(2)"d"** as follows:

d. Field duplicate sample. A laboratory shall prepare and run a duplicate sample ~~with every 10 to 20 samples for each analytical method~~ as described in the laboratory testing requirements and acceptance criteria document in subrule 154.69(1). The acceptance criterion between the primary sample and the duplicate sample is less than or equal to 20 percent relative ~~percentage~~ percent difference.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/5/19.