

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Pursuant to the authority of Iowa Code sections 17A.3(1)"b", 124E.10(2) and 136.3(9), the Department of Public Health hereby gives Notice of Intended Action to amend chapter 154, "Medical Cannabidiol Act Registration Card Program," Iowa Administrative Code.

On May 12, 2017, then Governor Branstad signed 2017 Iowa Acts, House File 524, which repealed existing Iowa Code chapter 124D and enacted new Iowa Code chapter 124E, the Medical Cannabidiol Act. The legislation was effective upon enactment. House File 524 expanded the state's existing Medical Cannabidiol Act in a number of ways, including expanding the list of conditions for which a patient is eligible to receive a medical cannabidiol patient or primary caregiver registration card, establishing a Medical Cannabidiol Board, providing for licensure of medical cannabidiol manufacturers and dispensaries, establishing a fee structure for registration cards and licensure applications, and adding a new requirement for a real-time, 24/7 statewide medical cannabidiol registry management and seed to sale tracking system.

These proposed amendments establish operational requirements for medical cannabidiol manufacturers and dispensaries as well as operating procedures for the newly created Medical Cannabidiol Board. The proposed amendments implement the duties of the department as related to manufacturing and dispensing, and establish annual licensing procedures, manufacturer and dispensary operational requirements and prohibited activities, facility security requirements, advertising and marketing restrictions, and requirements for packaging and labeling, medical cannabidiol transportation and disposal, record keeping, medical cannabidiol production, quality assurance and control, supply and inventory tracking, inspections, penalty assessment, license suspension or revocation proceedings and closure of operations.

Any interested person may make written comments or suggestions on the proposed amendments on or before November 14, 2017. Such written comments should be directed to Randy Mayer, Administrator, Office of Medical Cannabidiol, Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th St., Des Moines, Iowa 50219-0075. Comments may be sent by e-mail to randall.mayer@idph.iowa.gov. Due to the aggressive implementation timelines of House File 524, early notice of these proposed amendments was provided to interested stakeholders on September 8, 2017. These stakeholders were invited to provide feedback to the Department prior to filing this Notice, so significant concerns could be addressed at the outset of the rulemaking process.

There will be a public hearing on Friday, December 8, 2017, from 10 a.m. to 12 p.m. in room 517 – 518, Lucas State Office Building. The hearing will also be accessible via operated assisted conference call by dialing 877-844-7358.

Waiver provisions for these rules are located at 64—Chapter 178.

The Department anticipates implementation of 2017 Iowa Acts, House file 524, will cause the expenditure of state funds in excess of \$100,000 per year. Anticipated costs include personnel to oversee the startup and administration of the program, technology solutions that are required by the statute and administrative costs for equipment and office supplies.

After analysis and review of this rulemaking, no impact on jobs has been found.

These amendments are intended to implement 2017 Iowa Acts, House File 524.

The following amendments are proposed.

ITEM 1. Amend **641—Chapter 154**, title, as follows:

MEDICAL CANNABIDIOL ~~ACT~~ REGISTRATION ~~CARD~~ PROGRAM

ITEM 2. Adopt the following new rules 641—154.15(124E) to 641—154.65(124E):

641—154.15(124E) Definitions. For the purpose of rules 641—154.15(124E) to 641—154.65(124E), the following definitions shall apply:

"*Accredited nonpublic school*" means any nonpublic school accredited by the Iowa State Board of Education excluding home schools.

"*Audit*" means a financial review by an independent certified public accountant that includes select scope engagement or other methods of review that analyze operational or compliance issues.

"*Background investigation*" means a thorough review of an entity, owner, investors, and employees conducted by the department of public safety including but not limited to state and national criminal history records, credit records, and internal revenue service records.

"*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.

"*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. The batch number shall contain the manufacturer's number and a sequence to allow for inventory and traceability.

"*Biosecurity*" means a set of preventative measures designed to reduce the risk of transmission of:

1. Infectious diseases in crops;
2. Quarantined pests;
3. Invasive alien species; and
4. Living modified organisms.

"*Cannabis*" means seeds, plants, cuttings, or plant waste material from *Cannabis sativa* L. or *Cannabis indica* used in the manufacture of medical cannabidiol.

“*Crop input*” means any substance applied to or used in the cultivation and growth of a *Cannabis* plant. It includes, but is not limited to, pesticides, fungicides, fertilizers, and other soil or medium amendments.

“*Department*” means the Iowa department of public health.

“*Director*” means the director of the Iowa department of public health.

“*Dispensary*” means an individual or entity licensed by the department to dispense medical cannabidiol to patients and primary caregivers pursuant to Iowa Code chapter 124E and these rules. It includes the employees and agents of the dispensary.

“*Dispensary facility*” means any secured building, space, grounds, and physical structure of a dispensary licensed by the department to dispense medical cannabidiol and where the dispensing of medical cannabidiol is authorized.

“*Dispense*” or “*dispensing*” means to supply medical cannabidiol to patients pursuant to Iowa Code chapter 124E and these rules.

“*Disqualifying felony offense*” means a violation under federal or state law of a felony under federal or state law, which has as an element the possession, use, or distribution of a controlled substance, as defined in 21 U.S.C. §802(6).

“*Edible medical cannabidiol products*” means food items containing medical cannabidiol. It does not include pills, tinctures, oils, or other forms of medical cannabidiol that may be consumed orally or through the nasal cavity that do not contain food or food additives; provided that food or food additives used as carriers, excipients, or processing aids shall not be considered food or food additives.

“*Form and quantity*” means the types and amounts of medical cannabidiol allowed to be dispensed to a patient or primary caregiver as approved by the department subject to recommendation by the

medical cannabidiol board and approval by the board of medicine.

“Health care practitioner” means an individual licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery who is a patient’s primary care provider.

“Health care practitioner” shall not include a physician assistant licensed under Iowa Code chapter 148C or an advanced registered nurse practitioner licensed pursuant to Iowa Code chapter 152 or 152E.

“Inspection” means an on-site evaluation by the department, the department of public safety, or a department-approved independent consultant of facilities, records, personnel, equipment, methodology, and quality assurance practices for compliance with these rules.

“International Electrotechnical Commission” or *“IEC”* means an independent, nongovernmental membership organization that prepares and publishes international standards for all electrical, electronic, and related technologies.

“International Organization for Standardization” or *“ISO”* means an independent, nongovernmental membership organization and the largest developer of voluntary international standards.

“Laboratory” means the state hygienic laboratory at the university of Iowa or other independent medical cannabidiol testing facility accredited to Standard ISO/IEC 17025 by an ISO-approved accrediting body, with a controlled substance registration certificate from the drug enforcement administration of the US department of justice and a certificate of registration from the Iowa Board of Pharmacy, and approved by the department to examine, analyze, or test samples of medical cannabidiol or any substance used in the manufacture of medical cannabidiol.

“Lot” means a specific quantity of medical cannabidiol that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged,

and labeled during a specified time period according to a single manufacturing, packaging, and labeling record.

“Lot number” means a unique numeric or alphanumeric identifier assigned to a lot by a manufacturer when medical cannabidiol is produced. The lot number shall contain the manufacturer’s number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of a lot of medical cannabidiol.

“Manufacture” or *“manufacturing”* means the process of converting harvested *Cannabis* plant material into medical cannabidiol.

“Manufacturer” means an individual or entity licensed by the department to produce medical cannabidiol and distribute it to dispensaries pursuant to Iowa Code chapter 124E and these rules. It includes the employees and agents of the manufacturer.

“Manufacturing facility” means any secured building, space, grounds, and physical structure of a manufacturer for the cultivation, harvesting, packaging, processing, storage, and distribution of *Cannabis* or medical cannabidiol and where access is restricted to designated employees of a manufacturer and escorted visitors.

“Market withdrawal” means the voluntary removal of medical cannabidiol from dispensaries and patients by a manufacturer for minor issues that do not pose a serious health threat.

“Medical cannabidiol” means any pharmaceutical grade cannabinoid found in the plant *Cannabis sativa* L. or *Cannabis indica* or any other preparation thereof that has a tetrahydrocannabinol level of no more than 3 percent and that is delivered in a form approved by the department subject to recommendation by the medical cannabidiol board and approval by the board of medicine.

“Medical cannabidiol waste” means medical cannabidiol that is returned, damaged, defective, expired, or contaminated.

“National criminal history background check” means fingerprint processing through the department of public safety and the federal bureau of investigation (FBI) and review of records on file with national organizations, courts, and law enforcement agencies to the extent allowed by law.

“Patient” means a person who is a permanent resident of the state of Iowa who suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E and these rules.

“Plant material” means any *Cannabis* plant, cutting, trimming, or clone that has roots or that is cultivated with the intention of growing roots.

“Plant material waste” means plant material that is not used in the production of medical cannabidiol in a form allowable under these rules.

“Primary caregiver” means a person who is a resident of this state or a bordering state, including but not limited to a parent or legal guardian, at least 18 years of age, who has been designated by a patient’s health care practitioner as a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol pursuant to Iowa Code chapter 124E and these rules.

“Primary care provider” means any health care practitioner involved in the diagnosis and treatment of a patient’s debilitating medical condition.

“Production” or *“produce”* means:

1. Cultivating or harvesting plant material;
2. Processing or manufacturing; or
3. Packaging of medical cannabidiol.

“Public or private school” means any property operated by a school district, charter school, or

accredited nonpublic school for elementary, middle, or secondary school, or secondary vocation center purposes.

“*Recall*” means the return of medical cannabidiol from patients and dispensaries to a manufacturer because of the potential for serious health consequences from the use of the medical cannabidiol.

“*Restricted access area*” means a building, room, or other contiguous area on the premises where plant material is grown, cultivated, harvested, stored, packaged, or processed for sale under control of the manufacturer, and where no person under the age of 18 is permitted.

MANUFACTURING

641—154.16(124E) Duties of the department.

154.16(1) *Interagency agreements.* The department may enter into any interagency agreements with other state agencies for technical services or other assistance related to the regulation or inspection of manufacturers.

154.16(2) *Notice to law enforcement.* The department shall notify local law enforcement agencies and the department of public safety of the locations of manufacturers. If the department determines there is a threat to public safety, the department shall notify local law enforcement agencies and the department of public safety of any conditions that pose a threat to public safety including but not limited to:

- a. Loss or theft of medical cannabidiol or plant material;
- b. Diversion or potential diversion of medical cannabidiol or plant material;
- c. Unauthorized access to the secure sales and inventory tracking system or other patient and caregiver information system or file; or

d. Other violations of law.

154.16(3) *Inspection of manufacturers.* The department or its agents shall conduct regular inspections of manufacturers and manufacturing facilities as described in rule 154.28.

154.16(4) *Establish and maintain a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available twenty-four hours a day, seven days a week to track:

- a. Inventory of plant material, medical cannabidiol, and waste material;
- b. Transport of plant material, waste material, and laboratory samples;
- c. Application and use of crop inputs and other solvents and chemicals;
- d. Sales of medical cannabidiol to dispensaries;
- e. Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

154.16(5) *License and renew manufacturers.* The department shall issue a request for proposals to select and license by December 1, 2017, up to two manufacturers to manufacture and to possess, cultivate, harvest, transport, package, process, and supply medical cannabidiol within the state consistent with the provisions of Iowa Code chapter 124E and these rules.

- a. To be eligible for licensure, an applicant manufacturer shall provide information on forms and in a manner required by the department of public safety for the completion of a background investigation. In addition, the applicant manufacturer shall submit to the department of public safety necessary funds to satisfy the full reimbursement of costs associated with completing the background investigations. If an applicant manufacturer is not found suitable for licensure as a result of the background investigation, a license shall not be issued by the department.
- b. As a condition for licensure, an applicant manufacturer shall agree to begin supplying

medical cannabidiol to licensed medical cannabidiol dispensaries in Iowa no later than December 1, 2018.

- c. The initial license to manufacture medical cannabidiol shall be valid from December 1, 2017, through November 30, 2018. The license shall be renewed annually unless a manufacturer relinquishes the license, there is a change in state law prohibiting the department from renewing the license, or the license is revoked pursuant to Iowa Code chapter 124E or these rules.
- d. A license to manufacture issued by the department pursuant to these rules is not assignable or transferable.
- e. The department shall consider the following factors in determining whether to select and license a medical cannabidiol manufacturer:
 - (1) The technical expertise of an applicant manufacturer regarding medical cannabidiol;
 - (2) The qualifications of an applicant manufacturer's employees;
 - (3) The long-term financial stability of an applicant manufacturer;
 - (4) The ability to provide appropriate security measures on the premises of an applicant manufacturer.
 - (5) Whether an applicant manufacturer has demonstrated an ability to meet certain medical cannabidiol production needs for medical use regarding the range of recommended dosages for each debilitating medical condition, the range of chemical compositions of any plant of the genus *Cannabis* that will likely be medically beneficial for each of the debilitating medical conditions, and the form or forms of medical cannabidiol that may be appropriate for the approved debilitating medical conditions.
 - (6) An applicant manufacturer's projection of and ongoing assessment of wholesale product

costs.

- f. Pursuant to Iowa Code section 124E.5(1)"b", information submitted during the application process shall be confidential until the licensure process is completed unless otherwise protected from disclosure under state or federal law.
- g. A licensed manufacturer shall submit an application to renew its license with the department at least six months before the license expires on a form created by the department.
- h. The department shall notify a manufacturer of the decision to approve or deny the manufacturer's license by August 1 of the year the renewal application is submitted.

154.16(6) *Collection of fees from manufacturers.* Except as provided in this rule, all fees are nonrefundable, shall be retained by the department, and shall be considered repayment receipts as defined in Iowa Code section 8.2.

a. Fees to the department.

- (1) Each application for licensure as a manufacturer shall include a nonrefundable application fee of \$7,500.00.
- (2) Licensed manufacturers shall pay an annual fee to the department to cover costs associated with regulating and inspecting manufacturers and for other expenses necessary for the administration of the medical cannabidiol program. The department shall assess the fee with the notice of approval of license renewal each year by August 1, payable by the manufacturer to the department no later than December 1.

b. Fees to the department of public safety.

- (1) An applicant manufacturer shall be responsible to reimburse the department of public safety the full cost of conducting background investigations related to an application for

licensure and operation as a licensed manufacturer. The department of public safety shall retain the right to bill a manufacturer for additional background investigations, as needed.

- (2) Each manufacturer submitting an application for licensure shall, at time of application, submit to the department of public safety a deposit of \$10,000 for each business owner subject to a background investigation and a national criminal history background check. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the applicant shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the manufacturer.
- (3) A licensed manufacturer shall pay a deposit of \$200 per employee to the department of public safety for a background investigation and a national criminal history background check on any person being considered for hire as an employee of the manufacturer. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the manufacturer shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the manufacturer. The department shall retain the right to preclude a potential employee from hire based upon the results of the background investigation and national criminal history background check.

641—154.17(124E) Manufacturer operations.

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

of the following:

- a. Procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:
 - (1) The forms and quantities of medical cannabidiol products that are produced at the manufacturing facility;
 - (2) The methods of planting, harvesting, drying, and storing *Cannabis*;
 - (3) The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;
 - (4) The estimated types and amounts of medical cannabidiol waste and plant material waste to be generated;
 - (5) The disposal methods for all waste materials;
 - (6) Employee training methods for the specific phases of production;
 - (7) Biosecurity measures used in the production and manufacturing of medical cannabidiol;
 - (8) Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;
 - (9) Sampling strategy and quality testing for labeling purposes;
 - (10) Medical cannabidiol packaging and labeling procedures;
 - (11) Procedures for recall and market withdrawal of medical cannabidiol;
 - (12) Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary;
 - (13) A business continuity plan;
 - (14) Records relating to all transport activities; and
 - (15) Other information requested by the department.

- b. Procedures to ensure accurate recordkeeping.
- c. 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.

154.17(2) *Prohibited activities.* A manufacturer shall not:

- a. Own or operate a medical cannabidiol manufacturing facility unless the manufacturer is licensed by the department pursuant to Iowa Code 124E and these rules.
- b. Produce or manufacture medical cannabidiol in any location except in those areas approved by the department;
- c. Sell, deliver, transport, or distribute medical cannabidiol from any location except its manufacturing facility or a dispensary facility;
- d. Produce or manufacture medical cannabidiol in Iowa for sales or distribution outside of Iowa;
- e. Sell or distribute medical cannabidiol to any person or business other than a dispensary;
- f. Refuse to sell, deliver, transport, or distribute medical cannabidiol in any form or quantity produced by the manufacturer to a dispensary, unless deemed appropriate in the manufacturer's reasonable business judgment and approved by the department in writing;
- g. Transport or deliver medical cannabidiol to any location except as allowed in subrule 154.22(1);
- h. Sell medical cannabidiol that is not packaged and labeled in accordance with rule 154.21;
- i. Sell medical cannabidiol in any form or quantity other than those approved by the

department subject to recommendation by the medical cannabidiol board and approval by the board of medicine;

- j.* Permit any person to consume medical cannabidiol on the property of the manufacturer.
- k.* Employ a person who is under eighteen years of age or who has been convicted of a disqualifying felony offense.
- l.* Manufacture edible medical cannabidiol products.

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.

154.17(4) *Relationship to health care practitioners.* A manufacturer shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.

641—154.18(124E) Security requirements. The department may request assistance from the department of public safety in ensuring manufacturers meet the security requirements in this rule.

154.18(1) *Visitor logs.* Visitors to the manufacturing facility shall sign visitor manifests with name, date, and times of entry and exit, and shall wear badges that are visible at all times and identify them as visitors.

154.18(2) *Restricted access.* A manufacturer shall use a controlled access system and written

manifests to limit entrance to all restricted access areas of its manufacturing facility and retain a record of all persons who entered the secured areas.

- a. The controlled access system shall do all of the following:
 - (1) Limit access to authorized individuals;
 - (2) Maintain a log of individuals with approved access, including dates of approvals and revocations.
 - (3) Track times of personnel entry to and exit from the facility;
 - (4) Track times of personnel movement between secured areas;
 - (5) Store data for retrieval for a minimum of five years; and
 - (6) Remain operable in the event of a power failure.
- b. Separate written manifests of visitors to restricted areas shall be kept and stored for a minimum of five years if the controlled access system does not include electronic records of visitors to the restricted areas.
- c. A manufacturer shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.
- d. Restricted access areas shall be identified with signs that state: “Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only.”

154.18(3) *Perimeter intrusion detection system.*

- a. Computer-controlled video surveillance system. A manufacturer shall operate and maintain in good working order a computer-controlled, closed-circuit television surveillance system on its premises that operates 24 hours per day, seven days a week, and visually records:
 - (1) All phases of medical cannabidiol production;

- (2) All areas that might contain plant material and medical cannabidiol, including all safes and vaults;
- (3) All points of entry and exit;
- (4) The entrance to the video surveillance control room; and
- (5) Parking areas, which shall have appropriate lighting for the normal conditions of the area under surveillance.

b. Camera specifications. Cameras shall:

- (1) Capture clear and certain identification of any person entering or exiting a manufacturing facility or its parking areas;
- (2) Have the ability to produce a clear, color, still photo live or from a recording;
- (3) Have an embedded date-and-time stamp on all recordings that are synchronized and do not obscure the picture; and
- (4) Continue to operate during a power outage.

c. Video recording specifications.

- (1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.
- (2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.
- (3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.
- (4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

d. Additional requirements. A manufacturer shall maintain all security system equipment

and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. Retention. A manufacturer shall ensure that 24-hour recordings from all video cameras are:

- (1) Available for viewing by the department upon request;
- (2) Retained for at least one year;
- (3) Maintained free of alteration or corruption; and
- (4) Retained longer, as needed, if a manufacturer is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

f. Required signage. A manufacturer shall post a sign in capital letters in a conspicuous location at every entrance to the manufacturing facility that reads, "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."

154.18(4) Security alarm system requirements.

a. A manufacturer shall install and maintain a professionally monitored security alarm system that provides intrusion and fire detection of all:

- (1) Facility entrances and exits;
- (2) Rooms with exterior windows;
- (3) Rooms with exterior walls;
- (4) Roof hatches;
- (5) Skylights; and
- (6) Storage rooms.

b. For the purposes of this subrule, a security alarm system means a device or series of

devices that summons law enforcement personnel during, or as a result of, an alarm condition. Devices may include:

- (1) Hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audio, visual, or electronic signal;
- (2) Motion detectors;
- (3) Pressure switches;
- (4) A duress alarm;
- (5) A panic alarm;
- (6) A holdup alarm;
- (7) An automatic voice dialer; and
- (8) A failure notification system that provides an audio, text, or visual notification of any failure in the surveillance system.

c. A manufacturer's security alarm system and all devices shall continue to operate during a power outage.

d. A manufacturer's security alarm system shall be inspected and all devices tested annually by a qualified alarm vendor. A manufacturer shall provide documentation of the annual inspection and device testing to the department upon request.

154.18(5) *Personnel identification system.* A manufacturer shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the manufacturing facility and that meets the requirements of this subrule and subrule 154.18(1).

a. Requirement for employee identification card. An employee identification card shall contain:

- (1) The name of the employee;
 - (2) The date of issuance and expiration;
 - (3) An alphanumeric identification number that is unique to the employee; and
 - (4) A photographic image of the employee.
- b.* A manufacturer's employee shall keep the identification card visible at all times when in a manufacturing facility, a dispensary, or a vehicle transporting medical cannabidiol.
- c.* Upon termination or resignation of an employee, a manufacturer shall immediately:
- (1) Revoke the employee's access to the manufacturing facility; and
 - (2) Obtain and destroy the employee's identification card, if possible.

641—154.19(124E) Location. All of a manufacturer's manufacturing, cultivating, harvesting, packaging, processing, and storage of medical cannabidiol shall take place in one secured manufacturing facility location at a physical address provided to the department during the licensure and application processes.

154.19(1) Proximity to dispensaries. A manufacturer shall not operate a manufacturing facility at the same physical location as a medical cannabidiol dispensary.

154.19(2) Proximity to schools. A manufacturer shall not operate a manufacturing facility in any location, whether for manufacturing, possessing, cultivating, harvesting, transporting, packaging, processing, storing, or supplying, within one thousand feet of a public or private school existing before the date of the manufacturer's licensure by the department.

641—154.20(124E) Advertising and marketing.

154.20(1) Permitted marketing and advertising activities. A manufacturer may:

a. Display the manufacturer's business name and logo on medical cannabidiol labels, signs, Website, and informational material provided to patients. The name or logo shall not include:

- (1) Images of *Cannabis* or cannabis-use paraphernalia;
- (2) Colloquial references to *Cannabis*;
- (3) Names of *Cannabis* plant strains or varieties;
- (4) Unsubstantiated medical claims; or
- (5) Medical symbols that bear a reasonable resemblance to established medical associations.

Examples of established medical organizations include the American Medical Association or American Academy of Pediatrics. The use of medical symbols is subject to approval by the department.

b. Display signs on the manufacturing facility; and

c. Maintain a business Website that contains the following information:

- (1) The manufacturer's name and contact information;
- (2) The medical cannabidiol forms and quantities manufactured in Iowa; and
- (3) Other information as approved by the department.

d. The business Website shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

e. The department reserves the right to review a manufacturer's marketing and advertising materials and to require a manufacturer to make changes to the content. The department has 30 calendar days following submission to approve or deny marketing and advertising materials of a manufacturer.

154.20(2) Other marketing and advertising activities. A manufacturer shall request and receive

the department's written approval before beginning marketing or advertising activities that are not specified in subrule 154.20(1). The department has 30 calendar days to approve or deny marketing and advertising activity requests from a manufacturer.

154.20(3) *Inconspicuous display.* A manufacturer shall arrange displays of medical cannabidiol, interior signs, and other exhibits to prevent public viewing from outside the manufacturing facility.

641—154.21(124E) Packaging and labeling.

154.21(1) *Medical cannabidiol packaging.* A manufacturer shall package all medical cannabidiol intended for distribution according to the following standards:

- a. Properly package medical cannabidiol in compliance with the United States Poison Prevention Packing Act regarding child-resistant packaging and exemptions for packaging for elderly patients;
- b. Label packaged medical cannabidiol as described in subrule 154.21(3);
- c. Use medical containers that are:
 - (1) Plain;
 - (2) Of sufficient size to accommodate a separate dispensary label containing the information described in rule 154.46;
 - (3) Designed to maximize the shelf life of the contained medical cannabidiol;
 - (4) Tamper-evident; and
 - (5) Child resistant.
- d. Medical cannabidiol packaging shall not bear a reasonable resemblance to commonly available non-medical commercial products.
- e. Medical cannabidiol packaging shall be packaged to minimize its appeal to children and

shall not depict images other than the manufacturer's business name or logo.

154.21(2) Trade names. A manufacturer's medical cannabidiol trade names shall comply with the following standards:

- a. Names that are limited to those that clearly reflect the form's medical cannabidiol nature;
- b. Any name that is identical to, or similar to, the name of an existing non-medical-cannabidiol product is prohibited;
- c. Any name that is identical to, or similar to, the name of an unlawful product or substance is prohibited; and
- d. Any name that contains language that suggests using medical cannabidiol for recreational purposes or for a condition other than a qualifying debilitating medical condition is prohibited.

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 chemical composition, including levels of tetrahydrocannabinol and cannabidiol;
 - (3) Directions for use of the product, including recommended and maximum amount by age and weight, if applicable;
 - (4) 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) Instructions for storage, including light and temperature requirements, if any;
 - (6) Date of expiration;
 - (7) The date of manufacture and lot number;
 - (8) 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) The universal warning symbol provided by the department; and
 - (10) 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 regarding health or physical benefits to the patient.
 - 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.

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. Dispensaries;

- b. A laboratory for testing;
- c. A waste facility for disposal;
- d. 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. Other sites only with departmental approval.

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

a. A manufacturer shall use the secure sales and inventory tracking system, if available, or department-approved manifest system to track shipping of medical cannabidiol. The system shall include a chain of custody that records:

- (1) The name and address of the destination;
- (2) The weight and description of each individual package that is part of the shipment, and the total number of individual packages;
- (3) The date and time the medical cannabidiol shipment is placed into the transport vehicle;
- (4) The date and time the shipment is accepted at the delivery destination;
- (5) The person's identity, and the circumstances, duration, and disposition of any other person who had custody or control of the shipment; and
- (6) Any handling or storage instructions.

b. Before transporting medical cannabidiol, a manufacturer shall:

- (1) Record information about the material to be transported in the secure sales and inventory tracking system or on the manifest; and
- (2) Notify the dispensary, laboratory, or waste facility, as applicable, of the expected arrival

time and transmit a copy of the manifest to the dispensary, laboratory, or waste facility, if applicable.

c. Each transport shall be approved electronically or in writing by:

(1) An authorized manufacturer employee when departing the manufacturing facility; and

(2) An authorized employee of the receiving dispensary, laboratory, or waste facility.

d. An authorized employee at the dispensary, laboratory, or waste facility receiving medical cannabidiol shall:

(1) Verify and document the type and quantity of the transported medical cannabidiol against the information in the secure sales and inventory tracking system or written manifest;

(2) Approve the transport electronically or return a signed copy of the manifest to the manufacturing facility; and

(3) Record the medical cannabidiol that is received as inventory according to rule 154.27 and these rules.

e. A manufacturer shall maintain all manifests for at least five years and make them available upon request of the department.

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. Manufacturer employees who are transporting 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;
 3. The location of the stop; and
 4. All activities of employees exiting the vehicle.
- 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 employee in a transport motor vehicle shall have communication access with the manufacturer's personnel, and have the ability to contact law enforcement 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.

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

154.23(1) *Return of medical cannabidiol from dispensaries and laboratory.* A manufacturer shall collect at no charge unused, excess, or expired medical cannabidiol 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 from dispensaries no less often than once a month;
- b. Collect waste medical cannabidiol from the laboratory on a schedule mutually agreed upon by the manufacturer and laboratory;
- c. Dispose of the returned medical cannabidiol 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 was returned;
 - (3) The quantity of medical cannabidiol returned; and
 - (4) The type and lot number of medical cannabidiol returned.

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. The manufacturer shall dispose of medical cannabidiol waste at a waste facility according to federal and state law, and in a manner which renders it unusable.
- b. The manufacturer shall dispose of plant material waste by composting as follows:
 - (1) At the manufacturing facility, according to federal and state law; or
 - (2) At an approved solid waste composting facility, according to federal and state law.
- c. Before transport, the manufacturer shall render 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) *Liquid and chemical waste disposal.* A manufacturer shall dispose of all liquid and chemical product waste generated in the process of cultivating, manufacturing, and distributing medical cannabidiol in accordance with all applicable federal, state, and local regulations.

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

641—154.24(124E) Record-keeping requirements.

154.24(1) Sales and distribution. A manufacturer shall maintain complete and accurate electronic sales transaction records in the department's secure sales and inventory tracking system, including:

- a. The date of each sale or distribution;
- b. The item number, product name and description, and quantity of medical cannabidiol sold or otherwise distributed; and
- c. The sale price.

154.24(2) Financial transactions. A manufacturer shall maintain records that reflect all financial transactions and the financial condition of the business. The following records shall be maintained for at least five years and made available for review, upon request of the department:

- a. Purchase invoices, bills of lading, sales records, copies of bills of sale, and any supporting documents, to include the items or services purchased, from whom the items were purchased, and the date of purchase;
- b. Bank statements and canceled checks for all business accounts;
- c. Accounting and tax records;
- d. Records of all financial transactions, including contracts and agreements for services performed or services received;

154.24(3) Other records.

- a. A manufacturer shall maintain the following for at least five years and provide to the department upon request:

- (1) All personnel records;

- (2) Records of any theft, loss, or other unaccountability of any medical cannabidiol or plant material;
 - (3) Controlled access system data and visitor manifests;
 - (4) Transport manifests and incident reports; and
 - (5) Records of all samples sent to a testing laboratory and the quality assurance test results.
- b. A manufacturer shall use the department's secure sales and inventory tracking system to maintain the following:
- (1) Crop inputs records;
 - (2) Production records;
 - (3) Transportation records; and
 - (4) Inventory records, including disposal of waste.

641—154.25(124E) Production requirements.

154.25(1) *Cultivation and processing.*

- a. Only a licensed manufacturer is authorized to produce and manufacture medical cannabidiol.
- b. All phases of production shall take place in designated, restricted access areas that are monitored by a surveillance camera system in accordance with rule 154.18.
- c. All areas shall be compartmentalized based on function, and employee access shall be restricted between compartments.
- d. The production process shall be designed to limit contamination. Examples of contamination include mold, fungus, bacterial diseases, rot, pests, nonorganic pesticides, and mildew.

- e. Each production area shall have an open aisle for unobstructed access, observation, and inventory of each plant group.
- f. Biosecurity measures shall be in effect as described in the operating documents pursuant to subrule 154.17(1).

154.25(2) Record-keeping and tracking requirements.

- a. 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 section, including the square footage, that received the application by batch number;
 - (5) The amount of crop input that was applied; and
 - (6) A copy of the label of the crop input applied.
- b. 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. 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. 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.

154.25(3) Production of medical cannabidiol.

- a. A manufacturer shall comply with all state and local building and fire code requirements.
- b. A manufacturer shall obtain approval from the department for use of any hydrocarbon-based extraction process. Examples of a hydrocarbon-based extraction process include the use of butane, ethanol, hexane, and isopropyl alcohol.
- c. Medical cannabidiol shall be prepared, handled, and stored in compliance with the sanitation requirements in this rule.
- d. A manufacturer shall produce shelf-stable, non-perishable forms of medical cannabidiol.
- e. A manufacturer shall ensure that the cannabinoid content of the medical cannabidiol it produces is homogenous.
- f. Each lot of medical cannabidiol shall be assigned a unique lot number and recorded in the department's secure sales and inventory tracking system or other manifest system.

154.25(4) *General sanitation requirements.* A manufacturer shall take all reasonable measures and precautions to ensure that:

- a. Any employee who has a communicable disease does not perform any tasks that might contaminate plant material or medical cannabidiol;
- b. Hand-washing facilities are:
 - (1) Convenient and furnished with running water at a suitable temperature;
 - (2) Located in all production areas; and
 - (3) Equipped with effective hand-cleaning and sanitizing preparations and sanitary towel service or electronic drying devices;
- c. All employees working in direct contact with plant material and medical cannabidiol shall use hygienic practices while on duty, including:
 - (1) Maintaining personal cleanliness; and

- (2) Washing hands thoroughly in a hand-washing area before starting work and at any other time when the hands may have become soiled or contaminated;
- d.* Litter and waste are routinely removed and the operating systems for waste disposal are routinely inspected;
 - e.* Floors, walls, and ceilings are constructed with a surface that can be easily cleaned and maintained in good repair to inhibit microbial growth;
 - f.* Lighting is adequate in all areas where plant material and medical cannabidiol are processed, stored, or sold;
 - g.* Screening or other protection against the entry of pests is provided, including that rubbish is disposed of to minimize the development of odor and the potential for the waste becoming an attractant, harborage, or breeding place for pests;
 - h.* Any buildings, fixtures, and other facilities are maintained in a sanitary condition;
 - i.* Toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals are identified and stored in a separate location away from plant material and medical cannabidiol and in accordance with applicable local, state, or federal law;
 - j.* All contact surfaces, utensils, and equipment used in the production of plant material and medical cannabidiol are maintained in a clean and sanitary condition;
 - k.* The manufacturing facility water supply is sufficient for necessary operations;
 - l.* Plumbing size and design meets operational needs and all applicable state and local laws;
 - m.* Employees have accessible toilet facilities that are sanitary and in good repair; and
 - n.* Plant material and medical cannabidiol that could support the rapid growth of undesirable microorganisms are isolated to prevent the growth of those microorganisms.

154.25(5) Storage.

- a.* A manufacturer shall store plant material and medical cannabidiol during production, transport, and testing to prevent diversion, theft, or loss, including ensuring:

 - (1) Plant material and medical cannabidiol are returned to a secure location immediately after completion of the process or at the end of the scheduled business day; and
 - (2) The tanks, vessels, bins, or bulk containers containing plant material or medical cannabidiol are locked inside a secure area if a process is not completed at the end of a business day.
- b.* A manufacturer shall store all plant material and medical cannabidiol during production, transport, and testing, and all saleable medical cannabidiol:

 - (1) In areas that are maintained in a clean, orderly, and well-ventilated condition; and
 - (2) In storage areas that are free from infestation by insects, rodents, birds, and other pests of any kind.
- c.* To prevent degradation, a manufacturer shall store all plant material and medical cannabidiol in production, transport, and testing, and all saleable medical cannabidiol under conditions that will protect it against physical, chemical, and microbial contamination and deterioration of the product and its container.
- d.* A manufacturer shall maintain a separate secure storage area for medical cannabidiol that is returned from a dispensary, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until the returned medical cannabidiol is destroyed. For purposes of this rule, a separate, secure storage area includes a container, closet, or room that can be locked or secured.

641—154.26(124E) Quality assurance and control.

154.26(1) *Quality control program.* A manufacturer shall develop and implement a written quality assurance program that assesses the chemical and microbiological composition of medical cannabidiol. Assessment includes a profile of the active ingredients, including shelf life, and the presence of inactive ingredients and contaminants. A manufacturer shall use these testing results to determine appropriate storage conditions and expiration dates.

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.

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 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;
- c. Reject a medical cannabidiol lot that fails to meet established standards, specifications, and any other relevant quality-control criteria except for amounts of medical cannabidiol and tetrahydrocannabinol. Lots that fail quality assurance testing based on amounts of medical cannabidiol or tetrahydrocannabinol may be remixed and retested;
- d. Develop and follow a written procedure for responding to results indicating contamination. The procedure shall include destroying contaminated medical cannabidiol and determining the source of contamination; and
- e. 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 shelf life that addresses:
 - (1) Sample size and test intervals based on statistical criteria 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 shelf-life studies have not been completed before December 1, 2018, a manufacturer shall assign a tentative expiration date, 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 expiration date, or determines the appropriate expiration date, a manufacturer shall include that 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.

154.26(5) Reserve samples.

- a. A manufacturer shall retain a uniquely labeled reserve sample that represents each lot of medical cannabidiol and store it under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the medical cannabidiol is marketed, or in one that has similar characteristics. The reserve sample shall consist of at least twice the quantity necessary to perform all the required tests.
- b. A manufacturer shall retain the reserve for at least one year following the lot's expiration date.
- c. After one year, reserve samples shall be destroyed as provided in subrule 154.23(2).

154.26(6) Retesting. If the department deems that public health may be at risk, the department may require the manufacturer to retest any sample of plant material or medical cannabidiol.

154.26(7) Disposal of substandard product. A manufacturer shall dispose of all medical

cannabidiol whose samples fail to meet established standards, specifications, and other relevant quality control criteria as provided in subrule 154.23(2).

154.26(8) *Recall and market withdrawal procedures.* Each manufacturer shall establish a procedure for recalling or withdrawing from the market, as applicable, medical cannabidiol that has a reasonable probability of causing an unexpected or harmful response in a patient population, despite appropriate use, that outweighs the potential benefit of the medical cannabidiol. This procedure shall include:

- a. Factors that make a recall or market withdrawal necessary;
- b. Manufacturer's personnel who are responsible for overseeing the recall or market withdrawal; and
- c. How to notify affected parties of a recall or market withdrawal.

641—154.27(124E) Supply and Inventory.

154.27(1) *Reliable and ongoing supply.* A manufacturer shall provide a reliable and ongoing supply of medical cannabidiol to medical cannabidiol dispensaries.

154.27(2) *Inventory controls and procedures.* A manufacturer shall establish inventory controls and procedures for conducting inventory reviews to prevent and detect any diversion, theft, or loss in a timely manner.

154.27(3) *Real-time inventory 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 its 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;
- c. The names of the employees or employee conducting the inventory; and
- d. Other information deemed necessary and requested by the department.

154.27(4) *Waste inventory.* A manufacturer shall maintain a record of its inventory of all medical cannabidiol waste and plant material waste for disposal.

154.27(5) *Reconciliation.* At the close of business each day, a manufacturer shall reconcile its physical inventory with the secure sales and inventory tracking system. Inconsistencies shall be reported to the department or law enforcement within 24 hours of discovery. Reconciliation shall include:

- a. Plant material at the manufacturing facility and in transit; and
- b. Medical cannabidiol at the manufacturing facility, distribution and storage facilities, and in transit.

154.27(6) *Scales.* All scales used to weigh usable plant material for purposes of these rules shall be certified in accordance with the International Organization for Standardization (ISO)/International Electrotechnical Commission, ISO/IEC Standard 17025, which is incorporated by reference.

641—154.28(124E) *Inspection by department or independent consultant.* A manufacturer is subject to reasonable inspection by the department, a department-approved consultant, or other agency pursuant to Iowa Code chapter 124E and these rules and as authorized by laws and regulations.

154.28(1) *Types of inspections.* Inspections may include:

- a.* Aspects of the business operations;
- b.* The manufacturing facility;
- c.* Vehicles used for transport or delivery of medical cannabidiol or plant material;
- d.* Financial information and inventory documentation;
- e.* Physical and electronic security alarm systems; and
- f.* Other inspections as determined by the department.

154.28(2) *Local safety inspections.* A manufacturer may be subject to inspection of its manufacturing facility and grounds by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local licensing authority restrictions related to medical cannabidiol manufacturing or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

154.28(3) *Health and sanitary inspection.* The department has discretion to determine when an inspection by an independent consultant is necessary. The following is a non-exhaustive list of examples that may justify an independent inspection:

- a.* The department has reasonable grounds to believe that the manufacturer is in violation of one or more of the requirements set forth in these rules or other applicable public health or sanitary laws, rules or regulations; or
- b.* The department has reasonable grounds to believe that the manufacturer was the cause or source of contamination of medical cannabidiol.

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.

641—154.29(124E) Assessment of penalties. The department shall assess to a manufacturer a civil penalty of up to one thousand dollars per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.

641—154.30 Suspension or revocation of a manufacturer license.

154.30(1) The department may suspend or revoke a manufacturer license upon any of the following grounds:

- a.* Submission of false, inaccurate, misleading, or fraudulent information to the department in the application or inspection processes.
- b.* Failure to submit required reports and documents.
- c.* Violation of Iowa Code chapter 124E or these rules, or violation of state or local law related to operation of the licensee.
- d.* Conduct or practices detrimental to the safety, health, or welfare of a patient, primary caregiver, or the public.
- e.* Criminal, civil, or administration action taken against a license or registration in this or another state or country related to manufacturing or dispensing medical cannabidiol.
- f.* False, misleading, or deceptive representations to the department, another state or federal agency, or a law enforcement agency.
- g.* Discontinuance of operation for more than thirty days, unless the department approves an extension of such period for good cause shown.

- h.* Failure to maintain effective controls against diversion, theft, or loss of medical cannabidiol.
- i.* Failure to correct a deficiency within the time frame required by the department.
- j.* Failure of a manufacturer's business owner 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.

154.30(2) The department shall notify the licensee of the proposed action pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

154.30(3) A request for appeal concerning the suspension or revocation of a license shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Office of Medical Cannabidiol, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the suspension or revocation has been or will be removed. After the hearing, or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of suspension or revocation shall become the department's final agency action.

154.30(4) Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals. The information upon which the adverse action is based and any additional information which may be provided by

the aggrieved party shall also be provided to the department of inspections and appeals.

154.30(5) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

154.30(6) When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

154.30(7) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

154.30(8) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

- a.* All pleadings, motions, and rules.
- b.* All evidence received or considered and all other submissions by recording or transcript.
- c.* A statement of all matters officially noticed.
- d.* All questions and offers of proof, objections, and rulings thereon.
- e.* All proposed findings and exceptions.
- f.* The proposed decision and order of the administrative law judge.

154.30(9) The decision and order of the director becomes the department's final agency action

upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

154.30(10) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

154.30(11) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

154.30(12) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

154.30(13) Emergency adjudicative proceedings.

- a.* Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18A to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.
- b.* Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

- (1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;
- (2) Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;
- (3) Whether the licensee required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;
- (4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and
- (5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

- (1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.
- (2) The written emergency adjudicative order shall be immediately delivered to the licensee that is required to comply with the order by utilizing one or more of the following procedures:
 1. Personal delivery.
 2. Certified mail, return receipt requested, to the last address on file with the department.
 3. Fax. Fax may be used as the sole method of delivery if the licensee required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

- (3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.
- (4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the licensee that is required to comply with the order.
- (5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.
- (6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the licensee that is required to comply with the order is the party requesting the continuance.

641—154.31(124E) Closure of operations.

154.31(1) Notice. A manufacturer shall notify the department at least six months before the closure of the manufacturing facility.

154.31(2) Procedures. If a manufacturer ceases operation, the manufacturer shall work with the department to verify the remaining inventory of the manufacturer and ensure that any plant material, plant material waste, and medical cannabidiol is destroyed at a waste facility as provided in subrule 154.23(2).

641—154.32 to 154.39 Reserved.

DISPENSING

641—154.40(124E) Duties of the department.

154.40(1) *Interagency agreements.* The department may enter into any interagency agreements with other state agencies for technical services or other assistance related to the regulation or inspection of dispensaries.

154.40(2) *Notice to law enforcement.* The department shall notify local law enforcement agencies and the department of public safety of the locations of dispensaries. If the department has sufficient cause to believe that there is a threat to public safety, the department shall notify local law enforcement agencies and the department of public safety of any conditions that pose a threat to public safety including but not limited to:

- a. Loss or theft of medical cannabidiol;
- b. Diversion or potential diversion of medical cannabidiol;
- c. Unauthorized access to the secure sales and inventory tracking system or other patient and caregiver information system or file; or
- d. Other violations of law.

154.40(3) *Inspection of dispensaries.* The department or its agents shall conduct regular inspections of dispensaries and their facilities as described in rule 154.52.

154.40(4) *Establish and maintain a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available twenty-four hours a day, seven days a week to track:

- a. Inventory of medical cannabidiol and waste material;
- b. Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

154.40(5) License and renew dispensaries. The department shall issue a request for proposals to select and license by April 1, 2018, up to five dispensaries to dispense medical cannabidiol within the state consistent with the provisions of Iowa Code 124E and these rules.

- a. To be eligible for licensure, an applicant dispensary shall provide information on forms and in a manner required by the department of public safety for the completion of a background investigation. In addition, the applicant dispensary shall submit to the department of public safety necessary funds to satisfy the full reimbursement of costs associated with completing the background investigations. If the applicant dispensary is not found suitable for licensure as a result of the background investigation, a license shall not be issued by the department.
- b. As a condition for licensure, an applicant dispensary shall agree to begin dispensing medical cannabidiol to patients and primary caregivers in Iowa no later than December 1, 2018.
- c. The initial license to dispense medical cannabidiol shall be valid from April 1, 2018, through November 30, 2018. The license shall be renewed annually unless a dispensary relinquishes the license, there is a change in state law prohibiting the department from renewing the license, or the license is revoked pursuant to Iowa Code chapter 124E or these rules.
- d. A license to dispense medical cannabidiol issued by the department pursuant to these rules is not assignable or transferable.
- e. The department shall consider the following factors in determining whether to select and

license a medical cannabidiol dispensary:

- (1) Geographical location of the proposed dispensary facility;
 - (2) The technical expertise of an applicant dispensary's staff regarding medical cannabidiol;
 - (3) The qualifications of an applicant dispensary's employees;
 - (4) The long-term financial stability of an applicant dispensary;
 - (5) The ability of an applicant dispensary to provide appropriate security measures on the premises of the dispensary.
 - (6) An applicant dispensary's projection of and ongoing assessment of retail product costs, including any dispensing fees.
- f.* Pursuant to Iowa Code section 124E.5(1)"b", information submitted during the application process shall be confidential until an applicant dispensary is licensed by the department unless otherwise protected from disclosure under state or federal law.
- g.* A licensed dispensary shall submit an application to renew its license with the department at least six months before the license expires on a form created by the department.
- h.* The department shall notify a dispensary of the decision to approve or deny the dispensary's license by August 1 of the year the renewal application is submitted.

154.40(6) *Collection of fees from dispensaries.* Except as provided in this rule, all fees are nonrefundable, shall be retained by the department, and shall be considered repayment receipts as defined in Iowa Code section 8.2.

- a.* Fees to the department.
- (1) One application is required for each dispensary location.
 - (2) Each application for licensure as a dispensary shall include a nonrefundable application

fee of \$5,000.00 to the department.

- (3) Licensed dispensaries shall pay an annual fee to the department to cover costs associated with regulating and inspecting dispensaries and for other expenses necessary for the administration of the medical cannabidiol program. The department shall assess the fee with the notice of approval of license renewal each year on August 1, payable by the dispensary to the department no later than December 1.

b. Fees to the department of public safety.

- (1) An applicant dispensary shall be responsible to reimburse the department of public safety the full cost of conducting background investigations related to an application for licensure and operation as a licensed dispensary. The department of public safety shall retain the right to bill a dispensary for additional background investigations, as needed.
- (2) Each dispensary submitting an application for licensure shall, at time of application, submit to the department of public safety a deposit of \$10,000 for each business owner subject to a background investigation and a national criminal history background check. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the applicant shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the dispensary.
- (3) A licensed dispensary shall pay a deposit of \$200 per employee to the department of public safety for a background investigation and a national criminal history background check on any person being considered for hire as an employee of the dispensary. Background investigation costs shall be deducted from the funds deposited. If the

background investigation fees exceed the funds deposited, the dispensary shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the dispensary. The department shall retain the right to preclude a potential employee from hire based upon the results of the background investigation and national criminal history background check.

641—154.41(124E) Dispensary operations.

154.41(1) *Operating documents.* The operating documents of a dispensary shall include all of the following:

- a. Procedures for the oversight of the dispensary, including descriptions of operational and management practices regarding:
 - (1) The forms and quantities of medical cannabidiol products that will be stored and dispensed at the dispensary;
 - (2) The estimated forms and quantities of medical cannabidiol waste to be generated or collected;
 - (3) The disposal methods for all waste materials;
 - (4) Employee training methods for the dispensary employees;
 - (5) Strategies for identifying and reconciling discrepancies in inventory of medical cannabidiol;
 - (6) Medical cannabidiol labeling procedures;
 - (7) Procedures for recall or market withdrawal of medical cannabidiol;
 - (8) Plans for responding to a security breach at the dispensary facility;

- (9) A business continuity plan; and
 - (10) Other information requested by the department.
- b. Procedures to ensure accurate recordkeeping.
 - c. Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas of the dispensary facility containing medical cannabidiol.

154.41(2) Prohibited activities.

- a. A person or entity shall not own or operate a dispensary unless the person or entity is licensed by the department pursuant to Iowa Code 124E and these rules.
- b. A dispensary shall not:
 - (1) Dispense medical cannabidiol in any location except in those areas approved by the department;
 - (2) Sell, receive, transport, or distribute medical cannabidiol from any location except its dispensary;
 - (3) Sell, receive, or distribute medical cannabidiol from any entity other than a manufacturer licensed by the department;
 - (4) Sell or distribute medical cannabidiol to any person other than an approved patient or primary caregiver;
 - (5) Transport or deliver medical cannabidiol to any location, unless approved by the department;
 - (6) Sell medical cannabidiol that is not packaged and labeled in accordance with rule 154.45;
 - (7) Repackage medical cannabidiol or remove the manufacturer's label;

- (8) Sell medical cannabidiol in any form or quantity other than those approved by the department and adopted by rule.
- (9) Permit any person to consume medical cannabidiol on the property of the dispensary.
- (10) Employ a person who is under eighteen years of age or who has been convicted of a disqualifying felony offense.

154.41(3) *Criminal background checks.*

- a.* An owner of a dispensary 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.
- b.* An employee of a dispensary 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.

154.41(4) *Relationship to health care practitioners.* A dispensary shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.

641—154.42(124E) Security requirements. The department may request assistance from the department of public safety in ensuring dispensaries meet the security requirements in this rule.

154.42(1) *Restricted access.* A dispensary shall have a controlled access system to limit entrance to all restricted access areas of the dispensary facility. Visitors to restricted access areas shall sign manifests with name, date, and times of entry and exit, if the controlled access system cannot electronically record visitors. Visitors shall wear badges that are visible at

all times and identify them as visitors.

- a. The controlled access system shall do all of the following:
 - (1) Limit access to authorized individuals;
 - (2) Maintain a log of individuals with approved access, including dates of approvals and revocations.
 - (3) Track times of personnel entry to and exit from secured areas;
 - (4) Store data for retrieval for a minimum of five years; and
 - (5) Remain operable in the event of a power failure.
- b. A dispensary shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.
- c. Separate written manifests of visitors to restricted areas shall be kept and stored for a minimum of five years if the controlled access system does not include electronic records of visitors to the restricted areas.
- d. Restricted access areas shall be identified with signs that state: “Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only.”

154.42(2) *Perimeter intrusion detection system.*

- a. Computer-controlled video surveillance system. A dispensary shall operate and maintain in good working order a computer-controlled, closed-circuit television surveillance system on its premises that operates 24 hours per day, seven days a week, and visually records:
 - (1) All areas that might contain medical cannabidiol, including all safes, vaults, and storage areas;
 - (2) All points of entry and exit;

- (3) The entrance to the video surveillance control room; and
- (4) Parking areas, which shall have appropriate lighting for the normal conditions of the area under surveillance.

b. Camera specifications. Cameras shall:

- (1) Capture clear and certain identification of any person entering or exiting a dispensary or its parking areas;
- (2) Have the ability to produce a clear, color, still photo live or from a recording;
- (3) Have an embedded date-and-time stamp on all recordings that are synchronized and do not obscure the picture; and
- (4) Continue to operate during a power outage.

c. Video recording specifications.

- (1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.
- (2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.
- (3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.
- (4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

d. Additional requirements. A dispensary shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. Retention. A dispensary shall ensure that 24-hour recordings from all video cameras are:

- (1) Available for viewing by the department upon request;
 - (2) Retained for at least one year;
 - (3) Maintained free of alteration or corruption; and
 - (4) Retained longer, as needed, if a dispensary is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.
- f.* Required signage. A dispensary shall post a sign in capital letters in a conspicuous location at every entrance to the dispensary that reads, "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."

154.42(3) *Security alarm system requirements.*

- a.* A dispensary shall install and maintain a professionally monitored security alarm system that provides intrusion and fire detection of all:
- (1) Dispensary entrances and exits;
 - (2) Rooms with exterior windows;
 - (3) Rooms with exterior walls;
 - (4) Roof hatches;
 - (5) Skylights; and
 - (6) Storage rooms.
- b.* For the purposes of this subrule, a security alarm system means a device or series of devices that summons law enforcement personnel during, or as a result of, an alarm condition. Devices may include:
- (1) Hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audio, visual, or

- electronic signal;
 - (2) Motion detectors;
 - (3) Pressure switches;
 - (4) A duress alarm;
 - (5) A panic alarm;
 - (6) A holdup alarm;
 - (7) An automatic voice dialer; and
 - (8) A failure notification system that provides an audio, text, or visual notification of any failure in the surveillance system.
- c. A dispensary's security alarm system and all devices shall continue to operate during a power outage.
- d. A dispensary's security alarm system shall be inspected and all devices tested annually by a qualified alarm vendor. A dispensary shall provide documentation of the annual inspection and device testing to the department upon request.

154.42(4) *Personnel identification system.* A dispensary shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the dispensary and that meets the requirements of this subrule and subrule 154.42(1).

- a. Requirement for employee identification card. An employee identification card shall contain:
- (1) The name of the employee;
 - (2) The date of issuance and expiration;
 - (3) An alphanumeric identification number that is unique to the employee; and
 - (4) A photographic image of the employee.

- b. A dispensary's employees shall keep the identification card visible at all times when in a dispensary or a vehicle transporting medical cannabidiol.
- c. Upon termination or resignation of an employee, a dispensary shall immediately:
 - (1) Revoke the employee's access to restricted areas of the dispensary; and
 - (2) Obtain and destroy the employee's identification card, if possible.

641—154.43(124E) Location. All dispensing of medical cannabidiol shall take place in an enclosed facility at one physical address provided to the department during the licensure process.

154.43(1) Proximity to manufacturers. A dispensary shall not operate at the same physical location as a manufacturer.

154.43(2) Proximity to schools. A dispensary shall not operate in any location within one thousand feet of a public or private school existing before the date of the dispensary's licensure by the department.

641—154.44(124E) Advertising and marketing.

154.44(1) Permitted marketing and advertising activities. A dispensary may:

- a. Display the dispensary's business name and logo on medical cannabidiol labels, signs, Website, and informational material provided to patients. The name or logo shall not include:
 - (1) Images of *Cannabis* or cannabis-use paraphernalia;
 - (2) Colloquial references to *Cannabis*;
 - (3) Names of *Cannabis* plant strains or varieties;
 - (4) Unsubstantiated medical claims; or

(5) Medical symbols that bear a reasonable resemblance to established medical associations.

Examples of established medical organizations include the American Medical Association or American Academy of Pediatrics. The use of medical symbols is subject to approval by the department.

b. Display signs on the dispensary; and

c. Maintain a business Website that contains the following information:

(1) The dispensary's name and contact information;

(2) The medical cannabidiol forms and quantities provided;

(3) Medical cannabidiol pricing;

(4) Hours of operation; and

(5) Other information as approved by the department.

d. The business Website shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

e. The department reserves the right to review a dispensary's marketing and advertising materials and to require a dispensary to make changes to the content. The department has 30 calendar days following submission to approve or deny marketing and advertising materials of a dispensary.

154.44(2) *Other marketing and advertising activities.* A dispensary shall request and receive the department's written approval before beginning marketing or advertising activities that are not specified in subrule 154.44(1). The department has 30 calendar days to approve or deny marketing and advertising activity requests from a dispensary.

154.44(3) *Inconspicuous display.* A dispensary shall arrange displays of medical cannabidiol, interior signs, and other exhibits to prevent public viewing from outside the dispensary.

641—154.45(124E) Storage.

154.45(1) *Storage of saleable medical cannabidiol.*

a. A dispensary shall store medical cannabidiol to prevent diversion, theft, or loss, including ensuring:

- (1) Medical cannabidiol is kept in a secure and monitored location within the dispensary; and
- (2) Cabinets or storage containers inside the secure and monitored area are locked at the end of a business day.

b. A dispensary shall store all medical cannabidiol:

- (1) In areas that are maintained in a clean, orderly, and well-ventilated condition;
- (2) In areas that are free from infestation by insects, rodents, birds, and other pests of any kind;
- (3) According to the manufacturer's requirements regarding temperature, light exposure, or other environmental conditions;
- (4) Under conditions that will protect it against physical, chemical, and microbial contamination and deterioration of the product and its container.

154.45(2) *Storage of returned medical cannabidiol.* A dispensary shall maintain a separate secure storage area for medical cannabidiol that is to be returned to a manufacturer for disposal, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until the medical cannabidiol is collected by a manufacturer. For purposes of this subrule, a separate, secure storage area includes a container, closet, or room that can be locked or secured.

641—154.46(124E) Dispensing.

154.46(1) A dispensary shall provide access to all medical cannabidiol forms produced by each licensed manufacturer.

154.46(2) *Dispensing to a patient.*

a. Prior to dispensing any medical cannabidiol to a patient, a dispensary shall do all of the following:

- (1) Verify the patient's identity;
- (2) Verify that the patient is registered and listed in secure sales and inventory tracking system and has a valid medical registration card;
- (3) Assign a tracking number to any medical cannabidiol that is to be dispensed to the patient;
- (4) Issue a label that contains the following information:
 1. The medical cannabidiol tracking number;
 2. The date and time the medication is being dispensed;
 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.

b. The dispensary shall record the patient name, the amount dispensed, the price, the medical cannabidiol tracking number, the time and date, and other information required by the department in the secure sales and inventory system within 1 business day.

154.46(3) *Dispensing to a primary caregiver.*

a. Prior to dispensing any medical cannabidiol to a primary caregiver, a dispensary shall do all of the following:

- (1) Verify the primary caregiver's identity;
- (2) Verify that the patient and the primary caregiver are registered and listed in secure sales and inventory tracking system and have valid medical registration cards;
- (3) Assign a medical cannabidiol tracking number to any medical cannabidiol that is to be dispensed to the primary caregiver;
- (4) Issue a label that contains the following information:
 1. The medical cannabidiol tracking number;
 2. The date and time the medication is being dispensed;
 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.

b. The dispensary shall record the names of the patient and primary caregiver, the amount dispensed, the price, the medical cannabidiol tracking number, the time and date, and other information required by the department in the secure sales and inventory system within 1 business day.

641—154.47(124E) Transportation of medical cannabidiol. A dispensary is not authorized to transport medical cannabidiol, unless approved by the department. Any approved transport shall be logged in the secure sales and inventory tracking system.

641—154.48(124E) Disposal of medical cannabidiol.

154.48(1) *Identification of excess, expired, or damaged medical cannabidiol.*

- a. Dispensaries shall identify unused, excess, expired, or damaged medical cannabidiol for return to manufacturers.
- b. Unused, excess, expired, or damaged medical cannabidiol shall be stored as described in subrule 154.45(2).

154.48(2) *Return of medical cannabidiol from a patient or primary caregiver to a dispensary.*

- a. A dispensary shall accept at no charge unused, expired, or unwanted medical cannabidiol from any patient or primary caregiver.
- b. The dispensary shall enter the following information into the secure sales and inventory tracking system for all medical cannabidiol returned from a patient or primary caregiver:
 - (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 was returned;
 - (3) The quantity of medical cannabidiol returned; and
 - (4) The type and lot number of medical cannabidiol returned.
- c. A dispensary shall store medical cannabidiol returned from patients and primary caregivers as described in subrule 154.45(2).

154.48(3) *Return of medical cannabidiol to a manufacturer.*

- a.* A manufacturer shall collect and dispose of medical cannabidiol from dispensaries as provided in rule 154.23.
- b.* A dispensary shall record information on all medical cannabidiol collected by the manufacturer in the secure sales and inventory tracking system. Information shall include:
 - (1) The date the medical cannabidiol was collected by the manufacturer;
 - (2) The quantity of medical cannabidiol collected; and
 - (3) The type and lot number of medical cannabidiol collected.

641—154.49(124E) Record-keeping requirements.

154.49(1) *Sales.* A dispensary shall maintain complete and accurate electronic sales transaction records in the department's secure sales and inventory tracking system, including:

- a.* The name of the patient and the name of the primary caregiver, if purchased by the primary caregiver;
- b.* The date of each sale;
- c.* The item number, product name and description, and quantity of medical cannabidiol sold;
- d.* The sale price;
- e.* Other information required by the department.

154.49(2) *Financial transactions.* A dispensary shall maintain records that reflect all financial transactions and the financial condition of the business. The following records shall be maintained for at least five years and made available for review, upon request of the department:

- a. Purchase invoices, bills of lading, sales records, copies of bills of sale, and any supporting documents, to include the items or services purchased, from whom the items were purchased, and the date of purchase;
- b. Bank statements and canceled checks for all business accounts;
- c. Accounting and tax records;
- d. Records of all financial transactions, including contracts and agreements for services performed or services received;

154.49(3) Other records.

- a. A dispensary shall maintain the following for at least five years and provide to the department upon request:
 - (1) All personnel records; and
 - (2) Records of any theft, loss, or other unaccountability of any medical cannabidiol.
- b. A dispensary shall use the department's secure sales and inventory tracking system to maintain the following:
 - (1) Inventory records;
 - (2) Return of medical cannabidiol from a patient or primary caregiver; and
 - (3) Return of unused, excess, expired, or damaged medical cannabidiol to a manufacturer.

641—154.50(124E) Quality assurance and control. A dispensary shall cooperate with manufacturers and the department on quality assurance and control procedures, including participating in stability testing studies, developing sampling strategies, and returning medical cannabidiol that has been recalled or withdrawn from the market.

641—154.51(124E) Inventory.

154.51(1) *Inventory controls and procedures.* A dispensary shall establish inventory controls and procedures for conducting inventory reviews to prevent and detect any diversion, theft, or loss in a timely manner.

154.51(2) *Real-time inventory required.* A dispensary shall use the department-approved secure sales and inventory tracking system to maintain a real-time record of its inventory of medical cannabidiol to include:

- a. The quantity and form of saleable medical cannabidiol maintained at the dispensary on a daily basis;
- b. The amount of damaged, expired, or returned medical cannabidiol being held at the dispensary for return to a manufacturer; and
- c. Other information deemed necessary and requested by the department.

154.51(3) *Reconciliation.* At the close of business each day, a dispensary shall reconcile all medical cannabidiol at the dispensary with the secure sales and inventory tracking system. Inconsistencies shall be reported to the department or law enforcement within 24 hours of discovery.

641—154.52(124E) Inspection by department or independent consultant. A dispensary is subject to reasonable inspection by the department, a department-approved consultant, or other agency as authorized by Iowa Code chapter 124E and these rules or state or local laws and regulations.

154.52(1) *Types of inspections.* Inspections may include:

- a. Aspects of the business operations;

- b. The physical location of a dispensary, including any storage facilities;
- c. Financial information and inventory documentation;
- d. Physical and electronic security alarm systems; and
- e. Other aspects or areas as determined by the department.

154.52(2) *Local safety inspections.* A dispensary may be subject to inspection of its dispensary by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local licensing authority restrictions related to medical cannabidiol dispensing or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

154.52(3) *Health and sanitary inspection.* The department has discretion to determine when an inspection by an independent consultant is necessary. The following is a non-exhaustive list of examples that may justify an independent inspection:

- a. The department has reasonable grounds to believe that the dispensary is in violation of one or more of the requirements set forth in these rules or other applicable public health or sanitary laws, rules or regulations;
- b. The department has reasonable grounds to believe that the dispensary was the cause or source of contamination of medical cannabidiol; or.
- c. The department has reasonable grounds to believe that the dispensary was the cause of loss of product quality or change in chemical composition due to improper storage and handling of medical cannabidiol.

154.52(4) *Compliance Required.* A dispensary 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.

641—154.53(124E) Assessment of penalties. The department shall assess to a dispensary a civil penalty of up to one thousand dollars per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.

641—154.54 Suspension or revocation of a dispensary license.

154.54(1) The department may suspend or revoke a dispensary license upon any of the following grounds:

- a.* Submission of false, inaccurate, misleading, or fraudulent information to the department in the application or inspection processes.
- b.* Failure to submit required reports and documents.
- c.* Violation of Iowa Code chapter 124E or these rules, or violation of state or local law related to operation of the licensee.
- d.* Conduct or practices detrimental to the safety, health, or welfare of a patient, primary caregiver, or the public.
- e.* Criminal, civil, or administration action taken against a license or registration in this or another state or country related to manufacturing or dispensing medical cannabidiol.
- f.* False, misleading, or deceptive representations to the department, another state or federal agency, or a law enforcement agency.
- g.* Discontinuance of operation for more than thirty days, unless the department approves an extension of such period for good cause shown.
- h.* Failure to maintain effective controls against diversion, theft, or loss of medical

cannabidiol.

- i.* Failure to correct a deficiency within the time frame required by the department.
- j.* Failure of a dispensary's business owner 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.

154.54(2) The department shall notify the licensee of the proposed action pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

154.54(3) A request for appeal concerning the suspension or revocation of a license shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Office of Medical Cannabidiol, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the suspension or revocation has been or will be removed. After the hearing, or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of suspension or revocation shall become the department's final agency action.

154.54(4) Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

154.54(5) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

154.54(6) When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

154.54(7) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

154.54(8) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

- a.* All pleadings, motions, and rules.
- b.* All evidence received or considered and all other submissions by recording or transcript.
- c.* A statement of all matters officially noticed.
- d.* All questions and offers of proof, objections, and rulings thereon.
- e.* All proposed findings and exceptions.
- f.* The proposed decision and order of the administrative law judge.

154.54(9) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt

requested, or by personal service.

154.54(10) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

154.54(11) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

154.54(12) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

154.30(13) Emergency adjudicative proceedings.

- a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18A to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.
- b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:
 - (1) Whether there has been a sufficient factual investigation to ensure that the department is

proceeding on the basis of reliable information;

- (2) Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;
- (3) Whether the licensee required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;
- (4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and
- (5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

- (1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.
- (2) The written emergency adjudicative order shall be immediately delivered to the licensee that is required to comply with the order by utilizing one or more of the following procedures:
 1. Personal delivery.
 2. Certified mail, return receipt requested, to the last address on file with the department.
 3. Fax. Fax may be used as the sole method of delivery if the licensee required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.
- (3) To the degree practicable, the department shall select the procedure for providing written

notice that best ensures prompt, reliable delivery.

- (4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the licensee that is required to comply with the order.
- (5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.
- (6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the licensee that is required to comply with the order is the party requesting the continuance.

641—154.55(124E) Closure of operations.

154.55(1) Notice. A dispensary shall notify the department at least six months before the closure of the dispensary.

154.55(2) Procedures. If a dispensary ceases operation, the dispensary shall work with the department to verify the remaining inventory of the dispensary and ensure that any medical cannabidiol is returned to a manufacturer.

641—154.56 to 154.59 Reserved.

MEDICAL CANNABIDIOL BOARD

641—154.60(124E) Purpose and duties of board. The purpose of the board is to administer the provisions of Iowa Code section 124E.4A. Responsibilities include but are not limited to:

154.60(1) Accepting and reviewing petitions to add medical conditions, medical treatments, or debilitating diseases to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial under Iowa Code chapter 124E.

154.60(2) Making recommendations to the board of medicine relating to the removal or addition of debilitating medical conditions to the list of allowable debilitating medical conditions for which the medical use of cannabidiol under Iowa Code chapter 124E would be medically beneficial.

154.60(3) Working with the department regarding the requirements for the licensure of manufacturers and dispensaries, including licensure procedures.

154.60(4) Advising the department regarding the location of manufacturers and dispensaries throughout the state.

154.60(5) Making recommendations to the board of medicine relating to the form and quantity of allowable medical uses of cannabidiol.

154.60(6) Considering recommendations to the general assembly for statutory revisions to the definition of medical cannabidiol to increase the tetrahydrocannabinol (THC) level to more than three percent.

154.60(7) Submitting an annual report to the general assembly detailing the activities of the board no later than January 1.

641—154.61(124E) Organization of board and proceedings.

154.61(1) *Membership.* The board shall be composed of 9 members appointed by the governor pursuant to Iowa Code section 124E.4A. The appointments, unless provided otherwise by law, shall be for three-year staggered terms which shall expire on June 30. Board members shall be knowledgeable about the use of medical cannabidiol. The medical practitioners shall be licensed in Iowa and be nationally board-certified in their area of specialty.

154.61(2) *Vacancies.* Vacancies shall be filled in the same manner in which the original appointments were made for the balance of the unexpired term.

154.61(3) *Absences.* Three consecutive unexcused absences shall be grounds for the governor to consider dismissal of a board member and to appoint another. Department staff is charged with providing notification of absences to the governor's office.

154.61(4) *Board meetings.*

- a. The board shall convene at least twice but no more than four times a year.
- b. Board meetings shall be conducted in accordance with the open meetings requirements of Iowa Code chapter 21.
- c. The department's office of medical cannabidiol shall schedule the time, date and location of meetings.
- d. A majority of the members shall constitute a quorum for conducting business of the board.
- e. An affirmative vote of a majority of the board members present at a meeting is required for a motion to pass.

154.61(5) *Facilities and staffing.* The department shall furnish the board with the necessary facilities and employees to perform the duties required by this chapter but shall be reimbursed for all costs incurred by fee revenue generated from licensing activities and registration card applications.

154.61(6) *Subcommittees.* The board may designate one or more subcommittees to perform such duties as may be deemed necessary.

641—154.62(124E) Official communications. All official communications, including submissions, petitions and requests, may be addressed to the Medical Cannabidiol Board, Office of Medical Cannabidiol, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa, 50319-0075.

641—154.63(124E) Office hours. The board office is open for public business from 8 a.m. to 4:30 p.m., Monday to Friday of each week, except holidays.

641—154.64(124E) Public meetings. Members of the public may be present during board meetings unless the board votes to hold a closed session. Dates and location of board meetings may be obtained through the Iowa department of public health's Web site (<https://idph.iowa.gov/mcarcp>) or directly from the board office.

154.64(1) *Exclusion of participants.* The person presiding at a meeting of the board may exclude a person from an open meeting for behavior that obstructs the meeting.

154.64(2) *Recording of meetings.* Cameras and recording devices may be used at open meetings, provided the cameras or recording devices do not obstruct the meeting. If the user of a

camera or recording device obstructs the meeting by the use of such device, the presiding department staff member at the meeting may request the user to discontinue use of the camera or device.

641—154.65(124E) Petitions for the addition or removal of medical conditions, medical treatments or debilitating diseases. Petitions for the addition or removal of medical conditions, medical treatments, or debilitating conditions for which the medical use of cannabidiol would be medically beneficial under Iowa Code chapter 124E may be submitted to the board pursuant to this rule.

154.65(1) *Petition form.* Any person or entity may file a petition to add or remove medical conditions, medical treatments or debilitating diseases with the board. A petition is deemed filed when it is received by the medical cannabidiol office. The board must provide the petitioner with a file-stamped copy of the petition if the petitioner provides the board an extra copy for this purpose. The petition must be typewritten or legibly handwritten in ink and must substantially conform to the following form:

BEFORE THE MEDICAL CANNABIDIOL BOARD

Petition by (Name of Petitioner) for the (addition or removal) of (medical conditions, medical treatments or debilitating diseases) to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial.	}	PETITION FOR (ADDITION or REMOVAL)
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The petition must provide the following information:

- a. A statement of the specific medical condition, medical treatment or debilitating disease the petitioner is seeking to add or remove from the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial.

- b. A brief summary of the petitioner's arguments in support of the action urged in the petition.
- c. A brief summary of any data or scientific evidence supporting the action urged in the petition.
- d. A list of reference material supporting the petition.
- e. A list of subject matter experts who are willing to testify in support of the petition. The list of subject matter experts must contain names, credentials (if applicable), email addresses, phone numbers, and mailing addresses.
- f. The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by, or interested in, the proposed action which is the subject of the petition.

154.65(2) *Signature and address.* The petition must be dated and signed by the petitioner or the petitioner's representative. It must also include the name, mailing address, telephone number and email address of the petitioner and petitioner's representative, and a statement indicating the person to whom communications concerning the petition should be directed.

154.65(3) *Denial for format.* The board may deny a petition because it does not substantially conform to the required form.

154.65(4) *Briefs.* The petitioner may attach a brief to the petition in support of the action urged in the petition. The board may request a brief from the petitioner or from any other person or entity concerning the substance of the petition.

154.65(5) *Inquiries.* Inquiries concerning the status of a petition may be made to the Office of Medical Cannabidiol, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50139-0075.

154.65(6) Additional information. The board may request the petitioner to submit additional information concerning the petition. The board may also solicit comments from any person on the substance of the petition. Comments on the substance of the petition may be submitted to the board by any person.

154.65(7) Presentation to the board. The board may request or allow the petitioner to make an oral presentation of the contents of a petition at a board meeting following submission of the petition.

154.65(8) Board response. Within 6 months after the filing of the petition, or within any longer period agreed to by the petitioner, the board must, in writing, either deny the petition and notify petitioner of its action and the reasons therefore, or grant the petition and notify petitioner that it has recommended addition or removal of the medical condition, medical treatment, or debilitating disease to the board of medicine. A petitioner shall be deemed notified of the denial or recommendation on the date when the board mails the required notification to the petitioner.

154.65(9) Denials. Denial of a petition because it does not substantially conform to the required form does not preclude the filing of a new petition on the same subject that seeks to eliminate the grounds for the agency's rejection of the petition.

These rules are intended to implement Iowa Code section 124E.4A.