

CHAPTER 154
MEDICAL CANNABIDIOL PROGRAM

641—154.1(124E) Definitions. For the purposes of these rules, the following definitions shall apply:

“*Acceptance criteria*” means the specified limits placed on characteristics of an item or method that are used to determine data quality.

“*Accreditation*” means the procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks and verifies that the appropriate quality management system is in place.

“*Accredited nonpublic school*” means any nonpublic school accredited by the Iowa state board of education, excluding home schools.

“*Action level*” means the threshold value that provides the criterion for determining whether a sample passes or fails a test performed pursuant to these rules.

“*Aliquot*” means a portion of a sample that is used in an analysis.

“*Analyte*” means a chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured.

“*Analytical batch*” means a group of samples that are prepared together for the same analysis and analyzed sequentially using the same instrument calibration curve and common analytical quality control checks.

“*Analytical method*” means a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.

“*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, an 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;
4. Living modified organisms.

“*Bordering state*” means the same as defined in Iowa Code section 331.910.

“*Cannabinoid*” means a chemical compound that is unique to and derived from cannabis.

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

“*CAS number*” means a unique numerical identifier assigned to every chemical substance described in the open literature by Chemical Abstracts Service.

“*CBD*” means cannabidiol, Chemical Abstracts Service number 13956-29-1.

“*CBDA*” means cannabidiolic acid, Chemical Abstracts Service number 1244-58-2.

“*CBG*” means cannabigerol, Chemical Abstracts Service number 25654-31-3.

“*CBN*” means cannabinol, Chemical Abstracts Service number 521-35-7.

“*Certificate of analysis*” means the report prepared for the requester about the analytical testing performed and the results obtained by a laboratory.

“*Certification*” means a procedure by which a third party gives written assurance (certificate of conformity) that a product, process or service conforms to specified requirements.

“*Certified*” means that a laboratory demonstrates to the satisfaction of the department its ability to consistently produce valid data within the acceptance limits as specified in the department’s

requirements for certification and meets the minimum requirements of this chapter and all applicable regulatory requirements.

“Certified reference material” means a reference material prepared by a certifying body.

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

“Data-quality assessment” means a scientific and statistical process that establishes whether the collected data are of the right type, quality, and quantity to support the intended use of the data.

“Date of expiration” means one year from the date of issuance of the medical cannabidiol registration card by the department of transportation.

“Date of issuance” means the date of issuance of the medical cannabidiol registration card by the department of transportation.

“Debilitating medical condition” means any of the following:

1. Cancer, if the underlying condition or treatment produces one or more of the following:
 - Severe or chronic pain.
 - Nausea or severe vomiting.
 - Cachexia or severe wasting.
2. Multiple sclerosis with severe and persistent muscle spasms.
3. Seizures, including those characteristic of epilepsy.
4. AIDS or HIV as defined in Iowa Code section 141A.1.
5. Crohn’s disease.
6. Amyotrophic lateral sclerosis.
7. Any terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:

- Severe or chronic pain.
 - Nausea or severe vomiting.
 - Cachexia or severe wasting.
8. Parkinson’s disease.
 9. Untreatable pain.

10. Any medical condition that is recommended by the medical cannabidiol board and adopted by the board of medicine by rule pursuant to Iowa Code section 124E.5 and that is listed in 653—subrule 13.15(1).

“Department” means the Iowa department of public health.

“Department of transportation” means the Iowa department of transportation.

“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. “Dispensary” 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. “Edible medical cannabidiol products” 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.

“*Field duplicate sample*” means a sample that is taken in the identical manner and from the same batch, process lot, or lot being sampled as the primary sample. A field duplicate sample is analyzed separately from the primary sample and is used for quality control only.

“*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.

“*Frequency*” means the number of items occurring in a given category. Frequency may be determined by analytical method or laboratory-specific requirements for the purpose of accuracy, precision of the analysis, or statistical calculation.

“*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.

“*Increment*” or “*sample increment*” means a smaller sample that, together with other increments, makes up the primary sample.

“*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.

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

“*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 U.S. 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.

“*Limit of detection*” or “*LOD*” means the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.

“*Limit of quantitation*” or “*LOQ*” means the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

“*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. “Manufacturer” 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.

“Mass spectrometry” means an analytical technique that ionizes chemical species and sorts the ions based on their mass-to-charge ratio.

“Matrix” means the component or substrate that contains the analyte of interest.

“Matrix spike duplicate” means a duplicate sample prepared by adding a known quantity of a target analyte to a field sample matrix or other matrix that is as closely representative of the matrix under analysis as possible.

“Matrix spike sample” means a sample prepared by adding a known quantity of the target analyte to a field sample matrix or to a matrix that is as closely representative of the matrix under analysis as possible.

“Medical assistance program” means IA Health Link, Medicaid Fee-for-Service, or HAWK-I, as administered by the Iowa Medicaid enterprise of the Iowa department of human services.

“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 recommended by the medical cannabidiol board, approved by the board of medicine, and designated in this chapter.

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

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

“Medical cannabis goods” means medical cannabidiol process lots, medical cannabidiol products, and cannabis plant material, including dried tissue.

“Method blank” means an analyte-free matrix to which all reagents are added in the same volumes or proportions as are used in sample preparation.

“Moisture content” means the percentage of water in a dry sample by weight.

“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.

“Non-target organism” means an organism that the test method or analytical procedure is not testing for. Non-target organisms are used in evaluating the specificity of a test method.

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

“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.

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

“Percent recovery” means the percentage of a measured concentration relative to the added (spiked) concentration in a reference material, matrix spike sample, or matrix spike duplicate.

“Permanent resident” means a natural person who physically resides in Iowa as the person’s principal and primary residence and who establishes evidence of such residency by providing the department with one of the following:

1. A valid Iowa driver’s license,
2. A valid Iowa nonoperator’s identification card,
3. A valid Iowa voter registration card,
4. A current Iowa vehicle registration certificate,
5. A utility bill,
6. A statement from a financial institution,

7. A residential lease agreement,
8. A check or pay stub from an employer,
9. A child's school or child care enrollment documents,
10. Valid documentation establishing a filing for homestead or military tax exemption on property located in Iowa, or
11. Other valid documentation as deemed acceptable by the department to establish residency.

"Pharmaceutical grade" means medical cannabidiol that meets standards for content, contamination, and consistency set by the department as determined by testing conducted at a laboratory pursuant to Iowa Code chapter 124E and these rules.

"Plant material" means any plant of *Cannabis sativa* L. or *Cannabis indica*, or any part thereof, including flowers, leaves, trichomes, and tissue.

"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 the provisions of 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.

"Primary sample" means a portion of a batch, process lot, or lot that is used for testing for identity, strength, purity, and composition.

"Process lot" means any amount of cannabinoid concentrate or extract that is uniform, produced from one or more batches, and used for testing for identity, strength, purity, and composition prior to being packaged.

"Product expiration date" means the date after which a medical cannabidiol product may not be sold by a manufacturer or a dispensary.

"Production" or *"produce"* means:

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

"Proficiency test" means an evaluation of a laboratory's performance against preestablished criteria by means of interlaboratory comparisons of test measurements.

"Proficiency test sample" means a sample prepared by a party independent of the testing laboratory, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing laboratory and testing laboratory personnel.

"Public or private school" means any property operated by a school district, charter school, or accredited nonpublic school for purposes related to elementary, middle, or secondary schools or secondary vocation centers.

"Qualitative analysis" means identification of an analyte in a substance or mixture.

"Quality assurance" means a set of operating principles to produce data of known accuracy and precision. "Quality assurance" encompasses employee training, equipment preventative maintenance procedures, calibration procedures, and quality control testing, among other things.

"Quality control" means a set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control in which errors have been reduced to acceptable levels.

"Quality control samples" means samples produced and used for the purpose of assuring quality control. Quality control samples include but are not limited to blank samples, spike samples, duplicate samples, and reference material samples.

"Quantitative analysis" means measurement of the quantities of chemical components present in a substance or mixture. Quantitative analysis typically uses a certified reference material, if available, to create a calibration curve.

“*Reagent*” means a compound or mixture added to a system to cause a chemical reaction or to test if a reaction occurs. A reagent may be used to tell whether or not a specific chemical substance is present by causing a reaction to occur with the chemical substance.

“*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.

“*Reference material*” means a material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix. Reference material is used to document the bias of the analytical process.

“*Reference method*” means a method by which the performance of an alternate method is measured or evaluated.

“*Relative percent difference*” or “*RPD*” means a comparative statistic used to calculate precision or random error. RPD is calculated using the following equation: $RPD = \frac{\text{absolute value (primary sample measurement - duplicate sample measurement)}}{([\text{primary sample measurement} + \text{duplicate sample measurement}] / 2)} \times 100$.

“*Relative standard deviation*” or “*RSD*” means the standard deviation expressed as a percentage of the mean recovery. “RSD” is the coefficient of variation multiplied by 100. If any results are less than the limit of quantitation, then the absolute value of the limit of quantitation is used in the following equation: $RSD = (s / x) \times 100$, where s = standard deviation and x = mean recovery.

“*Requester*” means a person who submits a request to a licensed testing laboratory for state-mandated testing of medical cannabis goods. The requester may be a licensed manufacturer or the department.

“*Residual solvents and processing chemicals*” means volatile organic chemicals that are used or produced in the manufacture or production of 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.

“*Sample*” means a representative part of or a single item from a larger whole or group.

“*Sanitize*” means to sterilize, disinfect, or make hygienic.

“*Semiquantitative analysis*” means less than quantitative precision and does not involve a full calibration. Analyte identification is based on a single-point reference or high-probability library match. The determination of amount uses the ratio of the unknown chemical analyte to that of a known analyte added to the sample before analysis. Uncertainty for semiquantitative results is higher than for quantitative results.

“*Significant figures*” means the number of digits used to express a measurement.

“*Stability*” or “*stable*” means that after storage of an unopened package of medical cannabidiol at a licensed manufacturing facility or dispensary facility, the contents shall not vary in concentrations of THC and CBD by more than an amount determined by the department and listed in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

“*Standard operating procedure*” means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

“*State*” means a state of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

“*Synthetic cannabinoid*” means a designed compound with structural features that allow binding to the known cannabinoid receptors present in human cells and that produce biological effects similar to those of natural cannabinoids.

“*Tamper-evident*” means that one or more one-time-use seals are affixed to the opening of a package, allowing a person to recognize whether or not the package has been opened.

“*Target organism*” means an organism that is being tested for in an analytical procedure or test method.

“*Testing laboratory record*” means information relating to the testing laboratory and the analyses it performs that is prepared, owned, used, or retained by the laboratory and includes electronic files and video footage.

“*THC*” or “*delta-9 THC*” means tetrahydrocannabinol, Chemical Abstracts Service number 1972-08-3.

“*THCA*” means tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0.

“*Untreatable pain*” means any pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for the patient has been used without adequate result or with intolerable side effects.

“*Validation*” means the confirmation by examination and objective evidence that the particular requirements for a specific intended use are fulfilled.

“*Written certification*” means a document signed by a health care practitioner, with whom the patient has established a patient-provider relationship, which states that the patient has a debilitating medical condition and identifies that condition and provides any other relevant information.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17; ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

REGISTRATION CARDS

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

154.2(1) Prior to a patient’s submission of an application for a medical cannabidiol registration card pursuant to this rule, a health care practitioner shall do all of the following:

a. Determine, in the health care practitioner’s medical judgment, whether the patient whom the health care practitioner has examined and treated suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol as defined by this chapter, and if so determined, provide the patient with a written certification of that diagnosis by completing the health care practitioner section of the application form provided for this purpose on the department’s website (www.idph.iowa.gov).

b. Provide explanatory information to the patient as provided on the department’s website (www.idph.iowa.gov) about the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment.

154.2(2) Subsequently, the health care practitioner shall do the following:

a. Determine, on an annual basis, if the patient continues to suffer from a debilitating medical condition and, if so, issue the patient a new certification of that diagnosis.

b. Otherwise comply with all requirements in this chapter and requests from the department for more information.

154.2(3) A health care practitioner may provide, but has no duty to provide, a written certification pursuant to this rule.

154.2(4) Health care practitioner prohibitions.

a. A health care practitioner shall not accept, solicit, or offer any form of remuneration from or to any individual, including but not limited to a patient, a primary caregiver, or an employee, investor, or owner of a medical cannabidiol manufacturer or dispensary, to certify a patient’s condition, other than accepting a fee for a patient consultation to determine if the patient should be issued a certification of a qualifying debilitating medical condition.

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

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

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

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

f. A health care practitioner shall not receive or provide medical cannabidiol product samples.
[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17; ARC 4489C, IAB 6/5/19, effective 7/10/19]

641—154.3(124E) Medical cannabidiol registration card—application and issuance to patient.

154.3(1) Subject to subrule 154.3(7), the department may approve the issuance of a medical cannabidiol registration card by the department of transportation to a patient who:

a. Is at least 18 years of age.
b. Is a permanent resident of Iowa.
c. Submits a written certification to the department, provided to the patient pursuant to rule 641—154.2(124E) and signed by the patient’s health care practitioner certifying that the patient is suffering from a debilitating medical condition.

d. Submits an application to the department, on a form created by the department in consultation with the department of transportation and available at the department’s website (www.idph.iowa.gov), that contains all of the following:

(1) The patient’s full legal name, Iowa residence address, mailing address (if different from the patient’s residence address), telephone number, date of birth, and sex designation. The patient shall not provide as a mailing address an address for which a forwarding order is in place.

(2) A copy of the patient’s valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver’s license,
2. A valid Iowa nonoperator’s identification card, or
3. An alternative form of valid photo identification. A patient who possesses or is eligible for an Iowa driver’s license or an Iowa nonoperator’s identification card shall present such document as valid photo identification. A patient who is ineligible to obtain an Iowa driver’s license or an Iowa nonoperator’s identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A patient who applies for an exemption is subject to verification of the patient’s identity through a process established by the department and the department of transportation to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(3) Full name, address, and telephone number of the patient’s health care practitioner.

(4) Full legal name, residence address, date of birth, and telephone number of each primary caregiver of the patient, if any.

(5) An attestation as to the truthfulness and accuracy of the information provided by the patient on the application.

e. Has not been convicted of a disqualifying felony offense.

f. Submits the required fee, as described in subrule 154.12(1).

154.3(2) Upon the completion, verification, and approval of the patient’s application and the receipt of the required fee, the department shall notify the department of transportation that the patient may be issued a medical cannabidiol registration card.

154.3(3) A medical cannabidiol registration card issued to a patient by the department of transportation shall contain all of the following:

a. The patient’s full legal name, Iowa residence address, date of birth, and sex designation, as shown on the patient’s Iowa driver’s license, nonoperator’s identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)“d”(2)“3.” If the patient’s name, Iowa residence address, date of birth, or sex designation has changed since the issuance of the patient’s Iowa driver’s license, nonoperator’s identification card, or alternative form of valid photo identification, the patient shall first update the patient’s Iowa driver’s license or nonoperator’s identification card to reflect the current information, according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321), or shall update the alternative form of valid photo identification in accordance with the process of the issuing agency.

b. The date of issuance and the date of expiration, which shall be one year from the date of issuance.

c. A distinguishing registration number that is not the patient’s social security number.

d. The patient's signature. The signature shall be without qualification and shall contain only the patient's usual signature without any other titles, characters, or symbols. The patient's signature certifies, under penalty of perjury and pursuant to the laws of the state of Iowa, that the statements made and information provided in the patient's application for a medical cannabidiol registration card are true and correct. The patient's signature shall be captured electronically.

e. A color photograph of the patient.

f. A statement that the medical cannabidiol registration card is not valid for identification purposes.

154.3(4) Every patient 18 years of age or older must obtain a valid medical cannabidiol registration card to use medical cannabidiol in Iowa. The department may waive this requirement for a patient who is unable to obtain a card because of health, mobility, or other issues, but only when the patient:

a. Has submitted an application for a medical cannabidiol registration card;

b. Has had the application approved by the department;

c. Has been assigned a patient registration number;

d. Has designated a primary caregiver whose application has been approved and whose medical cannabidiol registration card has been issued; and

e. Complies with all provisions of Iowa Code chapter 124E.

154.3(5) An authorization to use medical cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E or these rules for the issuance of a medical cannabidiol registration card.

154.3(6) A valid medical cannabidiol registration card, or its equivalent, issued under the laws of another state that allow an out-of-state patient to possess or use medical cannabidiol in the jurisdiction of issuance shall have the same force and effect as a valid medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E, except that an out-of-state patient in Iowa shall not obtain medical cannabidiol from a medical cannabidiol dispensary in Iowa.

154.3(7) The department shall not approve the issuance of a medical cannabidiol registration card for a patient who is enrolled in a federally approved clinical trial for the treatment of a debilitating medical condition with medical cannabidiol.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17; ARC 4489C, IAB 6/5/19, effective 7/10/19]

641—154.4(124E) Medical cannabidiol registration card—application and issuance to primary caregiver.

154.4(1) For a patient in a primary caregiver's care, the department may approve the issuance of a medical cannabidiol registration card by the department of transportation to a primary caregiver who:

a. Is at least 18 years of age.

b. Submits a written certification to the department, provided to the patient pursuant to rule 641—154.2(124E) and signed by the patient's health care practitioner certifying that the patient is suffering from a debilitating medical condition.

c. Submits an application as a primary caregiver for each patient for whom the person is the primary caregiver. The primary caregiver application must be on a form created by the department in consultation with the department of transportation and available at the department's website (www.idph.iowa.gov) that contains all of the following:

(1) The primary caregiver's full legal name, residence address, mailing address (if different from the primary caregiver's residence address), telephone number, date of birth, and sex designation. The primary caregiver shall not provide as a mailing address an address for which a forwarding order is in place.

(2) The patient's full legal name, date of birth, and parent or legal guardian's name if the patient is under the age of 18.

(3) A copy of the primary caregiver's valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver's license,

2. A valid Iowa nonoperator's identification card,

3. If the primary caregiver is not a resident of the state of Iowa, a valid state-issued driver's license or nonoperator's identification card issued by a state other than Iowa, or

4. An alternative form of valid photo identification. A primary caregiver who possesses or is eligible for a driver's license or a nonoperator's identification card shall present such document as valid photo identification. A primary caregiver who is ineligible to obtain a driver's license or a nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A primary caregiver who applies for an exemption is subject to verification of the primary caregiver's identity through a process established by the department and the department of transportation to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(4) Full name, address, and telephone number of the patient's health care practitioner.

(5) An attestation as to the truthfulness and accuracy of the information provided by the primary caregiver on the application.

d. Has not been convicted of a disqualifying felony offense.

e. Submits the required fee, as described in subrule 154.12(2).

154.4(2) Upon the completion, verification, and approval of the primary caregiver's application, the department shall notify the department of transportation that the primary caregiver may be issued a medical cannabidiol registration card.

154.4(3) A medical cannabidiol registration card issued to a primary caregiver by the department of transportation shall contain all of the following:

a. The primary caregiver's full legal name, current residence address, date of birth, and sex designation, as shown on the primary caregiver's state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.4(1) "c"(3)"4." If the primary caregiver's name, current residence address, date of birth, or sex designation has changed since issuance of the primary caregiver's Iowa-issued driver's license, nonoperator's identification card, or other form of valid photo identification, the primary caregiver shall first update the primary caregiver's Iowa-issued driver's license or nonoperator's identification card according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321) or update the alternative form of valid photo identification in accordance with the process of the issuing agency.

b. The date of issuance and the date of expiration, which shall be one year from the date of issuance.

c. A distinguishing registration number that is not the primary caregiver's social security number.

d. The medical cannabidiol registration number for each patient in the primary caregiver's care. This number shall not be the primary caregiver's or patient's social security number. If the patient in the primary caregiver's care is under the age of 18, the full name of the patient's parent or legal guardian shall be printed on the primary caregiver's registration card in lieu of the patient's medical cannabidiol registration number.

e. The primary caregiver's signature. The signature shall be without qualification and shall contain only the primary caregiver's usual signature without any other titles, characters, or symbols. The primary caregiver's signature certifies, under penalty of perjury and pursuant to the laws of the state of Iowa, that the statements made and information provided in the primary caregiver's application for a medical cannabidiol registration card are true and correct. The primary caregiver's signature shall be captured electronically.

f. A color photograph of the primary caregiver.

g. A statement that the medical cannabidiol registration card is not valid for identification purposes.

h. A statement distinguishing the medical cannabidiol registration cardholder as a primary caregiver.

154.4(4) A patient who is 18 years of age or older must have an approved application and a distinguishing medical cannabidiol registration number that is not the patient's social security number prior to the issuance of a medical cannabidiol registration card to the patient's primary caregiver.

154.4(5) An authorization to use, or to act as a primary caregiver for a patient authorized to use, cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E or these rules for the issuance of a medical cannabidiol registration card.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

641—154.5(124E) Tamperproofing. The department of transportation shall issue a medical cannabidiol registration card by a method or process which prevents as nearly as possible the alteration, reproduction, or superimposition of a photograph on the cannabidiol registration card without ready detection.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

641—154.6(124E) Denial and cancellation. The department may deny an application for a medical cannabidiol registration card, or may cancel or direct the department of transportation to cancel a medical cannabidiol registration card, for any of the following reasons:

1. Information contained in the application is illegible, incomplete, falsified, misleading, deceptive, or untrue.

2. The department or the department of transportation is unable to verify the identity of the applicant from the photo identification or other documentation presented pursuant to paragraph 154.3(1)“d”(2)“3” or 154.4(1)“c”(3)“4.”

3. The applicant violates or fails to satisfy any of the provisions of Iowa Code chapter 124E or these rules.

4. A patient, the patient’s legal guardian, or other person with durable power of attorney requests in writing that the department cancel the patient’s medical cannabidiol registration card. The department shall notify a primary caregiver in writing when the registration card of the primary caregiver’s patient has been canceled.

5. A primary caregiver requests in writing that the department cancel the primary caregiver’s medical cannabidiol registration card. The department shall notify a patient in writing when the registration card of the patient’s primary caregiver has been canceled.

6. The department becomes aware of the death of a patient or primary caregiver.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17; ARC 4489C, IAB 6/5/19, effective 7/10/19]

641—154.7(124E) Appeal. If the department denies an application for or cancels a medical cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation and state the reasons for the denial or cancellation in writing. An applicant or cardholder may appeal the denial or cancellation of a medical cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department’s address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

641—154.8(124E) Duplicate card.

154.8(1) Lost, stolen, or destroyed card. To replace a medical cannabidiol registration card that is lost, stolen, or destroyed, a cardholder shall present to the department of transportation the cardholder’s valid state-issued driver’s license, nonoperator’s identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)“d”(2)“3” or 154.4(1)“c”(3)“4.”

154.8(2) Change in card information and voluntary replacement.

a. To replace a medical cannabidiol registration card that is damaged, the cardholder shall surrender to the department of transportation the card to be replaced and present the cardholder’s valid state-issued driver’s license, nonoperator’s identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)“d”(2)“3” or 154.4(1)“c”(3)“4.”

b. A patient or primary caregiver to whom a medical cannabidiol registration card is issued shall notify the department of a change in current residence address, name, or sex designation listed on the card, within ten calendar days of the change. To replace a medical cannabidiol registration card to change the current residence address, name, or sex designation listed on the card, the cardholder shall surrender to the department of transportation the card to be replaced and present a valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1) "d"(2)"3" or 154.4(1) "c"(3)"4" that has been updated according to the procedures established by the state or agency of issuance to reflect the requested residence address, name, or sex designation.

c. To replace a medical cannabidiol registration card held by a primary caregiver to change, add, or remove a patient's medical cannabidiol registration number or the name of a patient's parent or legal guardian listed on the primary caregiver's card, the primary caregiver shall submit a new application to the department pursuant to rule 641—154.4(124E). A medical cannabidiol registration card issued pursuant to this paragraph shall not be considered a duplicate card.

154.8(3) Expiration date. A duplicate medical cannabidiol registration card shall have the same expiration date as the medical cannabidiol registration card being replaced, changed, or amended.
[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

641—154.9(124E) Renewal. A medical cannabidiol registration card shall be valid for one year from the date of issuance unless canceled pursuant to rule 641—154.6(124E).

154.9(1) A cardholder seeking renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department at least 60 days prior to the date of expiration.

a. A patient applying for renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department on a form approved by the department.

b. A primary caregiver applying for a renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department on a form approved by the department.

154.9(2) A cardholder who fails to renew the medical cannabidiol registration card may not lawfully possess medical cannabidiol pursuant to this chapter.
[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

641—154.10(124E) Confidentiality. The department shall maintain a confidential file of the names of each patient to or for whom the department approves the issuance of a medical cannabidiol registration card and the name of each primary caregiver to whom the department issues a medical cannabidiol registration card under Iowa Code section 124E.4.

154.10(1) Personally identifiable information of patients and primary caregivers shall be maintained as confidential and is not accessible to the public. The department and the department of transportation shall release aggregate and statistical information regarding the medical cannabidiol act registration card program in a manner which prevents the identification of any patient or primary caregiver.

154.10(2) Personally identifiable information of patients and primary caregivers may be disclosed under the following limited circumstances:

a. To authorized employees or agents of the department and the department of transportation as necessary to perform the duties of the department and the department of transportation pursuant to Iowa Code chapter 124E.

b. To authorized employees of state or local law enforcement agencies located in Iowa, solely for the purpose of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E.

c. To a patient, primary caregiver, or health care practitioner, upon written authorization of the patient or primary caregiver.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

641—154.11(124E) Agreement with department of transportation. The department may enter into a chapter 28E agreement with the department of transportation to facilitate the issuance of medical cannabidiol registration cards. The agreement may include provisions which govern the issuance,

denial, and cancellation of medical cannabidiol registration cards, the sharing of information between the department and the department of transportation, and reimbursement for costs incurred by the department of transportation for issuing the card.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

641—154.12(124E) Fees. All fees are nonrefundable.

154.12(1) Patient medical cannabidiol registration card fee.

a. Each application fee is \$100 unless the patient qualifies for a reduced fee as described in paragraph 154.12(1) “b.”

b. Each reduced application fee is \$25 if the patient attests to receiving social security disability benefits, supplemental security income payments, or is enrolled in the medical assistance program as defined in rule 641—154.1(124E).

c. Each renewal fee is the same as the initial card application fee.

154.12(2) Primary caregiver medical cannabidiol registration card fee.

a. Each application fee is \$25.

b. Each renewal fee is \$25.

[ARC 3150C, IAB 7/5/17, effective 6/13/17]

641—154.13(124E) Use of medical cannabidiol—smoking prohibited. A patient shall not consume medical cannabidiol possessed or used pursuant to Iowa Code chapter 124E by smoking medical cannabidiol.

[ARC 3150C, IAB 7/5/17, effective 6/13/17]

641—154.14(124E) Form and quantity of medical cannabidiol. The form and quantity of medical cannabidiol authorized in this rule may be modified pursuant to recommendations by the medical cannabidiol board, subsequent approval of the recommendations by the board of medicine and adoption of the recommendations by the department by rule.

154.14(1) Quantity. A 90-day supply is the maximum amount of each product that shall be dispensed by a dispensary at one time.

154.14(2) Form.

a. A manufacturer may only manufacture medical cannabidiol in the following forms:

(1) Oral forms, including but not limited to:

1. Tablet.
2. Capsule.
3. Liquid.
4. Tincture.
5. Sublingual.

(2) Topical forms, including but not limited to:

1. Gel.
2. Ointment, cream or lotion.
3. Transdermal patch.

(3) Inhaled forms, limited to:

1. Nebulizable.
2. Vaporizable.

(4) Rectal/vaginal forms, including but not limited to suppository.

b. A manufacturer may not produce medical cannabidiol in any form that may be smoked.

c. A manufacturer may not produce medical cannabidiol in an edible form as defined in rule

641—154.1(124E).

[ARC 3150C, IAB 7/5/17, effective 6/13/17; ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4399C, IAB 4/10/19, effective 5/15/19]

641—154.15 Reserved.

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 641—154.28(124E).

154.16(4) *Establishment and maintenance of a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available 24 hours a day, seven days a week to track:

- a. Inventory of plant material, 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) *Licensure and licensure renewal of 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.6(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. The application shall be submitted 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 in which 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.

(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 the 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.

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

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

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

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

641—154.17(124E) Manufacturer operations.

154.17(1) Operating documents.

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

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

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

1. 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. A manufacturer may make operating documents for these procedures available on site only;

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. A manufacturer may make operating documents for these procedures available on site only;

7. Biosecurity measures and standard operating procedures used in the production and manufacturing of medical cannabidiol. A manufacturer may make operating documents for these procedures available on site only;

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

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

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. A manufacturer may make operating documents for these procedures available on site only;

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

14. Records relating to all transport activities; and

15. Other information requested by the department.

(2) Procedures to ensure accurate record keeping.

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

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

154.17(2) 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 chapter 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 641—154.21(124E);
- i. Sell medical cannabidiol in any form or quantity other than a form or quantity 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 18 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.

c. An applicant or licensed manufacturer shall respond within 30 days to a request from the department or the department of public safety for more information to complete a background investigation and national criminal history background check on an owner, investor, or employee.

154.17(4) 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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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 that 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 shall retain a record of all persons who entered the restricted access 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) Store data for retrieval for a minimum of one year; and
 - (5) Limit access to authorized individuals in the event of a power failure.
- b. Separate written manifests of visitors to restricted access areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted access 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 to the extent identification is technologically feasible with generally accepted commercial security cameras;
- (2) Have the ability to produce a clear, color still photograph live or from a recording;
- (3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does 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 recordings from all video cameras are:

- (1) Available for viewing by the department upon request;
- (2) Retained for at least 60 days;
- (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 the employee is 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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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 dispensary. A manufacturer shall not operate a manufacturing facility at the same physical location as a medical cannabidiol dispensary.

154.19(2) Proximity to school. A manufacturer shall not operate a manufacturing facility in any location, whether for manufacturing, possessing, cultivating, harvesting, transporting, packaging, processing, storing, or supplying, within 1,000 feet of a public or private school existing before the date of the manufacturer's licensure by the department.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

641—154.20(124E) Advertising and marketing.

154.20(1) Permitted marketing and advertising activities.

a. A manufacturer may:

- (1) 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;

- (2) Display signs on the manufacturing facility; and
- (3) 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.

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

c. 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, deny, or request additional information regarding marketing and advertising activity requests from a manufacturer. In the event the department fails to respond to a manufacturer within 30 days with an approval, denial, or request for additional information, the manufacturer's marketing and advertising activity requests shall be deemed approved.

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

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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. The manufacturer shall 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. The manufacturer shall label packaged medical cannabidiol as described in subrule 154.21(3).

c. The manufacturer shall use medical containers that are:

(1) Of sufficient size to accommodate a separate dispensary label containing the information described in rule 641—154.46(124E);

(2) Designed to maximize the shelf life of the contained medical cannabidiol;

(3) Tamper-evident; and

(4) Child-resistant.

d. Medical cannabidiol packaging shall not bear a reasonable resemblance to commonly available nonmedical commercial products.

e. The manufacturer shall package medical cannabidiol in a manner that minimizes the package's appeal to children.

f. The manufacturer shall not depict images other than the manufacturer's business name or logo on the packaging.

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

a. Names shall be 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 nonmedical 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 of the manufacturer;
- (2) The medical cannabidiol's primary active ingredients, including concentrations of tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid. Concentrations of tetrahydrocannabinolic acid and cannabidiolic acid may be omitted if the manufacturer uses chemical decarboxylation or other means to substantially remove the acids from the product prior to testing;
- (3) 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;
- (4) Instructions for storage, including light and temperature requirements, if any;
- (5) Product expiration date;
- (6) The date of manufacture and lot number;
- (7) A notice with the statement, including capitalization: "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.";
- (8) The universal warning symbol provided by the department; and
- (9) A notice with the statement: "This medical cannabidiol is for therapeutic use only. Use of this product by a person other than the patient listed on the label is unlawful and may result in the cancellation of the patient's medical cannabidiol registration card. Return unused medical cannabidiol to a dispensary for disposal."

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

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

d. A manufacturer shall ensure that directions for use of the product, including recommended and maximum amount by age and weight, if applicable, are included with the product.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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 a 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 in the secure sales and inventory tracking system or on the manifest information about the material to be transported; and

(2) Notify the dispensary, laboratory, 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 the transport vehicle is 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 in the secure sales and inventory tracking system, if available. If a manifest system is being used, the dispensary, laboratory, or waste facility shall also maintain a signed copy of manifest, and shall maintain records of the inventory received consistent with 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. When the motor vehicle contains medical cannabidiol, manufacturer employees who are transporting the medical cannabidiol on public roadways shall:

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

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

1. The reason for the stop;

2. The duration of the stop; and

3. The location of the stop.

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

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

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

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

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

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

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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 medical cannabidiol waste from dispensaries and from the laboratory that has tested samples submitted by the manufacturer. A manufacturer shall:

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

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

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

d. Maintain a written record of disposal that includes:

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

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

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

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

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 at an approved solid waste disposal facility, according to federal and state law.

c. Before transport of plant material waste, the manufacturer shall render the plant material waste unusable and unrecognizable by grinding and incorporating the waste with a greater quantity of nonconsumable, solid wastes including:

(1) Paper waste;

(2) Cardboard waste;

(3) Food waste;

(4) Yard waste;

(5) Vegetative wastes generated from industrial or manufacturing processes that prepare food for human consumption;

(6) Soil; or

(7) Other waste approved by the department.

154.23(3) *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. The records shall account for, reconcile, and evidence all waste activity related to the disposal of medical cannabidiol waste and plant material waste.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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, unless otherwise noted, 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) Transport manifests and incident reports; and

(4) Records of all samples sent to a testing laboratory and the quality assurance test results.

b. A manufacturer shall maintain for at least one year and provide to the department upon request its controlled access system data and visitor manifests.

c. A manufacturer shall use the department's secure sales and inventory tracking system to maintain the following:

(1) Crop input records;

(2) Production records;

(3) Transportation records; and

(4) Inventory records, including disposal of waste.

154.24(4) *Entry into the department's secure sales and inventory tracking system.* Unless otherwise provided in these rules, a manufacturer shall adhere to the following schedule for entering data into the department's secure sales and inventory tracking system.

a. A manufacturer shall enter data in real time for data related to:

(1) Transport of plant material, waste material, and laboratory samples; and

(2) Sales of medical cannabidiol to dispensaries.

b. A manufacturer shall enter data on changes to inventory of plant material, medical cannabidiol, and waste material by the end of the business day in which the changes occurred.

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

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

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

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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 641—154.18(124E).

c. The production process shall be designed to limit contamination. Examples of contamination include mold, fungus, bacterial diseases, rot, pests, nonorganic pesticides, and mildew.

d. Each production area shall allow for access, observation, and inventory of each plant group.

e. Biosecurity measures shall be in effect as described in the operating documents pursuant to subrule 154.17(1).

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

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

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

- (1) The date of input application;
- (2) The name of the employee applying the crop input;
- (3) The crop input that was applied;
- (4) The plants that received the application;
- (5) The amount of crop input that was applied; and
- (6) A copy of or electronic link to the safety data sheet for the crop input applied.

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

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

e. 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, nonperishable 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 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 that:
 - (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 the product and its container against physical, chemical, and microbial contamination and deterioration.
- 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 has 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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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 product 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;
- e.* Retain the results from the random samples for at least five years; and
- f.* Notify the department at least two business days prior to sample collection and allow the department or its designees to be present to observe the sampling procedures when the samples are to be sent to a laboratory for testing.

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

- a.* Work with the department and laboratory personnel to develop acceptance criteria for all potential contaminants based on the levels of metals, microbes, or other contaminants that the manufacturer uses in cultivating and producing medical cannabidiol;
- b.* Conduct sampling and testing of plant material and medical cannabidiol lots using acceptance criteria that are protective of patient health. The sampling and testing results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol meet allowable health risk limits for contaminants. Testing of plant material and lots shall occur as described in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).
- c.* Refrain from packaging or selling medical cannabidiol from a process lot that fails to meet established standards, specifications, and any other relevant quality control criteria. Medical cannabidiol from a process lot that fails quality assurance testing may be remixed and retested;
- d.* Reject and destroy medical cannabidiol from a lot that fails to meet established standards, specifications, and any other relevant quality control criteria when remixing and retesting are not warranted;
- e.* Develop and follow a written procedure for responding to results failing to meet established standards, specifications, and any other relevant quality control criteria, including:
 - (1) Criteria for when remixing and retesting are warranted;
 - (2) Instructions for destroying contaminated or substandard medical cannabidiol as provided in subrule 154.23(2) when remixing and retesting are not warranted; and
 - (3) Instructions for determining the source of contamination;
- f.* Retain documentation of test results, assessment, and destruction of medical cannabidiol for at least five years.

154.26(4) *Stability testing.*

- a.* The quality assurance program shall include procedures for performing stability testing of each product type produced to determine product expiration dates. The procedures shall describe:
 - (1) Sample size and test intervals based on statistical criteria and departmental guidance pursuant to subrule 154.69(1) for each attribute examined to ensure valid stability estimates;
 - (2) Storage conditions for samples retained for testing; and
 - (3) Reliable and specific test methods.
- b.* Stability studies shall include:
 - (1) Medical cannabidiol testing at appropriate intervals; and
 - (2) Medical cannabidiol testing in the same container-closure system in which the medical cannabidiol is marketed and dispensed.
- c.* If product-expiration-date studies have not been completed before December 1, 2018, a manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information. A manufacturer shall concurrently conduct stability studies to determine the actual product expiration date.
- d.* After a manufacturer verifies the tentative product expiration date, or determines the appropriate product expiration date, a manufacturer shall include that product expiration date on each lot of medical cannabidiol.
- e.* Stability testing shall be repeated if the manufacturing process or the product's chemical composition is changed.

154.26(5) *Reserve samples.*

a. A manufacturer shall retain a uniquely labeled reserve sample that represents each lot of medical cannabidiol and store the reserve sample 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 two years from the date of manufacture.

c. After two years from the date of manufacture, 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 as provided in subrule 154.23(2) when samples fail to meet established standards, specifications, and other relevant quality control criteria and when an adequate remedy for remixing and retesting as provided in paragraph 154.26(3) “c” is unavailable.

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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4078C, IAB 10/10/18, effective 11/14/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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 the manufacturer’s inventory of plant material and medical cannabidiol to include:

a. The quantity and form of medical cannabidiol maintained by the manufacturer at the manufacturing facility on a daily basis;

b. The amount of plants being grown at the manufacturing facility on a daily basis;

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. No less often than every two calendar weeks, a manufacturer shall reconcile its physical inventory with the inventory recorded in the department’s secure sales and inventory tracking system.

a. Reconciliation shall include:

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

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

b. Discrepancies between the physical inventory of the manufacturer and the inventory recorded in the department’s secure sales and inventory system shall be handled as follows:

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

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

154.27(6) Scales. All scales used to weigh usable plant material for purposes of these rules shall be certified in accordance with ISO/IEC Standard 17025, which is incorporated herein by reference.
[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4078C, IAB 10/10/18, effective 11/14/18]

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 nonexhaustive 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 respond to deficiencies found during inspections or inventory reconciliation as follows:

- a. Deficiencies not related to inventory reconciliation.
 - (1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a manufacturer shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.
 - (2) The department shall have up to two weeks to accept or require revision of the action plan.
- b. Deficiencies related to inventory reconciliation.
 - (1) Upon notifying the department that the manufacturer cannot reconcile the manufacturer's physical inventory with the inventory recorded in the department's secure sales and inventory tracking system, the manufacturer shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.
 - (2) The department shall have up to two business days to accept or require revision of the action plan.

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

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

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4078C, IAB 10/10/18, effective 11/14/18]

641—154.29(124E) Assessment of penalties. The department shall assess to a manufacturer a civil penalty of up to \$1,000 per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

641—154.30(124E) 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 30 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 or investors to have a satisfactory result in a background investigation or national criminal history background check conducted by the department of public safety and as determined by the department.

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. The order shall be delivered by one or more of the following methods:

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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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 are destroyed at a waste facility as provided in subrule 154.23(2).

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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 641—154.52(124E).

154.40(4) *Establishment and maintenance of a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available 24 hours a day, seven days a week to track:

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

154.40(5) *Licensure and licensure renewal of 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 chapter 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.8(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. The application shall be submitted 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 in which 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.
- (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.

154.40(7) Recall of medical cannabidiol products. The department may require a dispensary to recall medical cannabidiol from the dispensary facility and patients when there is potential for serious health consequences from use of the products as determined by the department. Situations that may require a recall include but are not limited to:

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

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

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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 record keeping.

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 chapter 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 rules 641—154.21(124E) and 641—154.46(124E);
- (7) Repackage medical cannabidiol or remove the manufacturer's label;
- (8) Sell medical cannabidiol in any form or quantity other than a form or quantity 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 18 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.

c. An applicant or licensed dispensary shall respond within 30 days to a request from the department or the department of public safety for more information to complete a background investigation and national criminal history background check on an owner, investor, or employee.

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.
[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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 restricted access areas;
- (4) Store data for retrieval for a minimum of one year; and
- (5) Limit access to authorized individuals 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 access areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted access 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 to the extent identification is technologically feasible with generally accepted commercial security cameras;

(2) Have the ability to produce a clear, color still photograph live or from a recording;

(3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does 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 recordings from all video cameras are:

(1) Available for viewing by the department upon request;

(2) Retained for at least 60 days;

(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 the employee is 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 access areas of the dispensary; and
- (2) Obtain and destroy the employee's identification card, if possible.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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 1,000 feet of a public or private school existing before the date of the dispensary's licensure by the department.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

641—154.44(124E) Advertising and marketing.

154.44(1) Permitted marketing and advertising activities.

a. A dispensary may:

(1) 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.

(2) Display signs on the dispensary; and

(3) 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.
- b.* The business website shall not include any false, misleading, or unsubstantiated statements.
- c.* 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, deny, or request additional information regarding marketing and advertising activity requests from a dispensary. In the event the department fails to respond to a dispensary within 30 days with an approval, denial, or request for additional information, the dispensary's marketing and advertising activity requests shall be deemed approved.

154.44(3) *Inconspicuous display.* A dispensary shall arrange displays of medical cannabidiol, interior signs, and other exhibits to reasonably prevent public viewing from outside the dispensary.
[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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 that:

- (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 the product and its container against physical, chemical, and microbial contamination and deterioration.

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 has 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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

641—154.46(124E) Dispensing.

154.46(1) *Access to all forms of product.* 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 the 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; and

2. The patient registration number;
 (5) Ensure the following information, which may be printed on a secondary label or package insert, is issued with dispensed medical cannabidiol:

1. The date and time the medical cannabidiol is dispensed;
2. The name and address of the dispensary;
3. Any specific instructions for use based upon manufacturer guidelines or department rules.

Text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

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 tracking system within one 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 the 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; and
2. The patient registration number;

(5) Ensure the following information, which may be printed on a secondary label or package insert, is issued with dispensed medical cannabidiol:

1. The date and time the medical cannabidiol is dispensed;
2. The name and address of the dispensary;
3. Any specific instructions for use based upon manufacturer guidelines or department rules.

Text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

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 tracking system within one business day.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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 medical cannabidiol waste from any patient or primary caregiver. A dispensary shall provide all medical cannabidiol waste to the manufacturer for disposal.

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 641—154.23(124E).

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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

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, if purchase is made by the primary caregiver, the name of 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, unless otherwise noted, 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 maintain for at least one year and provide to the department upon request its controlled access system data and visitor manifests.

c. 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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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 the dispensary's 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 least once a calendar week, a dispensary shall reconcile all medical cannabidiol at the dispensary with the inventory recorded in the department's secure sales and inventory tracking system. Discrepancies shall be handled as follows:

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

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

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4078C, IAB 10/10/18, effective 11/14/18]

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 nonexhaustive 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 respond to deficiencies found during inspections or inventory reconciliation as follows:

a. Deficiencies not related to inventory reconciliation.

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

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

b. Deficiencies related to inventory reconciliation.

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

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

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

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

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4078C, IAB 10/10/18, effective 11/14/18]

641—154.53(124E) Assessment of penalties. The department shall assess to a dispensary a civil penalty of up to \$1,000 per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

641—154.54(124E) 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 30 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.

154.54(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. The order shall be delivered by one or more of the following methods:

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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

641—154.56 to 154.59 Reserved.

MEDICAL CANNABIDIOL BOARD

641—154.60(124E) Purpose and duties of board.

154.60(1) The purpose of the board is to administer the provisions of Iowa Code section 124E.5.

154.60(2) Responsibilities of the board include but are not limited to:

a. 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.

b. 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.

c. Working with the department regarding the requirements for the licensure of manufacturers and dispensaries, including licensure procedures.

d. Advising the department regarding the location of manufacturers and dispensaries throughout the state.

e. Making recommendations to the board of medicine relating to the form and quantity of allowable medical uses of cannabidiol.

f. Considering recommendations to the general assembly for statutory revisions to the definition of medical cannabidiol to increase the tetrahydrocannabinol (THC) level to more than 3 percent.

g. Submitting an annual report to the general assembly detailing the activities of the board no later than January 1.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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

154.61(1) *Membership.* The board shall be composed of nine members appointed by the governor pursuant to Iowa Code section 124E.5. 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 appointed to the board 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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

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 website (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.

[ARC 360C, IAB 1/31/18, effective 3/7/18]

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 to 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, telephone 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 50319-0075.

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 six 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 the petitioner of the board's action and the reasons therefore, or grant the petition and notify the petitioner that the board 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.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

641—154.66 to 154.68 Reserved.

LABORATORY TESTING

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

154.69(1) *Laboratory testing requirements and acceptance criteria.* The department shall work with manufacturers and laboratories to create and maintain a document describing required sampling methodology, acceptance criteria, stability-testing procedures, and other guidance for manufacturers and laboratories on testing procedures. The department shall provide manufacturers and laboratories no less than 14 days in which to comment on proposed revisions to the document, and the department shall provide no less than 30 days' notice before a revision takes effect. The document shall:

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

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

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

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

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

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

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

[ARC 4078C, IAB 10/10/18, effective 11/14/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

641—154.70(124E) Requirements of a laboratory.

154.70(1) *Minimum testing requirements.* A laboratory shall establish and implement test methods and corresponding standard operating procedures for the analyses of cannabinoids, residual solvents and processing chemicals, pesticides, microbiological impurities, and metals.

154.70(2) *Additional tests upon request.* A laboratory shall establish and implement test methods and corresponding standard operating procedures for other analyses as requested by the department.

154.70(3) *Level of quantitation.* A laboratory shall be able to demonstrate that its LOQ is below any action level established by the department.

154.70(4) *Inventory tracking.*

a. A laboratory shall use the department's secure sales and inventory tracking system, if available, or a manifest system to record the receipt of medical cannabis goods from a manufacturer for testing.

b. A laboratory shall use the department's secure sales and inventory tracking system, if available, or a manifest system to record the return of medical cannabis goods or waste to a manufacturer.

154.70(5) *Hazardous waste disposal.*

a. A laboratory shall discard hazardous waste, including hazardous waste containing medical cannabis goods, in accordance with federal and state hazardous waste laws.

b. A laboratory shall document the waste disposal procedures followed for each sample.

[ARC 3836C, IAB 6/6/18, effective 7/11/18]

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

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

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

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

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

[ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4078C, IAB 10/10/18, effective 11/14/18]

641—154.72(124E) Content testing.

154.72(1) *Cannabinoids.*

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

- (1) THC;
- (2) THCA;
- (3) CBD; and
- (4) CBDA.

b. A laboratory shall report that the primary sample passed or failed THC potency testing according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

c. A laboratory shall report that the primary sample passed or failed CBD potency testing according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

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

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

(2) Whether the primary sample passed or failed the test in accordance with paragraph 154.72(1)“b.”

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

154.72(2) Contaminants—residual solvents and processing chemicals.

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall analyze primary samples for residual solvents and processing chemicals.

b. The department shall provide a list of residual solvents and processing chemicals for which primary samples are to be tested with corresponding action levels on the department’s website (www.idph.iowa.gov).

c. For each residual solvent or processing chemical for which a primary sample is tested, a laboratory shall report that the primary sample passed the testing if the concentration of residual solvent or processing chemical is at or below the action level approved by the department.

d. For each residual solvent or processing chemical for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of residual solvent or processing chemical is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for residual solvents and processing chemicals and the laboratory determines that a primary sample contains residual solvent or processing chemical analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the residual solvent or processing chemical analytes.

f. The laboratory may test for and provide test results for additional residual solvents or processing chemicals if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each residual solvent or processing chemical for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of “detected but not quantified” for any target residual solvent or processing chemical that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(2)“c” and 154.72(2)“d.”

(3) The names and amounts of any additional residual solvents and processing chemicals identified by the laboratory.

h. If the primary sample fails testing for residual solvents and processing chemicals, the lot fails laboratory testing.

i. When a laboratory identifies additional residual solvents and processing chemicals in a primary sample, the laboratory shall:

(1) Notify the department of the additional residual solvents and processing chemicals and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(3) Contaminants—pesticides.

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for pesticides.

b. The department shall provide a list of pesticides for which primary samples are to be tested with corresponding action levels on the department’s website (www.idph.iowa.gov).

c. For each pesticide for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of pesticide is at or below the action level approved by the department.

d. For each pesticide for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of pesticide is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for pesticides and the laboratory determines that a primary sample contains pesticide analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the pesticide analytes.

f. The laboratory may test for and provide test results for additional pesticides if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each pesticide for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of “detected but not quantified” for any pesticide that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(3) “c” and 154.72(3) “d.”

(3) The names and amounts of any additional pesticides identified by the laboratory.

h. If the primary sample fails testing for pesticides, the lot fails laboratory testing.

i. When a laboratory identifies additional pesticides in a primary sample, the laboratory shall:

(1) Notify the department of the additional pesticides and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(4) Contaminants—metals.

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for metals.

b. The department shall provide a list of metals for which primary samples are to be tested with corresponding action levels on the department’s website (www.idph.iowa.gov).

c. For each metal for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of metal is at or below the action level approved by the department.

d. For each metal for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of metal is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for metals and the laboratory determines that a primary sample contains metal analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the metal analytes.

f. The laboratory may test for and provide test results for additional metals if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each metal for which the primary sample was tested.

1. The concentrations shall be listed in micrograms per gram or other units as determined by the department.

2. The laboratory shall report a result of “detected but not quantified” for any metal that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(4) “c” and 154.72(4) “d.”

(3) The names and amounts of any additional metals identified by the laboratory.

- h.* If the primary sample fails testing for metals, the lot fails laboratory testing.
- i.* When a laboratory identifies additional metals in a primary sample, the laboratory shall:
 - (1) Notify the department of the additional metals and the amounts detected.
 - (2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(5) Contaminants—microbiological impurities.

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for microbiological impurities.

b. The department shall provide a list of microbiological impurities for which primary samples are to be tested on the department's website (www.idph.iowa.gov).

c. For each microbiological impurity for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the microbiological impurity is not detected in 1 gram of matrix or as approved by the department. A primary sample may be reported as passed if a screening procedure yields a negative result or if a presumptively positive result is not found to be positive on the confirmatory procedure.

d. For each microbiological impurity for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the microbiological impurity is detected in 1 gram of matrix or as approved by the department. Confirmatory procedures shall be conducted on all presumptively positive results.

e. If a laboratory is using methods to test primary samples for microbiological impurities and the laboratory determines that a primary sample contains microbiological impurities that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification of the biological impurity.

f. The laboratory may test for and provide test results for additional microbiological impurities if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

- (1) The name of each microbiological impurity for which the primary sample was tested.
- (2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(5)“*c*” and 154.72(5)“*d*.”
- (3) The names of any additional microbiological impurities identified by the laboratory.

h. If the primary sample fails testing for microbiological impurities, the lot fails laboratory testing.

i. When a laboratory identifies additional microbiological impurities in a primary sample, the laboratory shall:

- (1) Notify the department of the additional microbiological impurities detected.
- (2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(6) Additional tests. The laboratory may perform additional tests if asked to do so by a requester.

[ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4078C, IAB 10/10/18, effective 11/14/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

641—154.73(124E) Reporting requirements.

154.73(1) Reporting test results. The laboratory shall generate a certificate of analysis for each primary sample that it tests and make the certificate of analysis available to the manufacturer who ordered the tests and the department through the department's secure sales and inventory tracking system, if available, or another laboratory information management system.

154.73(2) Tentatively identified analytes. A laboratory shall report on the certificate of analysis any tentatively identified analytes detected during the analysis of the primary sample. When a laboratory identifies additional analytes in a primary sample, the laboratory shall:

- a.* Notify the department of the additional analytes detected.

b. Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.73(3) Additional reporting requirements.

a. In addition to the requirements described in rule 641—154.72(124E), the certificate of analysis shall contain, at a minimum, the following information:

- (1) All requirements of Standard ISO/IEC 17025;
- (2) Date of primary sample collection;
- (3) Date the primary sample was received by the laboratory;
- (4) Date of each analysis;
- (5) The LOQ and action level for each analyte, as applicable;
- (6) Whether the primary sample and lot passed or failed laboratory testing; and
- (7) A signature by the laboratory quality officer and the date the certificate of analysis was validated as being accurate by the laboratory quality officer.

b. Any test result that is not covered under the laboratory's ISO/IEC 17025 scope of accreditation shall be clearly identified on the certificate of analysis.

c. Measurements below a method's limit of detection shall be reported as "<" (less than) or "not detected" and reference the reportable limit. The reporting of zero concentration is not permitted.

d. Measurements \geq LOD but $<$ LOQ shall be reported as "detected but not quantified."

e. The number of significant figures reported shall reflect the precision of the analysis.

[ARC 3836C, IAB 6/6/18, effective 7/11/18]

641—154.74(124E) Record-keeping requirements.

154.74(1) Data package. A laboratory shall create a data package for each analytical batch of primary samples that the laboratory analyzes. The data package shall contain at minimum the following information:

- a. The name and address of the laboratory that performed the analytical procedures;
- b. The names, functions, and signatures (electronic or handwritten) of the laboratory personnel that performed the primary sample preparation, analyzed the primary samples, and reviewed and approved the data;
- c. All primary sample and analytical batch quality control sample results;
- d. Raw data for each primary sample analyzed;
- e. Instrument raw data, if any was produced;
- f. Instrument test method with parameters;
- g. Instrument tune report, if one was created;
- h. All instrument standard calibration data;
- i. Test-method worksheets or forms used for primary sample identification, characterization, and calculations, including chromatograms, sample-preparation worksheets, and final datasheets;
- j. The quality control report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis;
- k. The analytical batch sample sequence;
- l. The field sample log; and
- m. The chain-of-custody form.

154.74(2) Review of data package. After the laboratory has compiled a data package, another individual at the laboratory shall independently review the data package. The reviewer shall:

- a. Assess the analytical results for technical correctness and completeness;
- b. Verify that the results of each analysis carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively;
- c. Verify that the measurements can be traced back; and
- d. Approve the measurement results by signing and dating the data package prior to release of the certificate of analysis by the laboratory.

154.74(3) Data package record retention. The entire data package shall be stored by a laboratory for a minimum of five years and shall be made available upon request by the department or the requester of the laboratory testing.

154.74(4) Other records. A laboratory shall maintain all documents, forms, records, and standard operating procedures associated with the testing of medical cannabis goods.

a. A laboratory shall maintain analytical testing laboratory records in such a manner that the analyst, the date the analysis was performed, the approver of the certificate of analysis, the reviewer and approver of the data package, the test method, and the materials that were used can be determined by the department.

b. Records shall be stored in such a way that the data may be readily retrieved when requested by the department.

c. All testing laboratory records shall be kept for a minimum of five years, unless otherwise noted in these rules.

d. The department shall be allowed access to all electronic data, including standards records, calibration records, extraction logs, and laboratory notebooks.

e. A laboratory shall keep and make available to the department the following records related to the testing of medical cannabis goods:

(1) Personnel qualification, training, and competency documentation, including but not limited to résumés, training records, continuing education records, analytical proficiency testing records, and demonstration of competency records for laboratory work. These records shall be kept current.

(2) Method verification and validation records, including method modification records, method detection limit and quantitation limit determination records, ongoing verification records such as proficiency test records and reference material analysis records.

(3) Quality control and quality assurance records, including the laboratory's quality assurance manual and control charts with control limits.

(4) Chain-of-custody records, including chain-of-custody forms, field sample logs, sample-receipt records, sample-description records, sample-rejection records, laboratory information management system records, sample-storage records, sample-retention records, and disposal records.

(5) Purchasing and supply records, equipment-services records, and other equipment records, including purchase requisition records, packing slips, supplier records, and certificates of analysis.

(6) Laboratory equipment installation records, maintenance records, and calibration records. These records shall include the date and name of the person performing the installation of, calibration of, or maintenance on the equipment, with a description of the work performed, maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records, and daily verification-of-calibration records.

(7) Customer service records, including customer contracts, customer requests, certificates of analysis, customer transactions, customer feedback, records related to the handling of complaints and nonconformities, and corrective action pertaining to complaints.

(8) Nonconforming work and corrective action records, including corrective action, nonconformance, nonconformities resolved by correction, customer notification of nonconformities, internal investigations, implementation of corrective action, and resumption-of-work records.

(9) Internal-audit and external-audit records, including audit checklists, standard operating procedures, and audit observation and findings reports. These records shall include the date and name of the person performing the audit.

(10) Management review records, including technical data review reports and final management-review reports. These records shall include the review date and the name of the reviewer.

(11) Laboratory data reports, data review, and data approval records, including instrument and equipment identification records, records with unique sample identifiers, analysts' laboratory notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data, and test-method raw data. These records shall include the analysis date and the name of the analyst.

(12) Proficiency testing records, including the proficiency test schedule, proficiency tests, data-review records, data-reporting records, nonconforming work and corrective actions, and quality control and quality assurance records related to proficiency testing.

(13) Electronic data, backed-up data, records regarding the protection of data, including unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, and authorized personnel records.

(14) Security data, including laboratory-security records and laboratory-access records, surveillance-equipment records, and security-equipment records. These records shall be stored for at least one year.

(15) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' laboratory notebooks and logbooks, supplier records, and certificates of analysis, and all other data-related records.

(16) Laboratory contamination and cleaning records, including autoclave records, acid-wash logs and records, and general laboratory-safety and chemical-hygiene protocols.

[ARC 3836C, IAB 6/6/18, effective 7/11/18]

641—154.75(124E) Quality control. The laboratory shall have quality control protocols that include the following elements:

154.75(1) *Quality control samples required.*

a. The laboratory shall run quality control samples with every analytical batch of samples for chemical and microbiological analysis.

b. For microbiological analysis, the laboratory shall develop procedures for quality control requirements for each analytical batch of samples.

c. The laboratory shall analyze the quality control samples in exactly the same manner as the test samples to validate the laboratory testing results.

154.75(2) *Types of quality control samples.* At a minimum, a laboratory shall have the following quality control samples as part of every analytical batch tested for chemical analytes:

a. Negative control (method blank). A laboratory shall prepare and run at least one method blank sample with an analytical batch of 10 to 20 samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch, to demonstrate that the analytical process did not introduce contamination.

b. Positive control (laboratory control sample). A laboratory shall prepare and run at least one laboratory control sample with an analytical batch of 10 to 20 samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch.

c. Matrix spike sample. A laboratory shall prepare and run one or more matrix spike samples for each analytical batch.

(1) A laboratory shall calculate the percent recovery for quantitative chemical analysis by dividing the sample result by the expected result and multiplying that by 100. All quality control measures shall be assessed and evaluated on an ongoing basis, and quality control acceptance criteria shall be used. When necessary, the department may establish acceptance criteria on the department's website (www.idph.iowa.gov).

(2) If quality control acceptance criteria are not acceptable, a laboratory shall investigate the cause, correct the problem, and rerun the analytical batch of samples. If the problem persists, the laboratory shall reprepare the samples and run the analysis again, if possible.

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

154.75(3) *Certified reference material for chemical analysis.* The laboratory shall use a reference material for each analytical batch in accordance with the following standards:

a. The reference material should be certified and obtained from an outside source, if possible. If a reference material is not available from an outside source, the laboratory shall make its own in-house reference material.

b. Reference material made in-house should be made from a different source of standards than the source from which the calibration standards are made.

c. The test result for the reference material shall fall within the quality control acceptance criteria. If it does not, the laboratory shall document and correct the problem and run the analytical batch again.

154.75(4) Calibration standards. The laboratory shall prepare calibration standards by serially diluting a standard solution to produce working standards used for calibration of an instrument and quantitation of analyses in samples.

154.75(5) Quality control-sample report. A laboratory shall generate a quality control-sample report that includes quality control parameters and measurements, analysis date, and type of matrix.

154.75(6) Limit-of-detection and limit-of-quantitation calculations. For chemical method analysis, a laboratory shall calculate the limit of detection and limit of quantitation using generally accepted methodology.

[ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

641—154.76(124E) Security requirements. The department may request assistance from the department of public safety in ensuring a laboratory meets the security requirements in this rule.

154.76(1) Security policy requirement. A laboratory shall maintain a security policy to prevent the loss, theft, or diversion of medical cannabis goods and samples. The security policy shall apply to all staff and visitors at a laboratory facility.

154.76(2) Visitor logs. Visitors to a laboratory 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 that identify them as visitors.

154.76(3) Restricted access. A laboratory shall use a controlled access system and written manifests to limit entrance to all restricted access areas of its laboratory facility and shall retain a record of all persons who entered the restricted access 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;

(4) Track times of personnel movement between restricted access areas;

(5) Store data for retrieval for a minimum of one year; 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 one year if the controlled access system does not include electronic records of visitors to the restricted areas.

c. A laboratory shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

154.76(4) Personnel identification system. A laboratory shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the laboratory facility and that meets the requirements of this subrule and subrule 154.76(2).

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

(1) The name of the employee;

(2) The date of issuance;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A laboratory employee shall keep the identification card visible at all times when the employee is in the laboratory.

c. Upon termination or resignation of an employee, a laboratory shall immediately:

- (1) Revoke the employee's access to the laboratory; and
- (2) Obtain and destroy the employee's identification card, if possible.

154.76(5) Video monitoring and surveillance.

a. Video surveillance system. A laboratory shall operate and maintain in good working order a video surveillance system for its premises that operates 24 hours per day, seven days a week, and visually records all areas where medical cannabis goods are stored or tested.

b. Camera specifications. Cameras shall:

- (1) Capture clear and certain identification of any person entering or exiting a restricted access area containing medical cannabis goods;
- (2) Have the ability to produce a clear, color still photograph live or from a recording;
- (3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does 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 laboratory shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

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

- (1) Available for viewing by the department upon request;
- (2) Retained for a minimum of 60 days;
- (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.

154.76(6) Chain-of-custody policy and procedures. A laboratory shall maintain a current chain-of-custody policy and procedures. The policy should ensure that:

- a.* Chain of custody is maintained for samples which may have probable forensic evidentiary value; and
- b.* Annual training is available for individuals who will be involved with testing medical cannabis goods.

154.76(7) Information technology systems security. A laboratory shall maintain information technology systems protection by employing comprehensive security controls that include security firewall protection, antivirus protection, network and desktop password protection, and security patch management procedures.

[ARC 3836C, IAB 6/6/18, effective 7/11/18]

These rules are intended to implement Iowa Code chapter 124E.

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