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 and medical cannabidiol;

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.* Medical cannabidiol products may be recalled in the following ways:

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

b. By department. If the department determines, based on an evaluation of the health hazard presented, that there is a reasonable probability that use of, or exposure to, a violative medical cannabidiol product will cause a serious adverse health consequence or death, the department may require a manufacturer to recall such violative medical cannabidiol products from dispensaries. An evaluation of the health hazard presented by medical cannabidiol being considered for recall shall be

conducted by an ad hoc committee of scientists appointed by the director of the department and shall take into account, but need not be limited to, each of the following factors:

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

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

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

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

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

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

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

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter; **ARC 4928C**, IAB 2/12/20, effective 6/1/20; see correction note at end of chapter; **ARC 6343C**, IAB 6/15/22, effective 7/20/22]