

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.

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