

**641—154.26(124E) Manufacturer operations.****154.26(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 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 disposal methods for all waste materials;

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

6. 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;

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

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

9. Medical cannabidiol packaging and labeling procedures;

10. Procedures for recall of medical cannabidiol;

11. 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;

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

13. Records relating to all transport activities; and

14. Other information requested by the department.

(2) Procedures to ensure accurate recordkeeping.

(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.

**154.26(2) Prohibited activities.** In addition to following all provisions of Iowa Code section 124E.7, a manufacturer shall not:

*a.* Produce or manufacture medical cannabidiol in any location except in those areas approved by the department;

*b.* Sell, deliver, transport, or distribute medical cannabidiol from any location except its manufacturing facility or a dispensary facility;

*c.* Produce or manufacture medical cannabidiol in Iowa for sales or distribution outside of Iowa;

*d.* Sell or distribute medical cannabidiol to any person or business other than a dispensary or manufacturer licensed by the department under Iowa Code chapter 124E;

*e.* 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;

*f.* Transport or deliver medical cannabidiol to any location except as allowed in subrule 154.22(1);

*g.* Introduce synthetic or semisynthetic cannabinoids derived from hemp into medical cannabidiol products;

*h.* Produce synthetic or semisynthetic cannabinoids within the licensed manufacturing facility.