

4770.0400 MEDICAL CANNABIS MANUFACTURER; OPERATIONS.

Subpart 1. **Operating documents.** Under Minnesota Statutes, section 152.29, subdivision 1, the operating documents of a medical cannabis manufacturer must describe operational and management practices, including:

- A. record keeping;
- B. security measures to deter and prevent theft of medical cannabis;
- C. unauthorized entrance into areas containing medical cannabis;
- D. types and quantities of medical cannabis products that are produced at the manufacturing facility;
- E. methods of planting, harvesting, drying, and storage of medical cannabis;
- F. estimated quantity of all crop inputs used in production;
- G. estimated quantity of waste material to be generated;
- H. disposal methods for all waste materials;
- I. employee training methods for the specific phases of production;
- J. biosecurity measures used in production and in manufacturing;
- K. strategies for reconciling discrepancies in plant material or medical cannabis;
- L. sampling strategy and quality testing for labeling purposes;
- M. medical cannabis packaging and labeling procedures;
- N. procedures for the mandatory and voluntary recall of medical cannabis;
- O. plans for responding to a security breach at a manufacturing or distribution facility, or while medical cannabis is in transit to a manufacturing or distribution facility;
- P. business continuity plan;
- Q. records relating to all transport activities; and
- R. other information requested by the commissioner.

Subp. 2. Prohibited activities.

A. A person may not own and operate a manufacturing facility unless the person is registered as a medical cannabis manufacturer by the commissioner under Minnesota Statutes, section 152.25.

B. A medical cannabis manufacturer and its employees, agents, or owners may not:

(1) cultivate, produce, or manufacture medical cannabis in any location except in those areas designated for those activities in the registration agreement;

- (2) sell or distribute medical cannabis or medical cannabis products from any location except its distribution facilities;
- (3) produce or manufacture medical cannabis for use outside of Minnesota;
- (4) sell or distribute medical cannabis to any person other than a registered:
 - (a) patient;
 - (b) parent or legal guardian; or
 - (c) designated registered caregiver;
- (5) deliver or transport medical cannabis to any location except the manufacturer's production facility or distribution facilities, a waste-to-energy facility, another manufacturer's distribution facilities, a testing laboratory approved by the commissioner, and a laboratory selected by the commissioner to conduct audit testing under part 4770.3035;
- (6) sell medical cannabis that is not packaged and labeled in accordance with part 4770.0850; or
- (7) permit the consumption of medical cannabis at a distribution facility.

Subp. 3. **Criminal background checks.** A medical cannabis manufacturer is prohibited from employing any person who has a disqualifying felony offense as shown by a Minnesota criminal history background check or a federal criminal history background check performed by the Bureau of Criminal Apprehension under Minnesota Statutes, section 152.29, subdivision 1.

Subp. 4. **Conflict of interest; health care practitioner activity restrictions.** A medical cannabis manufacturer may not:

- A. permit a health care practitioner who certifies qualifying conditions for patients to:
 - (1) hold a direct or indirect economic interest in the medical cannabis manufacturer;
 - (2) serve on the board of directors or as an employee of the medical cannabis manufacturer; or
 - (3) advertise with the medical cannabis manufacturer in any capacity;
- B. accept or solicit any form of remuneration from a health care practitioner who certifies qualifying conditions for patients; or
- C. offer any form of remuneration from a health care practitioner who certifies qualifying conditions for patients.

Statutory Authority: *MS s 14.389; 152.25; 152.26*

History: *39 SR 1080; 46 SR 1011*

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