

## MINNESOTA RULES

## CHAPTER 4770

## DEPARTMENT OF HEALTH

## MEDICAL CANNABIS

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**MANUFACTURERS****4770.0100 APPLICABILITY AND PURPOSE.**

Parts 4770.0200 to 4770.2700 establish the criteria and procedures to be used by the commissioner for the registration and oversight of a medical cannabis manufacturer.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

**4770.0200 DEFINITIONS.**

Subpart 1. **Scope.** The terms used in this chapter have the meanings given them in this part.

Subp. 2. **Acceptable performance or acceptable results.** "Acceptable performance" or "acceptable results" means analytical test results generated by a laboratory using methods as specified in part 4770.2000 that are acceptable and allowed by the approved provider.

Subp. 3. **Approval.** "Approval" means acknowledgment by the commissioner that a laboratory has the policies, personnel, validation procedures, and practices to produce reliable data in the analysis of analytes and contaminants described in part 4770.1900.

Subp. 4. **Approved provider.** "Approved provider" means a provider of performance testing samples that the commissioner has determined:

- A. provides an adequate volume of samples to perform statistically valid analyses;
- B. calculates the number of standard deviations of the mean allowed using the results of all laboratories submitting test results after the exclusion of outlying values; and
- C. allows a range of standard deviations of the mean no less stringent than the range allowed by the general requirements for the competency of reference material producers in ISO Guide 34.

Subp. 5. **Audit.** "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.

Subp. 6. **Batch.** "Batch" means a specific quantity of medical cannabis 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 batch record.

Subp. 7. **Batch number.** "Batch number" means a unique numeric or alphanumeric identifier assigned to a batch by a manufacturing facility when the batch is first planted. The batch number must contain the manufacturing facility number and a sequence to allow for inventory and traceability.

Subp. 8. **Biosecurity.** "Biosecurity" means a set of preventative measures designed to reduce the risk of transmission of:

- A. infectious diseases in crops;
- B. quarantined pests;
- C. invasive alien species; and
- D. living modified organisms.

Subp. 9. **Certified financial audit.** "Certified financial audit" means the annual financial audit required under Minnesota Statutes, section 152.37, subdivision 2.

Subp. 10. **Commissioner.** "Commissioner" means the commissioner of the Department of Health or the commissioner's designee.

Subp. 11. **Disqualifying felony offense.** "Disqualifying felony offense" has the meaning given in Minnesota Statutes, section 152.22, subdivision 3.

Subp. 12. **Distribute or distribution.** "Distribute" or "distribution" means the delivery of medical cannabis to a patient, the patient's parent or legal guardian, or the patient's registered caregiver that is packaged in a suitable container appropriately labeled for subsequent administration to or use by a patient who is participating in the registry program and who is authorized to receive medical cannabis.

Subp. 13. **Distribution facility.** "Distribution facility" means any building or grounds of a medical cannabis manufacturer where the sale and distribution of medical cannabis and medical cannabis products are authorized.

Subp. 14. **Diversión.** "Diversión" means the intentional transfer of medical cannabis to a person other than a patient, the patient's designated registered caregiver, or the patient's parent or legal guardian if the parent or legal guardian is listed on the registry verification.

Subp. 15. **Field of testing.** "Field of testing" means the combination of product type and analyte for which a laboratory has applied or received approval by the commissioner.

Subp. 16. **Financial interest.** "Financial interest" means any actual or future right to ownership, investment, or compensation arrangement in a medical cannabis manufacturer with another person, either directly or indirectly, through business, investment, or spouse, parent, or child relationship. Financial interest does not include ownership of investment securities in a publicly held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by the person or the person's spouse, parent, or child, in the aggregate, do not exceed one percent ownership in the medical cannabis manufacturer.

Subp. 17. **Health care practitioner.** "Health care practitioner" has the meaning given in Minnesota Statutes, section 152.22, subdivision 4.

Subp. 18. **Inspection.** "Inspection" means an on-site evaluation of laboratory facilities, records, personnel, equipment, methodology, and quality assurance practices by the commissioner for compliance with this chapter.

Subp. 19. **International Standards Organization or ISO.** The "International Standards Organization" or "ISO" means an independent, nongovernmental membership organization and the largest developer of voluntary international standards.

Subp. 20. **Laboratory managing agent.** "Laboratory managing agent" means a person, as defined in Minnesota Statutes, section 326.71, subdivision 8, who is legally authorized to direct the activities of the laboratory and commit sufficient resources to comply with parts 4770.1900 to 4770.2400.

Subp. 21. **Laboratory.** "Laboratory" means a fixed-based or mobile structure, a person, corporation, or other entity, including a government or tribal entity, that examines, analyzes, or tests samples.

Subp. 22. **Laboratory owner.** "Laboratory owner" means a person who:

- A. is a sole proprietor of a laboratory;
- B. holds a partnership interest in a laboratory; or
- C. owns five percent or more of the shares in a corporation that owns a laboratory.

Subp. 23. **Laboratory technical manager.** "Laboratory technical manager" means a person who is scientifically responsible to ensure the achievement and maintenance of quality and analytical standards or practice and who is in a supervisory, lead worker, or similarly named position within an organization.

Subp. 24. **Manufacturing or manufacture.** "Manufacturing" or "manufacture" means the process of converting harvested cannabis plant material into medical cannabis.

Subp. 25. **Manufacturing facility.** "Manufacturing facility" means any secured building, space, grounds, and physical structure of a medical cannabis manufacturer for the cultivation, harvesting, packaging, and processing of medical cannabis and where access is restricted to designated employees of a medical cannabis manufacturer and escorted visitors.

Subp. 26. **Medical cannabis.** "Medical cannabis" has the meaning given in Minnesota Statutes, section 152.22, subdivision 6.

Subp. 27. **Medical cannabis manufacturer or manufacturer.** "Medical cannabis manufacturer" or "manufacturer" has the meaning given in Minnesota Statutes, section 152.22, subdivision 7.

Subp. 28. **Medical cannabis product.** "Medical cannabis product" has the meaning given in Minnesota Statutes, section 152.22, subdivision 8.

Subp. 29. **Medical cannabis waste.** "Medical cannabis waste" means medical cannabis that is returned, damaged, defective, expired, or contaminated.

Subp. 30. **Parent or legal guardian.** "Parent or legal guardian" has the meaning given in Minnesota Statutes, section 152.27, subdivision 5.

Subp. 31. **Patient.** "Patient" has the meaning given in Minnesota Statutes, section 152.22, subdivision 9.

Subp. 32. **Plant material.** "Plant material" means any cannabis plant, cutting, trimming, or clone that has roots or that is cultivated with the intention of growing roots.

Subp. 33. **Plant material waste.** "Plant material waste" means plant material that is not used in the production of medical cannabis in a form allowable under Minnesota Statutes, section 152.22, subdivision 6.

Subp. 34. **Production or produce.** "Production" or "produce" means:

- (1) cultivating or harvesting plant material;

(2) processing or manufacturing; or

(3) packaging of medical cannabis.

Subp. 35. **Proficiency testing sample or PT sample.** "Proficiency testing sample" or "PT sample" means a sample obtained from an approved provider to evaluate the ability of a laboratory to produce an analytical test result meeting the definition of acceptable performance. The concentration of the analyte in the sample is unknown to the laboratory at the time of analysis.

Subp. 36. **Registered designated caregiver.** "Registered designated caregiver" has the meaning given in Minnesota Statutes, section 152.22, subdivision 11.

Subp. 37. **Registry program.** "Registry program" has the meaning given in Minnesota Statutes, section 152.22, subdivision 12.

Subp. 38. **Registry verification.** "Registry verification" has the meaning given in Minnesota Statutes, section 152.22, subdivision 13.

Subp. 39. **Restricted access area.** "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 medical cannabis manufacturer, and where no person under the age of 21 is permitted.

Subp. 40. **Sufficient cause to believe.** "Sufficient cause to believe" means grounds asserted in good faith that are not arbitrary, irrational, unreasonable, or irrelevant and that make the proposition asserted more likely than not, provided the grounds are based on at least one of the following sources:

A. facts or statements supplied by a patient, the patient's parent or legal guardian, the patient's designated registered caregiver, or an employee or agent of a medical cannabis manufacturer;

B. reports from an approved laboratory that indicate concerns with the chemical or bacterial composition of the medical cannabis;

C. financial records of a medical cannabis manufacturer;

D. police records;

E. court documents; or

F. facts of which the commissioner or the commissioner's employees have personal knowledge.

**Statutory Authority:** *MS s 14.389; 152.25; 152.26; 152.261*

**History:** *39 SR 1080; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

**4770.0300 DUTIES OF COMMISSIONER.**

Subpart 1. **Interagency agreements.** The commissioner may enter into any interagency agreements with other state agencies for technical services or other assistance related to the regulatory or inspection duties of a medical cannabis manufacturer and the registry program.

Subp. 2. **Notice to law enforcement.** If the commissioner has sufficient cause to believe that there is a threat to public safety, then the commissioner must notify local law enforcement agencies of any conditions that pose a threat to public safety, including:

- A. loss or theft of medical cannabis or plant material;
- B. diversion or potential diversion of medical cannabis or plant material; or
- C. unauthorized access to the patient registry.

Subp. 3. **Inspection of medical cannabis manufacturer.** A medical cannabis manufacturer is subject to reasonable inspection by the commissioner under Minnesota Statutes, section 152.29, subdivision 1. For purposes of this part, "reasonable inspection" means unannounced inspections by the commissioner of all:

- A. aspects of the business operations;
- B. physical locations of the medical cannabis manufacturer, its manufacturing facility, and distribution facilities;
- C. financial information and inventory documentation; and
- D. physical and electronic security alarm systems.

Subp. 4. **Fees.** Any fees collected by the commissioner under Minnesota Statutes, section 152.35, are not refundable.

Subp. 5. **Patient costs; pricing.**

A. A medical cannabis manufacturer must follow the requirements under Minnesota Statutes, section 152.35, paragraph (d), in establishing a reasonable fee.

B. The commissioner may annually review price costing by a medical cannabis manufacturer.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

**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) produce or manufacture medical cannabis in any location except in those areas designated in the registration agreement;
  - (2) sell, deliver, transport, or distribute medical cannabis or medical cannabis products from any location except its manufacturing facility or its distribution facility;
  - (3) produce or manufacture medical cannabis for use outside of Minnesota;
  - (4) sell or distribute medical cannabis to any person other than a:
    - (a) patient;



(b) parent or legal guardian; or

(c) designated registered caregiver;

(5) deliver or transport medical cannabis to any location except its distribution facilities and a laboratory approved by the commissioner;

(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*

**Published Electronically:** *February 20, 2015*

#### **4770.0500 MEDICAL CANNABIS MANUFACTURER; QUALITY CONTROL; ASSURANCE PROGRAM.**

Subpart 1. **Quality control program.** A medical cannabis manufacturer must develop and implement a written quality assurance program that assesses the chemical and microbiological composition of medical cannabis. Assessment includes a profile of the active ingredients, including shelf life, and the presence of inactive ingredients and contaminants. A medical cannabis manufacturer must use these testing results to determine appropriate storage conditions and expiration dates.

Subp. 2. **Sampling protocols.** A medical cannabis manufacturer must develop and follow written procedures for sampling medical cannabis 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 commissioner upon request;
- C. describe all sampling and testing plans in written procedures that include the sampling method and the number of units per batch to be tested;
- D. ensure that random samples from each batch are:
  - (1) taken in an amount necessary to conduct the applicable test;
  - (2) labeled with the batch unique identifier; and
  - (3) submitted for testing; and
- E. retain the results from the random samples for at least five years.

Subp. 3. **Sampling; testing levels.** A medical cannabis manufacturer must:

- A. 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 cannabis. The testing levels are subject to approval by the commissioner;
- B. conduct sampling and testing using acceptance criteria that are protective of patient health. The sampling and testing results must ensure that batches of medical cannabis meet allowable health risk limits for contaminants;
- C. reject a medical cannabis batch that fails to meet established standards, specifications, and any other relevant quality-control criteria;
- D. develop and follow a written procedure for responding to results indicating contamination. The procedure must include destroying contaminated medical cannabis and determining the source of contamination; and
- E. retain documentation of test results, assessment, and destruction of medical cannabis for at least five years.

Subp. 4. **Quality assurance program; stability testing.**

- A. The quality assurance program must include procedures for performing stability testing of each product type produced to determine product shelf life that addresses:
  - (1) sample size and test intervals based on statistical criteria 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 must include:

(1) medical cannabis testing at appropriate intervals;

(2) medical cannabis testing in the same container-closure system in which the drug product is marketed; and

(3) testing medical cannabis for reconstitution at the time of dispensing, as directed in the labeling, and after the samples are reconstituted.

C. If shelf-life studies have not been completed before July 1, 2015, a medical cannabis manufacturer may assign a tentative expiration date, based on any available stability information. The manufacturer must concurrently conduct stability studies to determine the actual product expiration date.

D. After the manufacturer verifies the tentative expiration date, or determines the appropriate expiration date, the medical cannabis manufacturer must include that expiration date on each batch of medical cannabis.

E. Stability testing must be repeated if the manufacturing process or the product's chemical composition is changed.

**Subp. 5. Reserve samples.**

A. A medical cannabis manufacturer must retain a uniquely labeled reserve sample that represents each batch of medical cannabis and store it under conditions consistent with product labeling. The reserve sample must be stored in the same immediate container-closure system in which the medical cannabis is marketed, or in one that has similar characteristics. The reserve sample must consist of at least twice the quantity necessary to perform all the required tests.

B. A medical cannabis manufacturer must retain the reserve for at least one year following the batch's expiration date.

Subp. 6. **Retesting.** If the commissioner deems that public health may be at risk, the commissioner may require the manufacturer to retest any sample of plant material or medical cannabis.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

**4770.0600 LOCATION; DISTANCE FROM SCHOOL.**

Under Minnesota Statutes, section 152.29, paragraph (j), a medical cannabis manufacturer may not operate within 1,000 feet of an existing public or private school. The medical cannabis manufacturer must measure the distance between the closest point of the manufacturing or distribution facility property lines to the closest point of the school's property lines.

For purposes of this part, "public or private school" means any property operated by a school district, charter school, or accredited nonpublic school for elementary, middle, or secondary school, or secondary vocation center purposes.

"Accredited nonpublic school" means any nonpublic school accredited by an accrediting agency recognized by the Minnesota nonpublic education council under Minnesota Statutes, section 123B.445, excluding home schools.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

#### **4770.0700 HOURS OF OPERATION; ACCESS.**

Subpart 1. **Limiting hours of operation.** The commissioner may limit the hours of operation of a manufacturing facility if there is sufficient cause to believe that limiting the hours of operation protects public safety.

Subp. 2. **Restricted access areas.** A medical cannabis manufacturer must use an electronic controlled access system to limit entrance to all restricted access areas of its manufacturing facility and its distribution facilities.

A. An electronic controlled access system must:

- (1) limit access to authorized individuals;
- (2) track personnel entry and exit times;
- (3) lock down the facility in the event of a security threat;
- (4) store data for retrieval;
- (5) remain operable in the event of power failure; and
- (6) enable remote administration.

B. A medical cannabis manufacturer must immediately submit stored controlled-access-system data to the commissioner upon the commissioner's request.

C. Restricted access areas must be identified with a sign that states: "Do Not Enter -- Restricted Access Area -- Access Limited to Authorized Personnel Only."

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

#### **4770.0800 ADVERTISING AND MARKETING.**

Subpart 1. **Permitted marketing and advertising activities.** A medical cannabis manufacturer may:

A. display the manufacturer's business name and logo on medical cannabis labels, signs, website, and informational material provided to patients. The name or logo must not include:

- (1) images of cannabis or cannabis-smoking paraphernalia;
- (2) colloquial references to cannabis;
- (3) names of cannabis plant strains; or

(4) 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 commissioner;

B. display signs on the manufacturing facility and distribution facility; and

C. maintain a business website that contains the following information:

- (1) the medical cannabis manufacturer name;
- (2) the distribution facility location;
- (3) the contact information;
- (4) the distribution facility's hours of operation;
- (5) the medical cannabis products provided;
- (6) product pricing; and
- (7) other information as approved by the commissioner.

**Subp. 2. Marketing and advertising activities; commissioner approval required.**

A. A medical cannabis manufacturer must request and receive the commissioner's written approval before beginning marketing or advertising activities that are not specified in subpart 1.

B. The commissioner has 30 calendar days to approve marketing and advertising activities submitted under this subpart.

**Subp. 3. Inconspicuous display.** A medical cannabis manufacturer must arrange displays of merchandise, interior signs, and other exhibits to prevent public viewing from outside the manufacturing facility and distribution facility.

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

**History:** *39 SR 1080*

**Published Electronically:** *September 7, 2018*

**4770.0850 PACKAGING AND LABELING.**

Subpart 1. **Medical cannabis packaging.** The medical cannabis manufacturer must package all medical cannabis intended for distribution according to the following standards:

A. In addition to the requirements in Minnesota Statutes, section 152.29, subdivision 3, paragraph (c), clause (5), medical cannabis containers must be:

- (1) plain;
- (2) designed to maximize the shelf life of contained medical cannabis;
- (3) tamper-evident; and
- (4) child-resistant.

B. Medical cannabis packaging must not bear a reasonable resemblance to any commercially available product.

C. Medical cannabis packaging must be packaged to minimize its appeal to children and must not depict images other than the medical cannabis manufacturer's business name or logo.

Subp. 2. **Medical cannabis trade names.** The medical cannabis manufacturer's medical cannabis trade names must comply with the following standards and are subject to approval by the commissioner:

- A. names that are limited to those that clearly reflect the product's medical cannabis nature;
- B. any name that is identical to, or confusingly similar to, the name of an existing noncannabis product is prohibited;
- C. any name that is identical to, or confusingly similar to, the name of an unlawful product or substance is prohibited; and
- D. any name that contains language that suggests using medical cannabis for recreational purposes or for a condition other than a qualifying medical condition is prohibited.

Subp. 3. **Labeling.**

A. A medical cannabis manufacturer must ensure that all medical cannabis that is distributed is labeled with the following information:

- (1) the patient's registry identification number, name, and date of birth;
- (2) the name and date of birth of the designated registered caregiver, if applicable;
- (3) the name of the patient's parent or legal guardian, if listed on the registry verification, if applicable;
- (4) the patient's address;
- (5) the name and address of the medical cannabis manufacturer where the medical cannabis was manufactured;
- (6) the medical cannabis's chemical composition;
- (7) the recommended dosage;

(8) directions for use of the product;

(9) 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;

(10) the date of manufacture and batch number;

(11) 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. Do not drive or operate heavy machinery when under the influence of this product. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN."; and

(12) a notice with the statement: "This medical cannabis is for therapeutic use only. Diversion of this product is unlawful and may result in the revocation of the patient's registration."

B. Labeling text must not include any false or misleading statements regarding health or physical benefits to the patient.

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

**Statutory Authority:** *MS s 14.389; 152.25; 152.26; 152.261*

**History:** *39 SR 1080; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

#### **4770.0900 MONITORING AND SURVEILLANCE REQUIREMENTS.**

Subpart 1. **24-hour closed-circuit television.** A medical cannabis manufacturer must operate and maintain in good working order a closed-circuit television (CCTV) surveillance system on all of its premises, which must operate 24 hours per day, seven days per week, and visually record:

A. all phases of production;

B. all areas that might contain plant material and medical cannabis, including all safes and vaults;

C. all points of entry and exit, including sales areas;

D. the entrance to the video surveillance room; and

E. any parking lot, which must have appropriate lighting for the normal conditions of the area under surveillance.

Subp. 2. **Camera specifications.** Cameras must:

A. capture clear and certain identification of any person entering or exiting a manufacturing facility or distribution facility;

B. have the ability to produce a clear, color, still photo either live or from a recording;

C. have an embedded date-and-time stamp on all recordings that must be synchronized and not obscure the picture; and

D. continue to operate during a power outage.

**Subp. 3. Video recording specifications.**

A. A video recording must export still images in an industry standard image format, including .jpg, .bmp, and .gif.

B. Exported video must be archived in a proprietary format that ensures authentication and guarantees that the recorded image has not been altered.

C. Exported video must also be saved in an industry standard file format that can be played on a standard computer operating system.

D. All recordings must be erased or destroyed before disposal.

**Subp. 4. Additional requirements.** The manufacturer must maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

**Subp. 5. Retention.** The manufacturer must ensure that 24-hour recordings from all video cameras are:

A. available for viewing by the commissioner upon request;

B. retained for at least 90 calendar days;

C. maintained free of alteration or corruption; and

D. retained longer, as needed, if the 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.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

**4770.1000 ALARM SYSTEM REQUIREMENTS.**

A. A medical cannabis manufacturer must 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 purposes of this part, 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 must continue to operate during a power outage.

D. The commissioner must have the ability to access a medical cannabis manufacturer's security alarm system.

E. The manufacturer's security alarm system must be inspected and all devices tested annually by a qualified alarm vendor.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

#### **4770.1100 TRANSPORTATION OF MEDICAL CANNABIS.**

##### **Subpart 1. Transportation of medical cannabis and plant material; when authorized.**

A. A medical cannabis manufacturer is authorized to transport medical cannabis:

- (1) from its manufacturing facility to its distribution facilities;
- (2) from its manufacturing facility to a laboratory for testing; and
- (3) from its manufacturing facility or distribution facility to a waste-to-energy facility.

B. A medical cannabis manufacturer is authorized to transport plant material:

- (1) from its manufacturing facility to a waste disposal site; and
- (2) when a specific nonroutine transport request from the manufacturer is approved by the commissioner.

**Subp. 2. Transporting medical cannabis.**

A. A medical cannabis manufacturer must use a manifest system, approved by the commissioner, to track shipping of medical cannabis. The manifest system must 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 cannabis 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 cannabis, a medical cannabis manufacturer must:

- (1) complete a manifest on a form approved by the commissioner; and
- (2) transmit a copy of the manifest to the manufacturer's distribution facility, a laboratory, or a waste-to-energy facility, as applicable.

C. The manifest must be signed by:

- (1) an authorized manufacturer employee when departing the manufacturing facility; and
- (2) an authorized employee of the receiving distribution facility, laboratory, or waste-to-energy facility.

D. An authorized employee at the facility receiving medical cannabis must:

- (1) verify and document the type and quantity of the transported medical cannabis against the manifest;
- (2) return a copy of the signed manifest to the manufacturing facility; and
- (3) record the medical cannabis that is received as inventory according to part 4770.1800.

E. A manufacturer must maintain all manifests for at least five years and make them available upon request of the commissioner.

Subp. 3. **Transportation of medical cannabis; vehicle requirements.**

A. A manufacturer must ensure that:

(1) all medical cannabis transported on public roadways is:

(a) packaged in tamper-evident, bulk containers;

(b) transported so it is not visible or recognizable from outside the vehicle; and

(c) transported in a vehicle that does not bear any markings to indicate that the vehicle contains cannabis or bears the name or logo of the manufacturer.

B. Manufacturer employees who are transporting medical cannabis on public roadways must:

(1) travel directly to the distribution facility; and

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

(a) the reason for the stop;

(b) the duration of the stop;

(c) the location of the stop; and

(d) all activities of employees exiting the vehicle.

C. If an emergency requires stopping the vehicle, the employee must notify 911 and complete an incident report form provided by the commissioner.

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

E. A medical cannabis manufacturer must staff all motor vehicles with a minimum of two employees when transporting medical cannabis between a manufacturing facility and a distribution facility. At least one employee must remain with the motor vehicle at all times that the motor vehicle contains medical cannabis. A single employee may transport medical cannabis to an approved laboratory.

F. Each employee in a transport motor vehicle must have communication access with the medical cannabis manufacturer's personnel, and have the ability to contact law enforcement through the 911 emergency system at all times that the motor vehicle contains medical cannabis.

G. An employee must carry the employee's identification card at all times when transporting or delivering cannabis and, upon request, produce the identification card to the commissioner or to a law enforcement officer acting in the course of official duties.

H. A medical cannabis manufacturer must not leave a vehicle that is transporting medical cannabis unattended overnight.

**Statutory Authority:** *MS s 14.389; 152.25; 152.26; 152.261*

**History:** 39 SR 1080; 40 SR 1599

**Published Electronically:** June 20, 2016

#### **4770.1200 DISPOSAL OF MEDICAL CANNABIS AND PLANT MATERIAL.**

Subpart 1. **Medical cannabis take-back.** A medical cannabis manufacturer must accept at no charge unused, excess, or contaminated medical cannabis. A manufacturer must:

- A. dispose of the returned medical cannabis as provided in subpart 2; and
- B. maintain a written record of disposal that includes:
  - (1) the name of the patient;
  - (2) the date the medical cannabis was returned;
  - (3) the quantity of medical cannabis returned; and
  - (4) the type and batch number of medical cannabis returned.

Subp. 2. **Medical cannabis and plant material waste.** A medical cannabis manufacturer must store, secure, and manage medical cannabis waste and plant material waste in accordance with all applicable federal, state, and local regulations.

A. The manufacturer must dispose of medical cannabis waste by incineration at a waste-to-energy facility according to federal and state law.

B. The manufacturer must dispose of plant material by composting as follows:

- (1) at the manufacturing facility, according to federal and state law; or
- (2) at an approved composting facility, according to federal and state law.

C. Before transport, the manufacturer must render 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 commissioner.

Subp. 3. **Liquid and chemical waste disposal.** The medical cannabis manufacturer must dispose of all liquid and chemical product waste generated in the process of cultivating, manufacturing, and distributing medical cannabis in accordance with all applicable federal, state, and local regulations.

Subp. 4. **Waste-tracking requirements.** The medical cannabis manufacturer must use forms provided by the commissioner to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of medical cannabis waste and plant material waste.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

#### **4770.1300 MANDATORY SIGNAGE.**

A. A medical cannabis manufacturer must post a sign in a conspicuous location at each entrance of the manufacturing facility that reads "PERSONS UNDER TWENTY-ONE YEARS OF AGE NOT PERMITTED IN RESTRICTED ACCESS AREAS."

B. A manufacturer must post a sign in a conspicuous location at every entrance to the manufacturing facility and each distribution facility that reads "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."

**Statutory Authority:** *MS s 14.389; 152.25; 152.26; 152.261*

**History:** *39 SR 1080; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

#### **4770.1400 PERSONNEL IDENTIFICATION SYSTEM.**

Subpart 1. **Identification system.** A medical cannabis manufacturer must use a personnel identification system that controls and monitors individual employee access to restricted access areas within the manufacturing facility and distribution facility and that meets the requirements of this part and part 4770.0700.

Subp. 2. **Employee identification card requirement.** An employee identification card must contain:

- A. the name of the cardholder;
- B. the date of issuance and expiration;
- C. an alphanumeric identification number that is unique to the cardholder; and
- D. a photographic image of the cardholder.

Subp. 3. **Visitor pass required.** A visitor must wear a visitor pass issued by the medical cannabis manufacturer that is visible at all times.

Subp. 4. **Employee identification card on person and visible at all times.** A manufacturer's employee must keep the employee's identification card visible at all times when in a manufacturing facility, distribution facility, or vehicle transporting medical cannabis.

Subp. 5. **Termination of employment.** Upon termination of an employee, a medical cannabis manufacturer must obtain and destroy the terminated employee's identification card.

**Statutory Authority:** *MS s 14.389; 152.25; 152.26; 152.261*

**History:** *39 SR 1080; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

#### **4770.1460 RENEWAL OF REGISTRATION.**

Subpart 1. **Application.** A registered manufacturer must submit an application to renew its registration with the commissioner at least six months before its registration term expires. The application must include:

- A. any material change in its previous application materials;
- B. information about each alleged incident involving theft, loss, or possible diversion of medical cannabis by an employee, agent, or contractor of the manufacturer;
- C. the manufacturer's compliance with all relevant state and local laws;
- D. information about the manufacturer's ability to continue manufacturing and distributing medical cannabis, including financial viability and ability to ensure adequate supply of medical cannabis; and
- E. any other information requested by the commissioner.

Subp. 2. **Criteria.** The commissioner must use criteria listed in Minnesota Statutes, section 152.25, subdivision 1, paragraph (c), when considering a manufacturer's application to renew its registration.

Subp. 3. **Notification.** The commissioner must notify the manufacturer of the commissioner's decision to approve or deny the manufacturer's registration application at least 120 days before the expiration of the registration agreement.

**Statutory Authority:** *MS s 152.26; 152.261*

**History:** *40 SR 1599*

**Published Electronically:** *June 20, 2016*

#### **4770.1500 CLOSURE OF OPERATIONS; DEREGISTRATION.**

Subpart 1. **Notice.** A medical cannabis manufacturer shall notify the commissioner at least six months before the closure of the manufacturing facility and its distribution facilities.

Subp. 2. **Procedures.** If a medical cannabis manufacturer ceases operation, the commissioner must verify the remaining inventory of the manufacturer and seize all plant material, plant material

waste, and medical cannabis. The commissioner must ensure that any plant material, plant material waste, and medical cannabis is destroyed by incineration at a waste-to-energy facility.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

#### **4770.1600 RECORD KEEPING; REQUIREMENTS.**

A. A medical cannabis manufacturer must maintain for at least five years complete, legible, and current records, including:

- (1) the date of each sale or distribution;
- (2) the registration number of all patients;
- (3) the item number, product name and description, and quantity of medical cannabis sold or otherwise distributed;
- (4) records of sale prices of medical cannabis to patients;
- (5) the quantity and form of medical cannabis maintained by the manufacturer at the manufacturing facility on a daily basis; and
- (6) the amount of plants being grown at the manufacturing facility on a daily basis.

B. A medical cannabis manufacturer must maintain records that reflect all financial transactions and the financial condition of the business. The following records must be maintained for at least five years and made available for review, upon request of the commissioner:

- (1) purchase invoices, bills of lading, transport manifests, 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;
- (2) bank statements and canceled checks for all business accounts;
- (3) accounting and tax records;
- (4) records of all financial transactions, including contracts and agreements for services performed or services received;
- (5) all personnel records;
- (6) crop inputs applied to the growing medium, plants, or plant material used in production;
- (7) production records;
- (8) transportation records;
- (9) inventory records;

(10) records of all samples sent to a testing laboratory and the quality assurance test results; and

(11) records of any theft, loss, or other unaccountability of any medical cannabis or plant material.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

#### **4770.1700 MEDICAL CANNABIS MANUFACTURER; PRODUCTION REQUIREMENTS.**

##### **Subpart 1. Cultivation and processing.**

A. Only a registered medical cannabis manufacturer is authorized to produce and manufacture medical cannabis.

B. All phases of production must take place in designated, restricted access areas that are monitored by a surveillance camera system in accordance with part 4770.0900.

C. All areas must be compartmentalized based on function, and employee access must be restricted between compartments.

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

E. Each production area must have an open aisle for unobstructed access, observation, and inventory of each plant group.

F. Biosecurity measures must be in effect and documented according to part 4770.0400, subpart 1.

G. The manufacturer must maintain a record at the facility of all crop inputs for at least five years. The record must include the following:

- (1) the date of application;
- (2) the name of the employee applying the crop input;
- (3) the crop input that was applied;
- (4) the section, including the square footage, that received the application by batch number;
- (5) the amount of crop input that was applied; and
- (6) a copy of the label of the crop input applied.

H. At the time of planting, all plants must be tracked in a batch process with a unique batch number that must remain with the batch through final packaging.



I. A manufacturer must record any removal of plants from the batch on a record maintained at the manufacturing facility for at least five years.

J. The batch number must be displayed on the label of the medical cannabis.

**Subp. 2. Production of medical cannabis.**

A. The commissioner must approve the manufacturer's use of any hydrocarbon-based extraction process. Examples of a hydrocarbon-based extraction process include the use of butane, ethanol, hexane, and isopropyl alcohol.

B. Medical cannabis must be prepared, handled, and stored in compliance with the sanitation requirements in this part.

C. A manufacturer must refrigerate perishable forms of medical cannabis.

D. A manufacturer must ensure that the cannabinoid content of the medical cannabis it produces is homogenous.

**Subp. 3. General sanitation requirements.** A manufacturer must 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 cannabis;

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 cannabis must 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 cannabis 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 cannabis 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 cannabis 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 cannabis that could support the rapid growth of undesirable microorganisms are isolated to prevent the growth of those microorganisms.

**Subp. 4. Storage.**

A. A manufacturer must store plant material and medical cannabis during production, transport, and testing to prevent diversion, theft, or loss, including ensuring:

(1) plant material and medical cannabis 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 cannabis are locked inside a secure area if a process is not completed at the end of a business day.

B. A manufacturer must store all plant material and medical cannabis during production, transport, and testing, and all saleable medical cannabis:

(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 must store all plant material and medical cannabis in production, transport, and testing, and all saleable medical cannabis under conditions that will protect it against physical, chemical, and microbial contamination and deterioration of the product and its container.

D. A manufacturer must maintain a separate secure storage area for medical cannabis that is returned, including medical cannabis that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until the returned medical cannabis is destroyed. For purposes of this part, a separate, secure storage area includes a container, closet, or room that can be locked or secured.

**Statutory Authority:** *MS s 14.389; 152.25; 152.26; 152.261*

**History:** *39 SR 1080; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

#### **4770.1750 MEDICAL CANNABIS DISTRIBUTION.**

Subpart 1. **Distribution; identity verification.** A registered patient, designated caregiver, or the registered patient's parent or legal guardian, if the parent or legal guardian will be acting as a caregiver, must present a government-issued photo identification at the distribution site. Distribution site staff must verify the identity of the person and the patient's enrollment in the registry.

Subp. 2. **Distribution; consultation.** The pharmacist employed by a manufacturer to distribute medical cannabis must consult with the registered patient, designated caregiver, or the registered patient's parent or legal guardian, if the parent or legal guardian will be acting as a caregiver, before distributing medical cannabis to the recipient. The consultation must include:

- A. a review of patient information in the medical cannabis registry;
- B. an assessment of the perceived effectiveness of medical cannabis in treating the condition or symptoms of the condition;
- C. a review of current medications the patient is taking, including the formulation and current dosage of medical cannabis; and
- D. a review of any changes in the patient's medical condition.

Subp. 3. **Distribution; dosage calculation.** After completing the consultation, the pharmacist will determine a recommended daily dosage and calculate an amount equal to a 30-day supply at maximum recommended dosage.

Subp. 4. **Purchasing limits.** A registered qualifying patient, registered designated caregiver, or a patient's registered parent or registered legal guardian may purchase medical cannabis in quantities less than or equal to the patient's 30-day supply determined under subpart 3 from any Minnesota distribution site at any time. The total quantity of medical cannabis purchased for a patient in a 23-day period must not exceed the patient's 30-day supply.

**Statutory Authority:** *MS s 14.389; 152.26; 152.261*

**History:** *39 SR 1760; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

#### **4770.1800 INVENTORY.**

Subpart 1. **Controls and procedures.** A medical cannabis manufacturer must establish inventory controls and procedures for conducting inventory reviews and comprehensive inventories of plant material and medical cannabis to prevent and detect any diversion, theft, or loss in a timely manner.

Subp. 2. **Reliable and ongoing supply.** A medical cannabis manufacturer must provide a reliable and ongoing supply of medical cannabis as required by Minnesota Statutes, section 152.29, subdivision 2.

Subp. 3. **Initial inventory.** A medical cannabis manufacturer must maintain a real-time record of its inventory of plant material and medical cannabis to include:

- A. the date and time of the inventory;
- B. a summary of inventory findings;
- C. the names of the employees or employee conducting the inventory; and
- D. other information deemed necessary and requested by the commissioner.

Subp. 4. **Waste inventory.** The medical cannabis manufacturer must maintain a record of its inventory of all medical cannabis waste and plant material waste for disposal.

Subp. 5. **Reconciliation.** At the close of business each day, a medical cannabis manufacturer must reconcile all:

- A. plant material at the manufacturing facility and in transit; and
- B. medical cannabis at the manufacturing facility, distribution facility, and in transit.

Subp. 6. **Scales.** All scales used to weigh usable plant material for purposes of this chapter must be certified in accordance with the International Organization for Standardization (ISO), ISO/IEC Standard 17025, which is incorporated by reference.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

#### **4770.1850 RECALL PROCEDURES.**

Each manufacturer must establish a procedure for recalling medical cannabis 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 medication. This procedure must include:

- A. factors that make a recall necessary;
- B. manufacturer's personnel who are responsible for overseeing the recall; and
- C. how to notify affected parties of a recall.

**Statutory Authority:** *MS s 152.26; 152.261*

**History:** *40 SR 1599*

**Published Electronically:** *June 20, 2016*

**4770.1900 MEDICAL CANNABIS LABORATORY APPROVAL.**

Subpart 1. **Commissioner's authority.** The commissioner must approve any medical cannabis laboratory that tests medical cannabis for a registered medical cannabis manufacturer under Minnesota Statutes, section 152.25, subdivision 1, paragraph (d). A medical cannabis laboratory may seek approval to use specific procedures to test the allowable product types and analytes according to parts 4770.1900 to 4770.2400, which specify the commissioner's requirements authorized by Minnesota Statutes, section 152.29, subdivision 1, paragraph (b).

Subp. 2. **Eligibility.** The commissioner may only approve a medical cannabis laboratory that tests under a contract with a medical cannabis manufacturer that can demonstrate its eligibility under this subpart. The laboratory must:

A. operate using proper laboratory equipment under a quality assurance system and test product types for analytes listed in the commissioner's list in subpart 3;

B. test medical cannabis delivered in the product types specified in subpart 4;

C. test accurately for the following elements:

(1) content, by testing for analytes for a cannabinoid profile;

(2) contamination, by testing for analytes for:

(a) metals;

(b) pesticide residues and plant growth regulators;

(c) microbiological contaminants and mycotoxins; and

(d) residual solvents; and

(3) consistency of medical cannabis by testing for stability.

Subp. 3. **Commissioner list of approved cannabis labs.**

A. The commissioner must publish a list of approved cannabis laboratories in the State Register and on the department's medical cannabis program website at least annually.

B. The commissioner must provide the following information for each approved laboratory:

(1) its scope of approval;

(2) name, telephone number, and e-mail address of primary laboratory contact; and

(3) physical and mailing address of laboratory.

Subp. 4. **Commissioner's approved medical cannabis product types.** The commissioner's approved product types include:

A. liquid, including in oil form;

B. pill;

- C. vaporized delivery method using liquid or oil, but not dried leaves or plant form; and
- D. any other method, excluding smoking, approved by the commissioner.

**Subp. 5. Commissioner's analyte list.**

A. The commissioner must maintain a list of analytes that laboratories must be able to test for. The analyte categories include:

- (1) cannabinoid profile;
- (2) metals;
- (3) pesticide residues and plant growth regulators;
- (4) microbiological contaminants and mycotoxins; and
- (5) residual solvents.

B. The commissioner must publish the analyte list in the State Register and on the department's medical cannabis program website.

C. The commissioner must review the analyte list and publish a notice of any analyte updates in the State Register and on the department's medical cannabis program website at least every six months.

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

**History:** *39 SR 1080*

**Published Electronically:** *September 7, 2018*

**4770.2000 MEDICAL CANNABIS LABORATORY APPROVAL; APPLICATION AND APPROVAL.**

**Subpart 1. Application requirements.**

A. A laboratory must apply for the commissioner's approval on a form provided by the commissioner.

B. A laboratory must also submit the following items:

(1) a signed and notarized attestation:

(a) declaring any conflict of interest, actual or perceived, relating to its direct or indirect financial interests in any medical cannabis manufacturer form; and

(b) stating that the laboratory is independent from the medical cannabis manufacturers;

(2) the fields of testing it is applying for approval to test;

(3) its quality assurance manual;

- (4) its standard operating procedures;
- (5) sample handling, receipt, and acceptance procedures and policies;
- (6) demonstration of laboratory capability and acceptable performance through a combination of:
  - (a) existing certificates and approvals;
  - (b) documented demonstrations of analytical capabilities; and
  - (c) documented and acceptable proficiency testing samples from an approved provider, where available;
- (7) method validation procedures for testing methods; and
- (8) the name and educational qualifications of at least one technical manager responsible for the laboratory achieving and maintaining the quality and analytical standards of practice.

C. A mobile laboratory is considered a separate laboratory and is subject to all requirements of parts 4770.1900 to 4770.2300. In addition to the requirements of subpart 1, a mobile laboratory must:

- (1) submit a vehicle identification number, license plate number, or other uniquely identifying information to the commissioner when applying for approval; and
- (2) designate which fields of testing, equipment, and personnel are associated with the mobile laboratory.

D. The following items are required and must be submitted to the commissioner before December 31, 2016:

- (1) a copy of the lab's ISO/IEC 17025:2005 Certificate and Scope of Accreditation; and
- (2) a copy of the lab's most recent assessment report, including the scope of the assessment to ensure the evaluation of the medical cannabis fields of testing.

**Subp. 2. Application requirements; commissioner's evaluation.**

A. The commissioner must evaluate completed applications using the following criteria.

- (1) A laboratory must operate formal management systems under the International Organization for Standardization (ISO). The ISO/IEC 17025, *General Requirements for the Competency of Testing and Calibration Laboratories*, includes technical and management system requirements which are incorporated by reference in part 4770.2800.
- (2) A laboratory seeking initial or renewal medical cannabis laboratory approval after December 31, 2016, must be accredited to Standard ISO/IEC 17025:2005, which is incorporated by reference.

(3) A laboratory must specify one or more fields of testing for which it seeks approval. A laboratory must be approved for at least one field of testing to test medical cannabis for a medical cannabis manufacturer.

B. The commissioner must approve or deny the application within 60 days of receiving the completed application and any applicable information required under part 4770.2000, subpart 1, and subpart 2.

C. No board member, officer, employee, or other person with a financial interest in a medical cannabis manufacturer may have an interest or voting rights in the laboratory.

D. The commissioner's decision on a laboratory's application is a final agency decision.

### Subp. 3. **Approval.**

A. When granting approval, the commissioner must notify the laboratory and include the following documentation:

- (1) a letter acknowledging compliance with approval requirements by the laboratory;
- (2) the scope of approval for the laboratory;
- (3) the logo of the Minnesota Department of Health;
- (4) the name of the laboratory;
- (5) the address of the laboratory; and
- (6) the expiration date of the approval.

B. If a laboratory's scope of approval changes, the commissioner must issue a new document that specifies the revised scope of approval.

C. A laboratory's approval is valid for one year from the date of the commissioner's awarding approval or renewal of approval, unless the commissioner rescinds approval under part 4770.2100.

**Statutory Authority:** *MS s 14.389; 152.25; 152.26; 152.261*

**History:** *39 SR 1080; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

## **4770.2100 MEDICAL CANNABIS LABORATORY APPROVAL; INSPECTION AND COMPLIANCE.**

### Subpart 1. **Laboratory inspection and reports.**

A. The commissioner may inspect a lab without prior notice at any time during normal business hours to verify compliance with parts 4770.1900 to 4770.2200. The commissioner may inspect:

- (1) approved laboratories; and



(2) laboratories requesting approval.

B. If the commissioner has sufficient cause to believe that a laboratory's proficiency, execution, or validation of analytical methodologies are deficient, the commissioner may require and a laboratory must obtain third-party validation and ongoing monitoring of the laboratory. The laboratory must pay for all costs associated with the commissioner-ordered third-party validation.

C. An approved laboratory must provide reports to the commissioner regarding chemical compositions, microbial compositions, dosages, and noncannabis drug interactions under Minnesota Statutes, section 152.25, as requested by the commissioner.

D. An approved laboratory must provide reports to the medical cannabis manufacturer on forms provided by the commissioner.

**Subp. 2. Laboratory approval requirements.**

A. An approved laboratory may not misrepresent its approval on any document or marketing material.

B. A laboratory must make its current approval documentation and corresponding scope of approval available upon the request of:

- (1) a client;
- (2) the commissioner; or
- (3) a regulatory agency.

**Subp. 3. Rescinding approval.**

A. The commissioner may rescind an approved cannabis laboratory's approval if the commissioner determines the laboratory has failed to:

- (1) submit accurate application materials to the commissioner under part 4770.2000;
- (2) comply with application requirements under part 4770.2000;
- (3) comply with all applicable laws, rules, standards, policies, and procedures;
- (4) allow the commissioner or designee to perform physical inspection of facilities;
- (5) submit copies of inspection and corrective reports issued by the approved ISO/IEC 17025 accreditation body, as requested by the commissioner;
- (6) provide the medical cannabis manufacturer with timely reports; or
- (7) provide the medical cannabis manufacturer with reports compliant with the commissioner's designated test report format.

B. A laboratory must return its approval letter to the commissioner immediately if the commissioner rescinds the laboratory's approval.

C. The commissioner's decision to rescind approval of an approved medical cannabis laboratory is a final agency decision.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

#### **4770.2200 MEDICAL CANNABIS LABORATORY APPROVAL; DUTY TO NOTIFY.**

##### **Subpart 1. Operational changes.**

A. A laboratory must notify the commissioner in writing within 30 days of a change in:

- (1) name of the laboratory;
- (2) physical location, postal mailing address, or e-mail address of the laboratory;
- (3) owner of the laboratory;
- (4) name, telephone numbers, or e-mail address of the designated contact person;
- (5) name of a technical manager;
- (6) major analytical equipment; or
- (7) test methods.

B. A laboratory that notifies the commissioner of an operational change under item A must include in the notice written results of proficiency testing samples or demonstrations of capability analyzed after the reported change.

##### **Subp. 2. Voluntary withdrawal.**

A. If a laboratory chooses to withdraw its application for approval or its current approval in total or in part, the laboratory must:

- (1) notify the commissioner in writing; and
- (2) specify the effective date of withdrawal.

B. By the effective date of the withdrawal of approval, in total or in part, the laboratory must:

- (1) notify current client manufacturers in writing of its intent to withdraw its approval;
- (2) indicate the effective date of the withdrawal; and
- (3) submit a copy of each notification to the commissioner.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

**4770.2300 MEDICAL CANNABIS LABORATORY APPROVAL; APPEAL OF ADMINISTRATIVE DECISION.**

A. The commissioner must notify a laboratory in writing the reason for the decision to deny or rescind laboratory approval under part 4770.2100.

B. A laboratory has 30 days from the commissioner's notice of denial or notice of rescinded approval to appeal the decision. A request to appeal must:

- (1) be in writing;
- (2) indicate the facts the laboratory disputes;
- (3) be signed by the laboratory managing agent; and
- (4) be sent to the commissioner.

C. The commissioner must notify a laboratory of the commissioner's acceptance or denial of an appeal request, in writing, within 60 days of receiving the request. The commissioner's decision is a final agency decision.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

**4770.2400 MEDICAL CANNABIS LABORATORY APPROVAL; VARIANCES.**

The commissioner may grant a variance from parts 4770.1900 to 4770.2200. To request a variance, a laboratory must indicate in writing:

- A. the rule part and language for which the variance is sought;
- B. reasons for the request;
- C. alternate measures that the laboratory will take if the commissioner grants its request for variance;
- D. the proposed length of time of the variance; and
- E. data that the laboratory will provide to ensure analytical results of equal or better reliability, if applicable.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

**4770.2700 MEDICAL CANNABIS MANUFACTURER; FINANCIAL EXAMINATIONS; PRICING REVIEWS.**

A. A medical cannabis manufacturer must maintain financial records in accordance with generally accepted accounting principles and, upon request, must provide any financial records to the commissioner.

B. The commissioner shall request an additional audit of the medical cannabis manufacturer, of the same time period, if the commissioner finds one or more of the following:

(1) credible evidence or allegations of financial reporting irregularities not revealed in the annual certified financial audit; or

(2) reasonable cause to believe there are operational or compliance concerns involving financing, budgeting, revenues, sales, or pricing.

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

**4770.2800 INCORPORATION BY REFERENCE.**

The International Organization for Standardization (ISO), ISO/IEC Standard 17025, is incorporated by reference, is not subject to frequent change, and is made a part of this rule where indicated. ISO/IEC Standard 17025 is published by the International Organization for Standardization, located at 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland. ISO/IEC Standard 17025 is available in the office of the commissioner of health and can be found online at [www.isoiec17025.com](http://www.isoiec17025.com) or [www.iso.org](http://www.iso.org).

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

**History:** *39 SR 1080*

**Published Electronically:** *February 20, 2015*

**MEDICAL CANNABIS REGISTRY****4770.4000 APPLICABILITY AND PURPOSE.**

Parts 4770.4000 to 4770.4018 establish the criteria and procedures to be used by the commissioner for establishing and overseeing the medical cannabis registry for enrolled patients and their designated caregivers.

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

**History:** *39 SR 1760*

**Published Electronically:** *July 7, 2015*

**4770.4002 DEFINITIONS.**

Subpart 1. **Applicability.** The terms used in this chapter have the meanings given them in this part and in Minnesota Statutes, sections 152.22 to 152.37.

Subp. 1a. **Adverse incident.** "Adverse incident" means any negative medical occurrence in a person after using medical cannabis, either physical or psychological, including any harmful reaction, symptom, or disease.

Subp. 2. **DEA Registration Certificate.** "DEA Registration Certificate" means a certificate to prescribe controlled substances issued by the United States Department of Justice's Drug Enforcement Administration.

Subp. 3. **Disqualifying felony offense.** "Disqualifying felony offense" has the meaning given in Minnesota Statutes, section 152.22, subdivision 3.

Subp. 4. **Diversion or diverting.** "Diversion" or "diverting" means the intentional transferring of medical cannabis to a person other than a patient, designated registered caregiver, or a parent or legal guardian of a patient if the parent or legal guardian of a patient is listed on the registry verification.

Subp. 4a. **Diversion involving adverse incidents.** "Diversion involving adverse incidents" means any suspected incident of diversion that results in an adverse incident.

Subp. 5. **Evidence-based medicine.** "Evidence-based medicine" means documentation of published, peer-reviewed best evidence on research related to the use of medical cannabis, which includes up-to-date information from relevant, valid research about the effects of medical cannabis on different forms of diseases and conditions, its use in health care, the potential for harm from exposure, a clinical assessment of the effectiveness of medical cannabis in an ongoing treatment paradigm, and any other relevant medical information.

Subp. 6. **Financial interest.** "Financial interest" means any actual or future right to ownership, investment, or compensation arrangement with another person, either directly or indirectly, through business, investment, spouse, parent, or child in a medical cannabis manufacturer. Financial interest does not include ownership of investment securities in a publicly held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by the person, the person's spouse, parent, or child, in the aggregate, do not exceed one percent ownership in the medical cannabis manufacturer.

Subp. 7. **Good standing.** "Good standing" means a person has a license or registration with a licensing board and is not subject to any restriction or oversight by the licensing board beyond others in the same class.

Subp. 8. **Health care practitioner.** "Health care practitioner" has the meaning given in Minnesota Statutes, section 152.22, subdivision 4.

Subp. 9. **Health record.** "Health record" has the meaning given in Minnesota Statutes, section 144.291, subdivision 2, paragraph (c).

Subp. 10. **Medical cannabis.** "Medical cannabis" has the meaning given in Minnesota Statutes, section 152.22, subdivision 6.

Subp. 11. **Medical cannabis manufacturer or manufacturer.** "Medical cannabis manufacturer" or "manufacturer" has the meaning given in Minnesota Statutes, section 152.22, subdivision 7.

Subp. 12. **Medical relationship.** "Medical relationship" means a treatment or counseling relationship, in the course of which the health care practitioner has completed a full assessment of the patient's medical history and current medical condition.

Subp. 13. **Minor.** "Minor" means an applicant who is under 18 years of age.

Subp. 14. **Parent or legal guardian.** "Parent or legal guardian" has the meaning given in Minnesota Statutes, section 152.27, subdivision 5.

Subp. 15. **Patient.** "Patient" has the meaning given in Minnesota Statutes, section 152.22, subdivision 9.

Subp. 15a. **Patient advocate.** "Patient advocate" means an individual with a knowledge of medical cannabis who promotes patient interests in safety, privacy, access, and affordability.

Subp. 15b. **Peace officer.** "Peace officer" has the meaning given in Minnesota Statutes, section 626.84, subdivision 1, paragraph (c).

Subp. 16. **Person.** "Person" means an individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, state or political subdivision of a state, or a legal successor, representative, agent, or agency of the person. Person does not include federal government agencies.

Subp. 17. **Qualifying medical condition.** "Qualifying medical condition" has the meaning given in Minnesota Statutes, section 152.22, subdivision 14.

Subp. 18. **Qualifying patient.** "Qualifying patient" means a resident of Minnesota who has been diagnosed by a health care practitioner as having a qualifying medical condition.

Subp. 19. **Registered.** "Registered" means licensed, permitted, or otherwise certified by the commissioner.

Subp. 20. **Registered designated caregiver.** "Registered designated caregiver" has the meaning given in Minnesota Statutes, section 152.22, subdivision 11.

Subp. 21. **Registry program.** "Registry program" has the meaning given in Minnesota Statutes, section 152.22, subdivision 12.

Subp. 22. **Registry verification.** "Registry verification" has the meaning given in Minnesota Statutes, section 152.22, subdivision 13.

Subp. 22a. **Serious adverse incident.** "Serious adverse incident" means any adverse incident that results in or would lead to one of these outcomes without medical intervention:

- A. in-patient hospitalization or additional hospital time for a patient who is already hospitalized;
- B. persistent or significant disability or incapacity;
- C. a life-threatening situation; or
- D. death.

Subp. 23. **Telemedicine.** "Telemedicine" means the practice of medicine as defined in Minnesota Statutes, section 147.081, subdivision 3, when the health care practitioner is not in the physical presence of the patient.

Subp. 24. **Therapeutic use.** "Therapeutic use" means the acquisition, possession, preparation, use, delivery, transfer, or transportation of medical cannabis or paraphernalia relating to the administration of medical cannabis to treat or alleviate a qualifying patient's qualifying medical condition or symptoms or results of treatment associated with the qualifying patient's qualifying medical condition.

Subp. 25. **Transport.** "Transport" means the movement of medical cannabis products from a manufacturer's distribution site to the residence of a registered qualified patient, or as otherwise provided by law.

Subp. 26. **Written certification.** "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 qualifying medical condition and identifies that condition and any other relevant information required by Minnesota Statutes, section 152.28, subdivision 1.

**Statutory Authority:** *MS s 14.389; 152.26; 152.261*

**History:** *39 SR 1760; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

#### **4770.4003 PROCESS FOR ADDING A QUALIFYING MEDICAL CONDITION OR DELIVERY METHOD.**

Subpart 1. **Condition added by commissioner.** The commissioner may periodically revise the list of qualified medical conditions eligible for treatment with medical cannabis.

- A. Revisions to the list must reflect:
  - (1) advances in medical science;
  - (2) evidence-based medicine and other peer-reviewed research demonstrating treatment efficacy; or
  - (3) other therapeutic factors that will improve patient care.

B. In determining whether a condition qualifies, the commissioner must consider the adequacy of available evidence that medical cannabis will provide relief and the report of the Medical Cannabis Review Panel established in subpart 3.

Subp. 2. **Requests for adding a condition.** Any person may request the commissioner to add a qualifying medical condition not listed in Minnesota Statutes, section 152.22, subdivision 14, to the list by applying on a form provided by the commissioner. Requests under this subpart will be accepted beginning June 1, 2016.

A. The commissioner shall only accept requests during June and July of each year and will dismiss requests received outside of this period.

B. The commissioner must post notice on the department's medical cannabis website by May 1 each year, announcing the open period for accepting requests and describing the procedure for submitting requests.

C. Each request must be limited to one proposed qualifying medical condition. The commissioner must dismiss a request if it contains multiple proposals.

D. The commissioner must dismiss a request to add a medical condition that has been previously considered and rejected by the commissioner, unless the request contains new scientific evidence or research or describes substantially different symptoms.

E. If the commissioner dismisses a timely request, the commissioner must notify the person making the request of the reason that the request was dismissed.

F. The commissioner must forward the request to the review panel for review unless the request is dismissed.

G. The commissioner must provide the review panel with a review of evidence-based medicine and other peer-reviewed research demonstrating treatment efficacy for the requested condition.

Subp. 3. **The Medical Cannabis Review Panel.**

A. The commissioner must appoint a Medical Cannabis Review Panel composed of seven members, including at least one medical cannabis patient advocate and two health care practitioners, one with expertise in pediatric medicine.

B. The Medical Cannabis Review Panel must review requests submitted under subpart 2 and report to the commissioner on the public health impacts, including therapeutic factors and known potential risks, of the proposed additional medical conditions.

C. Members serve a three-year term or until a successor is appointed and qualified. If a vacancy occurs, the commissioner must appoint a replacement to complete the original term created by the vacancy.

D. Members may serve multiple terms.



E. Members must not hold a direct or indirect economic interest in a registered medical cannabis manufacturer or serve on the board of directors or as an employee of a registered medical cannabis manufacturer.

F. Members must disclose all potential conflicts of interest having a direct bearing on any subject before the review panel.

**Subp. 4. Review panel meetings.**

A. The Medical Cannabis Review Panel must meet at least one time per year to:

(1) review requests that the commissioner has received for the approval of proposed qualifying medical conditions;

(2) review the status of those medical conditions for which the commissioner has deferred approval or rejection; and

(3) review new medical and scientific evidence about current qualifying medical conditions.

B. The commissioner must post a notice on the department's medical cannabis website at least 30 calendar days before a review panel meeting. Notice must include the date, time, and location of the meeting, a brief description of the requests received, and information on how public comment will be received, including a deadline, if any.

C. The Medical Cannabis Review Panel must submit a written report to the commissioner by November 1 after conducting the public meeting. The written report must include potential public health benefits and risks of adding or rejecting the proposed qualifying medical condition.

**Subp. 5. Commissioner review.**

A. Upon receiving the Medical Cannabis Review Panel's report, the commissioner must render a decision by December 1 and must:

(1) approve the request and forward the medical condition as required by item C; or

(2) reject the medical condition.

B. The commissioner must communicate the commissioner's decision to the requesting party along with the reasons for the decision and publish the decision on the department's medical cannabis website by December 1.

C. The commissioner must forward a newly approved qualifying medical condition to the chairs and ranking minority members of the legislative policy committees having jurisdiction over health and public safety by January 15 as required by Minnesota Statutes, section 152.27, subdivision 2. If the legislature does not provide otherwise by law, the commissioner must publish the newly approved qualifying medical condition in the State Register and on the department's medical cannabis website before its August 1 effective date.

Subp. 6. **Requests for adding a delivery method.** Any person may request that the commissioner add a delivery method not listed in Minnesota Statutes, section 152.22, subdivision 6, to the list by applying on a form provided by the commissioner. Requests under this subpart will be accepted beginning June 1, 2016.

A. The commissioner shall only accept requests during June and July of each year and will dismiss requests received outside of this period.

B. The commissioner must post notice on the department's medical cannabis website by May 1 each year, announcing the open period for accepting requests and describing the procedure for submitting requests.

C. The commissioner must post the request to add a delivery method, along with information about how to submit public comment on the department's medical cannabis website. The commissioner must allow at least 30 days for public comment.

D. Each request must be limited to one proposed delivery method. The commissioner must dismiss a request if it contains multiple proposals.

E. The commissioner must dismiss a request to add a delivery method that has been previously considered and rejected by the commissioner, unless the request contains new scientific evidence or research or describes substantially different therapeutic benefits.

F. If the commissioner dismisses a timely request, the commissioner must notify the person making the request of the reason that the request was dismissed.

G. The commissioner must consider the request and any written comments from the public. The commissioner must render a decision by December 1, and must:

(1) approve the request and forward the delivery method to be added as required by item I; or

(2) reject the delivery method.

H. The commissioner must communicate the commissioner's decision to the requesting party along with the reasons for the decision.

I. The commissioner must forward an approved delivery method to be added to the chairs and ranking minority members of the legislative policy committees having jurisdiction over health and public safety by January 15 as required by Minnesota Statutes, section 152.27, subdivision 2, and if the legislature does not provide otherwise by law, publish the addition in the State Register and on the department's medical cannabis website.

**Statutory Authority:** *MS s 14.389; 152.26; 152.261*

**History:** *39 SR 1760; 40 SR 1599*

**Published Electronically:** *September 7, 2018*

**4770.4004 SERIOUS ADVERSE INCIDENT REPORTING.****Subpart 1. Reporting requirements.**

A. Persons who must report any serious adverse incident are:

- (1) a registered patient;
- (2) a registered patient's certifying health care practitioner;
- (3) a patient's registered designated caregiver; or
- (4) a patient's parent or legal guardian, if the parent or legal guardian is acting as caregiver.

B. Reporters named in item A must report to the manufacturer where the patient's medical cannabis was dispensed within five business days of the reporter's learning of the incident.

C. A peace officer must report any serious adverse incident relating to overdose and any case of diversion involving an adverse incident within five business days of the incident by calling the general telephone number of the Office of Medical Cannabis. If part of an ongoing investigation, the report must be made within 72 hours of the conclusion of the investigation.

**Subp. 2. Manufacturer requirements.**

A. Each manufacturer must:

- (1) maintain a toll-free telephone line, which must be available 24 hours a day, seven days a week, that is staffed by professionals who are health care practitioners or state-licensed pharmacists trained in detecting, assessing, understanding, and preventing adverse effects or any other drug-related problem;
- (2) provide a method, approved by the commissioner, for reporting serious adverse incidents online;
- (3) monitor manufacturer-sponsored social media pages and websites routinely;
- (4) post instructions for reporting suspected adverse incidents and unauthorized possession on its website; and
- (5) make printed instructions for reporting suspected adverse incidents available at all its distribution sites.

B. Each manufacturer must follow up serious adverse incident reports and document all follow-up activities. The manufacturer must continue to follow up reports until the outcome has been established or the subject's condition is stabilized.

C. For adverse incident information collected, the manufacturer must:

- (1) document it on a form provided by the commissioner;

(2) classify it using Medical Dictionary for Regulatory Activities (MedDRA) coding; and

(3) store it in a database that complies with general validation principles in the United States Food and Drug Administration's Electronic Records; Electronic Signatures, Code of Federal Regulations, title 21, part 11.

**Subp. 3. Manufacturer reports.**

A. By the fifth day of every month, a medical cannabis manufacturer must compile and submit to the commissioner all adverse incident reports received in the prior calendar month.

B. Within ten business days of learning of an adverse incident, the manufacturer must report to the commissioner:

(1) any adverse incident that, based on reasonable medical judgment, might have resulted in a serious adverse incident without intervention or medical treatment; or

(2) a case of diversion resulting in an adverse incident.

C. On August 1 of every year beginning in 2016, each manufacturer must submit to the commissioner a report that contains a summary and a critical analysis of all reported adverse incidents reported to the manufacturer over the past July 1 to June 30.

**Statutory Authority:** *MS s 14.389; 152.26; 152.261*

**History:** *39 SR 1760; 40 SR 1599*

**Published Electronically:** *September 7, 2018*

## **QUALIFYING PATIENTS AND DESIGNATED CAREGIVERS**

### **4770.4005 REGISTRY ENROLLMENT APPLICATION FOR QUALIFYING PATIENTS.**

**Subpart 1. Patient application.**

A. A patient or the patient's parent or legal guardian must apply for the registry and sign a disclosure on forms provided by the commissioner that meet the requirements of Minnesota Statutes, section 152.27, subdivision 3.

B. A patient must provide proof of the patient's Minnesota residency. If the patient is a minor, the patient's parent or legal guardian must provide proof of the parent or legal guardian's Minnesota residency. Proof of Minnesota residency can be established with:

(1) a copy of a Minnesota driver's license, learner's permit, or identification card; or

(2) a copy of a state, federal, or tribal government-issued photo identification card and at least one form of other documentation that contains the name and current address of the patient, or the patient's parent or legal guardian and indicates Minnesota residency, such as:

(a) a current residential mortgage, lease, or rental agreement;

- (b) state tax documents from the previous calendar year;
- (c) a utility bill issued within the previous 90 days of the date of the application;
- (d) a rent or mortgage payment receipt dated less than 90 days before application;
- (e) a Social Security disability insurance statement, Supplemental Security Income benefits statement, or a medical claim or statement of benefits from a private insurance company or governmental agency that is issued less than 90 days before application; or
- (f) an affidavit from a person who will act as a designated caregiver for the patient, or a person who is engaged in health services or social services, which states the affiant knows the patient and believes the patient resides in Minnesota.

C. A patient or the patient's parent or legal guardian must submit the nonrefundable annual enrollment fee specified in Minnesota Statutes, section 152.35.

**Subp. 2. Application approval.**

A. The commissioner must approve an applicant and enroll the patient in the medical cannabis registry if the commissioner determines that the application is complete and no basis for denial exists under Minnesota Statutes, section 152.27, subdivision 6.

B. When a qualifying patient is enrolled in the registry program, the commissioner must:

- (1) issue a unique patient registry number; and
- (2) notify:
  - (a) the qualifying patient, designated caregiver, or parent or legal guardian if applicable;
  - (b) the health care practitioner who completed the patient's written certification of a qualifying condition; and
  - (c) the registered manufacturers.

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

**History:** *39 SR 1760*

**Published Electronically:** *July 7, 2015*

**4770.4007 DESIGNATED CAREGIVER APPLICATION.**

Subpart 1. **Application.** The designated caregiver must apply for registration on the form provided by the commissioner and submit to a background check, as required by Minnesota Statutes, section 152.27, subdivision 4, paragraph (b).

Subp. 2. **Application approval.** The commissioner must approve an applicant and register the designated caregiver if the commissioner determines that the application is complete and no basis for denial exists under Minnesota Statutes, section 152.27, subdivision 4.

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

**History:** *39 SR 1760*

**Published Electronically:** *July 7, 2015*

**4770.4008 RESPONSIBILITIES OF DESIGNATED CAREGIVERS.**

A. A designated caregiver, or the patient's parent or legal guardian if the parent or legal guardian will be acting as a caregiver, must:

(1) notify the commissioner within 30 business days after any change to the information that the registered qualifying patient was previously required to submit to the commissioner, including if the patient becomes an inmate confined in a correctional institution or facility under the supervision of the Department of Corrections;

(2) notify the commissioner promptly by telephone and in writing within ten calendar days following the death of the designated caregiver's registered qualifying patient; and

(3) dispose of all unused medical cannabis using the methods described in part 4770.4012, within ten days of the patient's ceasing to be enrolled in the program for any reason, including death of the patient or product recall.

B. A designated caregiver, or the patient's parent or legal guardian if the parent or legal guardian will be acting as a caregiver, may:

(1) transport a registered qualifying patient to and from a licensed medical cannabis distribution facility;

(2) obtain and transport an adequate supply of medical cannabis from a licensed medical cannabis distribution site on behalf of the registered qualifying patient;

(3) prepare medical cannabis for self-administration by the registered qualifying patient; and

(4) administer medical cannabis to the registered qualifying patient.

C. A designated caregiver, or the patient's parent or legal guardian if the parent or legal guardian will be acting as a caregiver, may not:

(1) consume, by any means, medical cannabis that has been dispensed on behalf of a registered qualifying patient; or

(2) sell, provide, or otherwise divert medical cannabis that has been dispensed for a registered qualifying patient.

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

**History:** *39 SR 1760*

**Published Electronically:** *July 7, 2015*

**4770.4009 REVOCATION OR SUSPENSION OF A QUALIFYING PATIENT OR DESIGNATED CAREGIVER REGISTRATION.**

Subpart 1. **Revocation of qualifying patient enrollment.** The commissioner may revoke the registration certificate of a qualifying patient under the provisions of Minnesota Statutes, section 152.27, subdivision 6, paragraph (d).

Subp. 2. **Suspension of qualifying patient enrollment.** The commissioner must suspend the registration of a qualifying patient under the following circumstances.

A. If the qualifying patient is incarcerated in a correctional institution or facility under the supervision of the Department of Corrections, the registration must be suspended for the term of incarceration.

B. If the qualifying patient provided false, misleading, or incorrect information to the commissioner, the patient's registration must be suspended until the information is corrected and the commissioner makes an eligibility determination.

C. If the qualifying patient, together with the qualifying patient's designated caregiver where applicable, obtains more than a 30-day supply of medical cannabis within a 23-day period and the commissioner has reason to believe the patient is abusing or diverting medical cannabis, the patient's registration must be suspended until the commissioner makes an eligibility determination.

Subp. 3. **Designated caregivers.** The commissioner must revoke the registration of a designated caregiver under the following circumstances:

A. the designated caregiver has a disqualifying felony offense conviction as defined in Minnesota Statutes, section 152.22, subdivision 3; or

B. the designated caregiver, together with the designated caregiver's patient, where applicable, obtains more than a 30-day supply of medical cannabis within a 23-day period and the commissioner has reason to believe the designated caregiver is abusing or diverting medical cannabis.

**Statutory Authority:** *MS s 14.389; 152.26; 152.261*

**History:** *39 SR 1760; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

**4770.4010 UNAUTHORIZED POSSESSION OF MEDICAL CANNABIS REPORTING.**

A. A licensed peace officer must report to the commissioner any reasonable suspicion of an individual possessing medical cannabis who is not authorized to possess medical cannabis under Minnesota Statutes, sections 152.22 to 152.37. The officer must report the reasonable suspicion within 72 hours by completing a form on the department's medical cannabis website. If part of an ongoing investigation, the report must be made within 72 hours of the investigation's conclusion.

B. A licensed peace officer who reasonably suspects a person who is otherwise authorized to possess medical cannabis has violated a provision of Minnesota Statutes, section 152.23, must

report the suspicion by completing a form on the department's medical cannabis website within 15 days of discovery of the occurrence.

**Statutory Authority:** *MS s 14.389; 152.26; 152.261*

**History:** *39 SR 1760; 40 SR 1599*

**Published Electronically:** *September 7, 2018*

**4770.4011** [Renumbered 4770.1750]

**Published Electronically:** *June 20, 2016*

**4770.4012 DISPOSAL OF MEDICAL CANNABIS BY QUALIFYING PATIENTS AND DESIGNATED CAREGIVERS.**

A. A qualifying patient or designated caregiver who is no longer registered with the medical cannabis patient registry must, within ten calendar days after the patient or caregiver ceases to be registered or eligible, dispose of any unused medical cannabis in their possession by one of the following methods by:

- (1) depositing it with a medical cannabis distribution site located in Minnesota;
- (2) depositing it with a law enforcement agency having local jurisdiction for destruction;
- (3) disposing of the medical cannabis at a government recognized drug take-back program located in Minnesota; or
- (4) rendering it nonrecoverable consistent with the commissioner's proper disposal instructions, which are available at the department's medical cannabis program website.

B. A qualifying patient or designated caregiver who is no longer registered with the medical cannabis patient registry must not transfer, share, give, sell, or deliver any unused medical cannabis in their possession to any other person, regardless of whether the person is participating in the medical cannabis patient registry program.

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

**History:** *39 SR 1760*

**Published Electronically:** *September 7, 2018*

**4770.4013 ANNUAL FEES.**

Each patient application or renewal must be accompanied by the payment of an annual fee. Payment must be made by credit card, bank debit card, cashier's check, or personal check. Annual qualifying patient application fee and reduced fee for patients enrolled in the federal Social Security Disability Income (SSDI), the Supplemental Security Income (SSI) disability, or the medical assistance or MinnesotaCare programs are established in Minnesota Statutes, section 152.35. All fees are nonrefundable.

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



**History:** 39 SR 1760

**Published Electronically:** July 7, 2015

## HEALTH CARE PRACTITIONERS

### 4770.4014 HEALTH CARE PRACTITIONER REQUIREMENTS.

Subpart 1. **Qualifications.** The commissioner must accept written certifications for the therapeutic use of medical cannabis only from health care practitioners who hold:

A. an active license, in good standing, under Minnesota Statutes, chapter 147, for physicians, under Minnesota Statutes, chapter 147A, for physician assistants, or Minnesota Statutes, sections 148.171 to 148.285, the Minnesota Nurse Practice Act, for advanced practice registered nurses; and

B. a DEA registration certificate.

Subp. 2. **Requirements.** Before issuing a written certification of qualifying condition, a health care practitioner must:

A. have a medical relationship between the health care practitioner and patient with a qualifying condition;

B. assess the patient's medical history and current medical condition, which includes:

(1) an in-person physical examination of the patient appropriate to confirm the diagnosis of a qualifying medical condition. This examination must not be performed by remote means, including telemedicine or via the Internet; and

(2) developing a treatment plan for the patient;

C. communicate, as appropriate, with subspecialists also treating the registered patient; and

D. certify that the patient has been diagnosed as having a qualifying medical condition, as defined in Minnesota Statutes, section 152.22, subdivision 14.

Subp. 3. **Duties.** When the certifying health care practitioner receives notice from the commissioner that a qualifying patient has been enrolled in the registry program, the certifying health care practitioner must:

A. participate in the patient registry reporting system as established by the commissioner for each patient for whom the practitioner has written a certification of qualifying condition. A health care practitioner must transmit patient data as required by Minnesota Statutes, section 152.28, subdivision 1, paragraph (b);

B. be available to provide continuing treatment of the patient's qualifying medical condition;

C. maintain health records under part 4770.4017 for all patients for whom the practitioner has issued a written certification that supports the certification of a qualifying medical condition;

D. report health record data as requested by the commissioner under Minnesota Statutes, section 152.28, subdivision 1, paragraph (b);

E. make a copy of the records that support the certification of a qualifying medical condition available to the commissioner, and otherwise provide information to the commissioner upon request about the patient's qualifying medical condition, course of treatment, and pathological outcomes to ensure compliance with the act;

F. annually assess whether the registered qualifying patient continues to suffer from a qualifying medical condition and, if so, issue the patient a new certificate of that diagnosis; and

G. notify the commissioner, in a manner prescribed by the commissioner, in writing within 14 calendar days of learning of the death of a registered patient whose medical condition was certified by the health care practitioner.

**Statutory Authority:** *MS s 14.389; 152.26; 152.261*

**History:** *39 SR 1760; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

#### **4770.4015 WRITTEN CERTIFICATION OF QUALIFYING CONDITION.**

A certifying health care practitioner must complete a written certification of a patient's qualifying medical condition on a form provided by the commissioner. The written certification must:

A. acknowledge that the qualifying patient is under the health care practitioner's care, either for the patient's primary care or for the qualifying medical condition;

B. confirm the patient's diagnosis of a qualifying medical condition, as defined in Minnesota Statutes, section 152.22, subdivision 14;

C. state whether a patient is developmentally or physically disabled and, as a result of the disability, is unable to self-administer medication or acquire medical cannabis from a distribution facility and requires a designated caregiver;

D. include any additional information the commissioner requests to assess the effectiveness of medical cannabis in treating the medical condition or symptoms;

E. contain an affirmation that the health care practitioner has:

(1) established a patient-provider relationship;

(2) conducted an in-person physical examination appropriate to confirm the diagnosis;

and

(3) reviewed the patient's medical history to confirm the diagnosis within the health care practitioner's professional standards of practice; and

F. include the date the certification of a qualifying medical condition was made.

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

**History:** 39 SR 1760

**Published Electronically:** July 7, 2015

#### **4770.4016 HEALTH CARE PRACTITIONER PROHIBITIONS.**

A health care practitioner who has issued or intends to issue a written certification must not:

- A. examine a qualifying patient to issue a written certification at a location where medical cannabis is manufactured, sold, or dispensed;
- B. refer a patient to a manufacturer or distributor of medical cannabis;
- C. refer a patient to a designated caregiver;
- D. issue a written certification for the health care practitioner;
- E. hold a financial interest in an enterprise that provides or distributes medical cannabis;
- F. directly or indirectly accept, solicit, or receive anything of value from a manufacturer, employee of a manufacturer, or any other person associated with a manufacturing facility;
- G. offer a discount or any other thing of value to a qualifying patient who uses or agrees to use a particular designated caregiver, distribution facility, or medical cannabis product; or
- H. directly or indirectly benefit from a patient obtaining a written certification. Such prohibition does not prohibit a health care practitioner from charging an appropriate fee for the patient visit.

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

**History:** 39 SR 1760

**Published Electronically:** July 7, 2015

#### **4770.4017 RECORDS MAINTAINED BY THE CERTIFYING HEALTH CARE PRACTITIONER.**

Subpart 1. **Health records maintained.** The health care practitioner must maintain a health record for each patient for whom the health care practitioner has certified a qualifying medical condition. These records need not be maintained separately from the health care practitioner's established records for the ongoing medical relationship with the patient.

Subp. 2. **Contents.** The records must be legible, accurately reflect the patient's evaluation and treatment, and must include the following:

- A. the patient's name and dates of visits and treatments;
- B. the patient's case history as it relates to the qualifying condition;
- C. the patient's health condition as determined by the health care practitioner's examination and assessment;

D. the results of all diagnostic tests and examinations as they relate to the qualifying condition; and any diagnosis resulting from the examination;

E. the patient's plan of care, which must state with specificity the patient's condition, functional level, treatment objectives, medical orders, plans for continuing care, and modifications to that plan; and

F. a list of drugs prescribed, administered and dispensed, and the quantity of the drugs.

Subp. 3. **Retention.** The health care practitioner must keep records for each qualifying patient for at least three years after the last patient visit, or seven years, whichever is greater.

**Statutory Authority:** *MS s 14.389; 152.26; 152.261*

**History:** *39 SR 1760; 40 SR 1599*

**Published Electronically:** *June 20, 2016*

#### **4770.4018 REPORTS.**

A participating health care practitioner must report health record data as requested by the commissioner under Minnesota Statutes, 152.28, subdivision 1, paragraph (b).

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

**History:** *39 SR 1760*

**Published Electronically:** *July 7, 2015*

#### **4770.4030 HEALTH CARE FACILITIES; STORAGE.**

Subpart 1. **Storage policy.** A health care facility, as defined in Minnesota Statutes, section 152.34, may adopt policies relating to the secure storage of a registered patient's medical cannabis. Policies may include:

A. secure storage with access limited to authorized personnel; or

B. allowing patients, patients' registered designated caregivers, or patients' parents or legal guardians if listed on the registry verification, to maintain direct possession of the medical cannabis.

Subp. 2. **Return of items.** Upon discharge, transfer, or death of a patient registered to use medical cannabis, the health care facility must return all medical cannabis to the patient or another person authorized to possess it. If the health care facility is unable to return any remaining medical cannabis to the patient or other authorized person, it must destroy the medical cannabis in a manner consistent with instructions posted on the department's medical cannabis website. The transfer or destruction must be recorded in the patient's health record.

**Statutory Authority:** *MS s 152.26; 152.261*

**History:** *40 SR 1599*

**Published Electronically:** *September 7, 2018*