Department of Health

Adopted Permanent Rules Pertaining to Medical Cannabis

4770.0200 DEFINITIONS.

[For text of subps 1 to 12, see M.R.]

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.

[For text of subps 14 to 24, see M.R.]

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.

[For text of subps 26 to 40, see M.R.]

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:

[For text of items A and B, see M.R.]

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.

[For text of subps 2 and 3, see M.R.]

4770.1100 TRANSPORTATION OF MEDICAL CANNABIS.

[For text of subp 1, see M.R.]

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) ~~by~~ 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;

[For text of units (b) and (c), see M.R.]

[For text of items B to D, see M.R.]

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.

[For text of items F to H, see M.R.]

4770.1300 MANDATORY SIGNAGE.

[For text of item A, see M.R.]

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."

4770.1400 PERSONNEL IDENTIFICATION SYSTEM.

[For text of subps 1 to 3, see M.R.]

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 ~~in a~~ vehicle transporting medical cannabis.

[For text of subp 5, see M.R.]

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.

4770.1700 MEDICAL CANNABIS MANUFACTURER; PRODUCTION REQUIREMENTS.

[For text of subps 1 and 2, see M.R.]

Subp. 3. **General sanitation requirements.** A manufacturer must take all reasonable measures and precautions to ensure that:

[For text of items A to I, see M.R.]

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;

[For text of items K to N, see M.R.]

Subp. 4. **Storage.**

[For text of item A, see M.R.]

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

[For text of subitems (1) and (2), see M.R.]

[For text of items C and D, see M.R.]

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.

4770.2000 MEDICAL CANNABIS LABORATORY APPROVAL; APPLICATION AND APPROVAL.

[For text of subp 1, see M.R.]

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

[For text of items A and B, see M.R.]

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.

[For text of subp 3, see M.R.]

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 ~~patient~~ person after using medical cannabis, either physical or psychological, including any harmful reaction, symptom, or disease.

[For text of subps 2 to 4, see M.R.]

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

[For text of subps 5 to 15, see M.R.]

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).

[For text of subps 16 to 22, see M.R.]

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.

[For text of subps 23 to 26, see M.R.]

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

~~[For text of subp 1, see M.R.]~~

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 ~~recommendation~~ report of the Medical Cannabis ~~Advisory~~ 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 Web site 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 ~~refuses~~ dismisses a timely request, the commissioner must notify the person making the request of the reason that the request was ~~refused~~ dismissed.

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

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

~~[For text of subp 3, see M.R.]~~

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

A. The commissioner must appoint a Medical Cannabis ~~Advisory~~ Review Panel composed of ~~nine~~ seven members, including~~:~~

~~(1)~~ at least one medical cannabis patient advocate~~;~~ and

~~(2) one pharmacist;~~

~~(3) one medical ethicist; and~~

~~(4)~~ ~~six~~ two health care practitioners, ~~including at least~~ one with expertise in pediatric medicine.

B. The Medical Cannabis ~~Advisory~~ Review Panel must review requests submitted under subpart 2 and ~~recommend~~ report to the commissioner on the public health impacts, including therapeutic factors and known potential risks, of the proposed additional medical conditions ~~that would benefit from the medical use of cannabis~~.

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 ~~advisory~~ review panel.

Subp. 4. **~~Advisory~~ Review panel meetings.**

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

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

[For text of subitems (2) and (3), see M.R.]

B. The commissioner must post a notice on the department's medical cannabis Web site at least 30 calendar days before ~~an advisory~~ 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. A person may request to close a portion of the meeting to protect private data from disclosure. The request for closure of the meeting must be submitted to the commissioner at least 48 hours before the meeting.~~

~~D~~ C. The Medical Cannabis ~~Advisory~~ Review Panel must ~~recommend the approval, rejection, or deferral for further review of each request by submitting~~ submit a written report to the commissioner by November 1 after conducting the public meeting. The written report must include ~~a medical justification for the recommendation~~ 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 ~~Advisory~~ Review Panel's ~~recommendations~~ report, the commissioner must render a ~~final~~ 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~~; or~~.

~~(3) defer approval or rejection of the medical condition for further review. The commissioner must approve or reject a request that is deferred for further review by May 1 from the date the request was deferred.~~

~~[For text of item B, see M.R.]~~

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 Web site 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 Web site 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 Web site by May 1 each year, announcing the open period for accepting requests and describing the procedure for submitting requests.

~~A~~ 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 Web site. 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.

~~B~~ G. The commissioner must consider the request and any written comments from the public. The commissioner ~~has 90 days to act on the request to either~~ 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 ~~C~~ I; or

(2) reject the delivery method~~; or~~.

~~(3) defer approval or rejection of the delivery method for further review. The commissioner must approve or reject a request that is deferred for further review within 180 days from the date the request was deferred.~~

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

~~D~~ 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 Web site.

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 ~~as follows:~~

~~(1)~~ ~~a serious adverse incident must be reported~~ within five business days of the reporter's learning of the incident~~; and~~.

~~(2) any other adverse incidents must be reported within 15 business days of 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 ~~15~~ 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 Web sites routinely;

(4) post instructions for reporting suspected adverse incidents and unauthorized possession on its Web site; 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 ~~event~~ 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.

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

[For text of subps 1 and 2, see M.R.]

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.

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 Web site. 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 Web site within 15 days of discovery of the occurrence.

4770.4011 MEDICAL CANNABIS DISTRIBUTION.

[For text of subp 1, see M.R.]

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:

[For text of items A to C, see M.R.]

D. a review of any changes in the patient's medical condition.

[For text of subps 3 and 4, see M.R.]

4770.4014 HEALTH CARE PRACTITIONER REQUIREMENTS.

[For text of subp 1, see M.R.]

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

[For text of item A, see M.R.]

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

[For text of subitem (1), see M.R.]

(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.

[For text of subp 3, see M.R.]

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.

[For text of subps 2 and 3, see M.R.]

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 Web site. The transfer or destruction must be recorded in the patient's health record.

RENUMBERING INSTRUCTION. In the next edition of Minnesota Rules, the revisor of statutes shall renumber Minnesota Rules, part 4770.4011, as part 4770.1750, and make any cross-reference changes in Minnesota Rules as a result of the renumbering.