4770.4003 PROCESS FOR ADDING A QUALIFYING MEDICAL CONDITION.

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 of the Medical Cannabis Advisory 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 beginning June 1, 2016.
 - A. The commissioner must forward the request to the advisory panel for review.
- B. If the commissioner rejects a request, the commissioner must notify the person making the request of the reason that the request is rejected.
- C. The commissioner must reject 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.
- D. The commissioner must provide the advisory 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 Advisory Panel.

- A. The commissioner must appoint a Medical Cannabis Advisory Panel composed of nine members, including:
 - (1) one medical cannabis patient advocate;
 - (2) one pharmacist;
 - (3) one medical ethicist; and
- (4) six health care practitioners, including at least one with expertise in pediatric medicine.

- B. The Medical Cannabis Advisory Panel must review requests submitted under subpart 2 and recommend to the commissioner 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 panel.

Subp. 4. Advisory panel meetings.

- A. The Medical Cannabis Advisory Panel must meet at least three times per year to:
- (1) review requests that the commissioner has received for the approval of 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 publish a notice on the department's medical cannabis Web site of an advisory panel meeting at least 30 calendar days in advance. Notice must include the date, time, and location of the meeting, a brief description of the requests received, and information on the requirements for public comment.
- C. A person may request to close a portion of the meeting to protect private data from disclosure. The request for closure of the hearing must be submitted to the commissioner at least 48 hours before the hearing.
- D. The Medical Cannabis Advisory Panel must recommend the approval, denial, or deferral for further review of each request by submitting a written report to the commissioner within 30 days after conducting the public meeting. The written report must include a medical justification for the recommendation.

Subp. 5. Commissioner review.

- A. Upon receiving the Medical Cannabis Advisory Panel's recommendations, the commissioner must render a final decision within 30 days and must:
- (1) approve the request and forward the medical condition as required by item C;
 - (2) reject the medical condition; or
 - (3) defer approval or rejection of the medical condition for further review.
- 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.
- C. The commissioner must forward an approved qualifying medical condition to be added to the chairs and ranking minority members of the legislative policy committees having jurisdiction over health and public safety 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.
- 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 beginning June 1, 2016.
- A. 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:
- (1) approve the request and forward the delivery method to be added as required by item C;
 - (2) reject the delivery method; or
 - (3) defer approval or rejection of the delivery method for further review.
- B. The commissioner must communicate the commissioner's decision to the requesting party along with the reasons for the decision.
- C. 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 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.

Statutory Authority: MS s 14.389; 152.26

History: 39 SR 1760

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