

**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*

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