

DRAFT FOR INFORMAL COMMENT

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Draft Rules for Medical Cannabis Registry: Patient Enrollment and Health Care Practitioners

CHAPTER 4770, MEDICAL CANNABIS REGISTRY PROGRAM; PATIENT, CAREGIVER AND HEALTH CARE PRACTITIONER REQUIREMENTS

GENERAL PROVISIONS

4770.XXXX. APPLICABILITY AND PURPOSE

Parts 4770.XXXX to 4770.XXXX 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.

4770.XXX2. 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.

Subpart 2. DEA Registration Certificate. “DEA Registration Certificate” means a certificate to prescribe controlled substances issued by the U.S. Department of Justice's Drug Enforcement Administration.”

Subpart 3. Disqualifying felony offense . “Disqualifying felony offense” has the meaning given in Minnesota Statutes section 152.22, subdivision 3.

Subpart 4. Diversion or Diverting. “Diversion” or “Diverting” means intentional transferring 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.”

Subpart 5. Evidence-based medical research. “Evidence-based medical research” 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, and other relevant medical information.”

Subpart 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 or 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 per cent ownership in the medical cannabis manufacturer.

Subpart 7. Good standing. “Good standing” means a person has a license or registration with licensing board and is not subject to any restriction or oversight by the licensing body/board beyond others in the same class.”

Subpart 8. Health care practitioner. “Health care practitioner” has the meaning given in Minnesota Statutes, section 152.22, subdivision 4.

Subpart 9. Health record. “Health record” has the meaning given in Minnesota Statutes section 144.291, subd. 2(c).

Subpart 10. Medical cannabis. “Medical cannabis” has the meaning given in Minnesota section 152.22, subdivision 6.

Subpart 11. Medical cannabis manufacturer or manufacturer. “Medical cannabis manufacturer” or “manufacturer” has the meaning given in Minnesota Statutes section 152.22, subdivision 7.

Subpart 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.

Subpart 13. Parent or legal guardian. “Parent or legal guardian” has the meaning given in Minnesota Statutes, section 152.27, subd. 5.

Subpart 14. Minor. “Minor” means an applicant who is under 18 years of age.”

Subpart 15. Patient. “Patient” has the meaning given in Minnesota Statutes, section 152.22, subdivision 9.

Subpart 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 foregoing. Person does not include federal government agencies.

Subpart 17. Public place. “Public place” has the meaning given in Minnesota Statutes section 144.413, subdivision 2.”

Subpart 18. Qualifying medical condition. “Qualifying medical condition” has the meaning given in Minnesota Statutes section 152.22, subdivision 14.

Subpart 19. Qualifying patient. “Qualifying patient” means a resident of Minnesota who has been diagnosed by a health care practitioner as having a qualifying medical condition and who possesses a valid registry verification under rule XXXX.

Subpart 20. Registered. “Registered” means licensed, permitted, or otherwise certified by the commissioner.

Subpart 21. Registered designated caregiver. “Registered designated caregiver” has the meaning given in Minnesota section 152.22, subdivision 11.

Subpart 22. Registered qualifying patient. “Registered qualifying patient” means a qualifying patient who has been approved by the commissioner and has received a registry identification number.

Subpart 23. Registry program. “Registry program” has the meaning given in Minnesota Statutes section 152.22, subdivision 12.

Subpart 24. Registry verification. “Registry verification” has the meaning given in Minnesota Statutes section 152.22, subdivision 13.”

Subpart 25. School. “School” means xxxx (*Placeholder being defined in Mf'r Rules*)

Subpart 26. Telemedicine. “Telemedicine” means the practice of medicine as defined in Minnesota Statutes section 147.081, subd. 3, when the health care practitioner is not in the physical presence of the patient.”

Subpart 27. 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.”

Subpart 28. Transport. “Transport” means the movement of medical cannabis products from a manufacturer’s distribution site to the residence of a registered qualified patient, or otherwise provided by law.

Subpart 29. 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.

2770.XXX3. 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 shall reflect:

1. advances in medical science,
2. 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 shall consider:

1. adequacy of available evidence that medical cannabis will provide relief and
2. absence of other treatment options.

The commissioner must forward the condition to be added to the chairs and ranking minority members of the legislative policy committees having jurisdiction over health and public safety, and if the legislature does not provide otherwise by law, publish the addition in the State Register.

Subpart 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.

A. The commissioner must consider the request and any written comments from the public. The commissioner has 60 days to act on the request, applying the criteria stated in subpart 1 to either:

1. Approve the request and forward the condition to be added to the chairs and ranking minority members of the legislative policy committees having jurisdiction over health and public safety.
2. Reject the condition, or
3. Defer the condition for further review.

B. The commissioner must communicate his or her decision to the requesting party along with the reasons for the decision.

QUALIFYING PATIENTS AND DESIGNATED CAREGIVERS

4770.XXX4. 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 a forms provided by the commissioner that meet the requirements of Minnesota Statutes, section 152.27, subdivision 3.

B. In addition, a patient or the patient's parent or legal guardian must provide proof of the patient's Minnesota residency:

[Placeholder for evidence for proof of residency]

C. A patient or the patient's parent or legal guardian must submit a non-refundable annual enrollment fee under Minnesota Statutes section 152.35.

Subpart 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 will:

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.

4770.XXX6. DESIGNATED CAREGIVER APPLICATION.

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

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

4770.XXX7. 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 his or her 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 Department promptly by telephone and in writing within 10 calendar days following the death of the designated caregiver's registered qualifying patient; and
3. dispose of all unused medical cannabis using methods described in Rule 4770.XX11, within 10 days of the patient's ceasing to be enrolled in the program for any reason, including death of the patient, [or in case of an adverse event or 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 his or her registered qualifying patient;

3. Prepare medical cannabis for self-administration by his or her registered qualifying patient; and
4. Administer medical cannabis to his or her 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;
2. Sell, provide, or otherwise divert medical cannabis that has been dispensed for a registered qualifying patient.

4770.XXX9. 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(d).

Subpart 2. Suspension of qualifying patient enrollment. The commissioner may suspend the registration certificate of a qualifying patient under the following circumstances:

- A. The qualifying patient is incarcerated in a correctional institution or facility under the supervision of the Department of Correction.
- B. The qualifying patient or primary caregiver provided false, misleading, or incorrect information to the department.
- C. The qualifying patient, together with the qualifying patient's designated caregiver where applicable, obtains more than a 30-day supply of medical cannabis with a 30-day period and the commissioner has reason to believe the patient is abusing or diverting medical cannabis.

Subpart 3. Designated caregivers. The department may revoke the registration of a designated caregiver under the following circumstances:

- A. The registration certification of the qualifying patient has been revoked or suspended;
- B. The qualifying patient's physician notifies the department that the qualifying patient is no longer in need of a designated caregiver;

C. The qualifying patient registers a different person to serve as the designated caregiver;

D. The designated caregiver has a disqualifying felony offense conviction as defined in Minnesota Statutes section 152.22, subd. 3;

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

4770.XX10. MEDICAL CANNABIS OBTAINED FROM A MEDICAL CANNABIS MANUFACTURER

Subpart 1. A registered qualifying patient, registered designated caregiver or, if listed on the registry verification, a parent or legal guardian of a patient must obtain medical cannabis only from a distribution facility of a registered medical cannabis manufacturer registered with the Medical Cannabis Registry Program and may not:

A. Grow or cultivate medical cannabis;

B. Purchase medical cannabis from non-authorized sources; or

C. Obtain medical cannabis from other registered qualifying patients or designated caregivers.

Subpart 2. A registered qualifying patient, registered designated caregiver or, if listed on the registry verification, a parent or legal guardian of a patient may purchase all or a portion of the patient's 30-day supply of medical cannabis at a time from any distribution site in Minnesota of a registered manufacturer. If a patient receives less than a 30-day supply, any distribution facility may dispense to the patient the remaining portion of the 30-day supply of medical cannabis at any time except that no registered qualifying patient or designated caregiver may receive more than a 30-day supply of medical cannabis in a 30-day period.

Placeholder for Medical Cannabis Delivery to Patient

Procedure:

- 1. Patient presents personal identification*
- 2. Unique registry identification number*
- 3. Manufacturer's pharmacist must offer consultation with patient about medical cannabis administration and dosage.*
- 4. Manufacturer delivers the packaged medical cannabis and offers consultation .*

4770.XX11. 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 or eligible to be enrolled in the registry must, within 10 calendar days after he or she ceases to be registered or eligible, dispose of any unused medical cannabis in his or her possession by one of the following methods:

1. By depositing it with a medical cannabis distribution site located in Minnesota.
2. By depositing it with a law enforcement agency having local jurisdiction for destruction.
3. By disposing of the medical cannabis at a government recognized drug take-back program located in Minnesota.
4. By rendering it non-recoverable 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 may not transfer, share, give, sell, or deliver any unused medical cannabis in his or her possession to any other person, regardless of whether the person is participating in the medical cannabis patient registry program.

4770.XX12. ANNUAL FEES

Subpart 1. Each application or renewal must be accompanied by the payment of an annual fee. All fees are nonrefundable.

A. 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.

B. Annual designated caregiver application fee for background check costs

C. Returned check fee \$35

Subpart 2. Payment method. A person submitting a fee as required in subpart 1 by mail shall make the fee payable to the "Minnesota Department of Health – OMC" and submit it with his or her application. A person submitting a fee as required in subpart 1 as part of an on-line application must pay by credit card or bank debit card.

HEALTH CARE PRACTITIONERS

4770.XX13. HEALTH CARE PRACTITIONER REQUIREMENTS

Subpart 1. Qualifications. The commissioner must accept written certifications for the therapeutic use of 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 advance practice registered nurses; and

B. A DEA registration certificate.

Subpart 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. Conduct a full assessment of the patient's medical history and current medical condition, which includes:

1. An in-person physical examination of the patient. This examination may not be performed by remote means, including telemedicine or via the internet.
2. A medical history of the patient,
3. Consultations about the patient's qualifying medical condition before the patient applies for enrollment in the registry.
4. A diagnosis of the patient's current medical condition; and,
5. The development of a treatment plan for the patient.

C. Diagnose the patient as having a qualifying medical condition, as defined in Minnesota Statutes section 152.22, subdivision 14.

Subpart 3. 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 he or she has written a certification of qualifying condition. A health care practitioner must transmit patient treatment, outcomes and medical findings, including quality of life data, in a form and at intervals as prescribed by the commissioner.

B. Be available to provide continuing treatment of the patient's qualifying medical condition. Continuing treatment means follow the patient clinically at appropriate

intervals at the discretion of the provider to provide follow-up care and treatment to the patient for his or her qualifying medical condition including, but not limited to, physical examinations, to determine the health effects of cannabis for treating the patient's qualifying medical condition or the symptom of the qualifying medical condition for which the written certification was issued.

C. Maintain health records under Rule 4770.XX17 for all patients for whom the practitioner has issued a written certification which support 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(b).

E. Make a copy of such 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.

G. Notify the Commissioner, in a manner prescribed by the commissioner, in writing within 14 calendar days of becoming aware of the death of a qualifying patient or after advising a qualifying patient for whom the health care practitioner has issued a written certification about a change in status of a qualifying medical condition if such change affects the patient's continued eligibility for medical cannabis.

4770.XX14. WRITTEN CERTIFICATION OF QUALIFYING CONDITION

The certifying health care practitioner must provide the qualifying patient with A written certification on a form provided by the commissioner.

A. The health care practitioner certifies that the qualifying patient is under the health care practitioner's care, either for the qualifying patient's primary care or for his or her qualifying medical condition.

B. The patient's qualifying medical condition, as defined in Minnesota Statutes section 152.22, subd 14;

C. An indication of which symptom or side effect the condition, or its treatment, has produced in the patient;

D. Additional comments the health care practitioner believes would be useful in assessing the qualifying patient's application for use of medical cannabis;

E. A statement that the health care practitioner has confirmed a diagnosis of a qualifying medical condition; has established a practitioner-patient relationship; has conducted an in-person physical examination; has conducted a review of the patient's medical history, including reviewing medical records from other treating physicians from the previous 12 months; and has explained the potential risks and benefits of the use of medical cannabis to the qualifying patient or to the qualifying patient's custodial parent or legal guardian/representative;

F. The health care practitioner's signature and date of certification.

G. The qualifying patient's signed consent for the release of medical information related to the patient's qualifying medical condition and treatment.

4770.XX16. HEALTH CARE PRACTITIONER PROHIBITIONS

A health care practitioner who has issued or intends to issue a written certification may 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 him or herself;

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 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.

4770.XX17. 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 recommended medical cannabis for his or her medical condition or continued treatment for conditions under the health

care practitioner's care. These records need not be maintained separately from the health care practitioner's established records for the patient's ongoing medical relationship with the patient.

Subpart 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 and health condition as determined by the health care practitioner's examination and assessment;
- C. The results of all diagnostic tests and examinations; and the diagnosis resulting from the examination;
- D. 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;
- E. A list of drugs prescribed, administered and dispensed, and the quantity of the drugs.

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

4770.XX18. REPORTS

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