ICSI Institute for Clinical Systems Improvement
Transforming health care, together

Health Care Practitioner Guidance for Minnesota's Medical Cannabis Program

Introduction

This document is the product of a work group that met at the Institute for Clinical Systems Improvement (ICSI) during May-June 2015 to create general guidance for practitioners in ambulatory care as medical cannabis becomes available in July of 2015. A general overview of this program About the Minnesota Medical Cannabis Program and other information is available on the MDH website. The following information focuses on the ambulatory setting and is provided to help organizations, practices and individuals build needed policies and workflows.

This should not be construed as support or non-support of the legalization of medical cannabis in Minnesota or as the support or non-support of use of medical cannabis in any given patient circumstance. It focuses on the certification process to assure that practitioners meet all the requirements in the legislation, so that they are afforded the protections in the legislation (2014 Minnesota Session Laws CHAPTER 311 – S.F. No. 2470).

The work group believes that clinicians' professional responsibilities to their patients are of high importance in this circumstance as in all discussions that include consideration of treatment options. For this discussion, the work group considered medical cannabis as an experimental treatment, and used principles that apply to all such treatments when recommending components of the "certifying visit" that are not specified in the legislation.

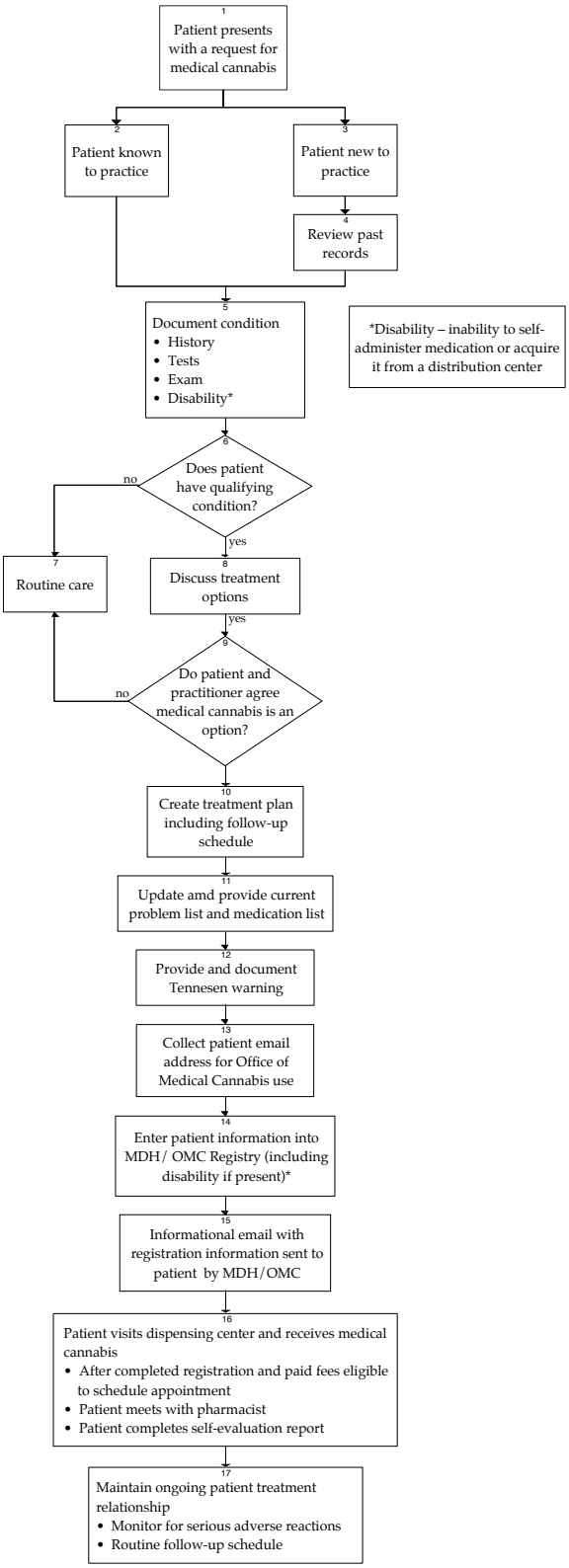
This work group did not conduct a literature review of uses of medical cannabis. We highly recommend that practitioners read the systematic review completed by the Minnesota Department of Health (MDH)/Office of Medical Cannabis (OMC) committee in December 2014 for specific information about what is known about use of medical cannabis in each of the specified qualifying conditions. An executive summary and a detailed systematic review area available – A Review of Medical Cannabis Studies relating to Chemical Compositions and Dosages for Qualifying Medical Conditions. Other information is available in the Medical Cannabis Clinical Information Resources section.

While the number of patients who are interested in participating in the medical cannabis program is roughly estimated to be 5,000, it is not clear that this number is accurate. Others have estimated that interest is much lower. MDH/OMC conducted a medical cannabis patient interest survey in February 2015. (Medical Cannabis Patient Interest Survey Results).

While the legislation is clear about some Health Care Practitioners (HCP) responsibilities, there are areas that require further clarification. During the work group discussions, which included representatives from the MDH's Office of Medical Cannabis (MDH/OMC), some, but not all issues, were clarified. This work will continue by the MDH/OMC even after the program has started. Updates and changes will be available on the Minnesota Department of Health Medical Cannabis website.

This document contains multiple links in an effort to assure that information is kept up to date, BUT its accuracy is only assured as of the publication date noted.

Medical Cannabis Qualifying Condition Certification Flow



Overview

Starting on June 1, 2015, health care practitioners (for this instance defined as "a medical doctor, physician's assistant or advanced practice registered nurse licensed in Minnesota") are able to set up an account on the Minnesota Medical Cannabis Registry that allows the HCP to certify patients who have a qualifying condition under the 2014 legislation.

An HCP who has registered as such in the Minnesota Medical Cannabis Registry **does not prescribe medical cannabis of any kind**. The HCP's role in the program is to determine, in the HCP's medical judgment, if a patient suffers from a qualifying medical condition, and, if the clinician is willing to certify the patient, if this is determined, provide the patient with a certification of that diagnosis. Once an HCP certifies a patient's qualifying condition and the patient has registered and been approved for enrollment by MDH, the patient will be able to visit one of eight Cannabis Patient Centers where a licensed pharmacist will incorporate the qualifying condition, current medical conditions and medication taken by the patient as well as other information provided on the patient's self-evaluation report to determine the form, dosage and frequency of the medical cannabis to be taken by the patient. All medical cannabis available in the Minnesota program is in either pills, oil, or liquid form as vaporization is allowed. No raw leaf, flowers, or edibles are allowed under Minnesota law.

Health Care Practitioner Registration

Only a medical doctor, physician's assistant or advanced practice registered nurse licensed in Minnesota, can certify that a patient has a qualifying condition. These HCPs must have an active MN license in good standing and a DEA registration certificate. HCPs are under no obligation to participate in this program.

MDH/OMC does not intend to maintain or share with the public any list of practitioners who are participating in the program or provide any referral information to patients seeking a registered HCP.

HCP Registry

HCPs will need to create an account to be able to certify a patient's condition. The following information is needed:

- General practice information: name, address, email and phone
- Medical license number
- DEA registration number

The Office of Medical Cannabis (OMC) will contact all account registrants to verify their identity. The registration process is designed to have a rapid turnaround time, so HCPs could choose to defer registration until a patient requests evaluation for this program.

Annotation 1: **Patient presents with request for medical cannabis**

- This is required to be an in-person visit.
- Patient must be a Minnesota resident. It is reasonable for the practice to check this before proceeding, but MDH/OMC is responsible for the final determination of residency.
- There may be patients requesting medical cannabis who do not have a qualifying condition under the current legislation, or have other misconceptions about the program. MDH/OMC has created a basic patient informational brochure – About the Minnesota Medical Cannabis Program or General Information about the Minnesota Medical Cannabis Program Fact Sheet.

- The work group supports the following foundational content for the visit, and recommends that it be supplemented as required based on patient care needs. This visit is to be considered part of the overall care of the patient for the condition, rather than a unique visit type.

Annotation 2: **Patient known to practice**

- Few medical groups have specific policies about what it means for a patient to be established in a practice, and there is no clear standard of practice in the community. The draft rules for this program define a medical relationship as: "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."
- Medical groups should consider and plan for the instance where a patient with a qualifying condition is cared for by both a specialist and a primary care practitioner. In this case, it might be important to determine who is managing the ongoing therapies for the qualifying condition. This determination may need case-by-case discussion based on specific patient needs.
- The MDH/OMC has provided guidance that allows for a medical group to develop a "designated-certifier" program (Office of Medical Cannabis Information Bulletin #1). This is in recognition of circumstances where a patient is cared for by a team of providers that cross specialties and care sites within a medical group. This "designated-certifier," who completes the registry certification, must remain sufficiently engaged in the patient's care to satisfy the statutory requirements, but is not required to provide all care. This option could allow a medical group to develop HCPs who have additional expertise in risks and benefits of medical cannabis.
- There may be instances where a particular HCP in a medical group chooses not to participate in the program in any way. This is a voluntary program, and variation in participation across and within medical groups creates challenges for both patients and other HCPs. Medical groups should plan a decision-making process for this circumstance that both supports optimal patient care and minimizes care fragmentation.

Annotation 3: **Patient new to practice**

- Whether the patient will or can be accepted into a practitioner's practice is based on the practice's usual routine.
- Few medical groups have specific policies about what it means for a patient to be established in a practice, and there is no clear standard of practice in the community. The draft rules for this program define a medical relationship as: "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."
- If a group chooses to develop a specific policy, consider a general policy, rather than one specific to this or any other particular program.

Annotation 4: **Review past records**

This review should be based on accepted standards of good medical practice for the condition under review.

Annotation 5: **Document condition: history, tests, exam (including assessment of disability, if warranted)**

The legislation has limited guidance about what must be included. The requirements state that a HCP must:

- Conduct a full assessment of the patient's history including the results of all diagnostic tests and examination as they relate to the qualifying condition.
- Review records relating to the qualifying condition from other treating physicians from previous 12 months.
- Conduct an assessment of the current medical condition including an in-person physical exam as appropriate to confirm the qualifying diagnosis.
- Also, if in the HCP's medical opinion, the patient is developmentally or physically disabled and if as a result of that disability, the patient is unable to self-administer medication or acquire medical cannabis from a distribution facility, this should also be recorded.
- Other, additional elements, of the history and exam are dictated by individual patient circumstances as needed for the HCP to provide care.

Annotation 6: **Does patient have a qualifying condition?**

Qualifying Conditions:

- Cancer associated with severe/chronic pain, nausea or severe vomiting, or cachexia or severe wasting.
- Glaucoma.
- HIV/AIDS.
- Tourette Syndrome.
- Amyotrophic Lateral Sclerosis (ALS).
- Seizures, including that characteristic of epilepsy.
- Severe and persistent muscle spasms, including those characteristic of multiple sclerosis.
- Crohn's Disease.
- Terminal illness, with a life expectancy of less than one year, if the illness or treatment produces severe/chronic pain, nausea or severe vomiting, cachexia or severe wasting

Note: Intractable pain is under review, but outside of cancer or terminal illness, is not a qualifying condition. Information about whether intractable pain will be added to the list of qualifying conditions will be available later in 2015 on the MDH/OMC website as it becomes available. If it is added, it will not happen before 2016.

Annotation 8: **Discuss treatment options**

The systematic review of the evidence for medical cannabis use in the qualifying conditions is available here:

A Review of Medical Cannabis Studies relating to Chemical Compositions and Dosages for Qualifying Medical Conditions

It is a complete review of the literature as of December 2014 and is highly recommended reading for practitioners prior to this discussion.

- The treatment options discussion might include a review of the standard, well-accepted treatment options, a review of treatments that have been tried and the outcomes of their use, as well as the potential use of medical cannabis.
- Medical cannabis is an experimental treatment in all the qualifying conditions, and should be discussed with patients as such. This is congruent with the information they will receive from MDH/OMC with registration material – Patient Information Sheet.
- Practitioners should review, with their patients, what is known about the use of medical cannabis for the patient's condition, including expected benefits, possible harms and interactions with other treatment(s).
- There may be situations where a discussion about the limitations of use in public places or when on the job that would be important to review. The legislation includes restrictions on use in these settings. The dispensing pharmacies will provide this information to patients in the program (see Patient Responsibilities Section).
- There is limited information about drug interactions. A 2014 summary article is available – Drug Interactions Cannabis – Horn, 2014.
- Patient registration for the medical cannabis program costs $200 ($50 for patients on SSD, SSI, Medicaid, MNCare or CHAMPVA only). A 30-day supply is estimated to cost between $200-$500. None of these costs are covered by any public or private Minnesota insurance plan.

Annotation 9: **Do patient and practitioner agree that medical cannabis is a treatment option?**

- Practitioners are under no obligation to certify a patient, even if he/she has a qualifying condition. As in all cases, practitioners should use good medical judgment about risks and benefits for an individual patient.
- Patients will have a further discussion about use of medical cannabis with the dispensing pharmacist. It is likely that this will include risks and benefits, but will also include more information about dose, administration and side effects based on the exact formulation.
- Recommendations made by practitioners to patients are considered free speech and are protected under the First Amendment.

Annotation 10: **Create treatment plan, including follow-up plan schedule, and communicate with remainder of the patient's care team as appropriate**

- By certifying a patient, the HCP is agreeing to continue to care for the patient. Standard practice would suggest that a treatment plan is documentation of an agreement regarding ongoing care. (See also Office of Medical Cannabis Information Bulletin #1 as noted in Annotation 2).

- Treatment plans might include treatment objectives, medical orders (including medication list), and the continuing treatment follow-up plan.
- "Continuing treatment means following the patient clinically at appropriate intervals at the discretion of the practitioner to provide follow-up care and treatment to the patient for the patient's qualifying condition."
- Patients need certification on an annual basis.
- There is currently no provision in the law for a HCP to "revoke" a certification, or to notify MDH/OMC that a patient is no longer under the HCP's care.
- Patient may utilize any of the eight distribution centers. Note: HCPs must not refer a patient to a specific manufacturer or distributor.
- A visit documentation template is available – see Appendix A.

Annotation 11: **Update and provide current problem list and medication lists**

This information is important to the dispensing pharmacist. A printed copy may be convenient. It is not clear whether or not the dispensing pharmacist will have patient available Internet access such that the patient could sign into a secure portal to provide this information.

Annotation 12: **Provide and document Tennessen warning**

- This document is available for download: Minnesota Medical Cannabis Program: Patient E-Mail and Acknowledgement Form.

  Note: The Tennessen warning requires that when "an individual is asked to supply to a government entity, private or confidential data concerning the individual he/she shall be informed of: (a) the purpose and intended use of the requested data within the collecting government entity; (b) whether the individual may refuse or is legally required to supply the requested data; (c) any known consequence arising from supplying or refusing to supply private or confidential data; and (d) the identity of other persons or entities authorized by state or federal law to receive the data.

- There is no requirement for a signature on the document, but it serves as clear documentation that it was given.

  Tennessen Warning Minnesota Statute 13.04 Rights of Subjects of Data

Annotation 13: **Collect patient's email address for office of medical cannabis use**

- This is the email address that MDH/OMC will use to provide further information to the patient along with the registration material that must be completed before the patient can visit a dispensing center.
- If the patient has a guardian or is a minor, the appropriate email should be collected. There is support for patients who do not have Internet access. They should be instructed to call the MDH/OMC Call Center at 651-201-5598 or 844-879-3381 (toll free).

Annotation 14: **Enter patient information into MDH/OMC registry (including disability if present)**

- The information required is: name, email address, qualifying condition and whether a disability is present that results in the patient's inability to self-administer medication or acquire it from a distribution center.
- Date of "certification visit."
- This certification also acknowledges that the patient is under the certifying HCP's care for the qualifying condition. Office of Medical Cannabis Information Bulletin # 1 document provides further guidance for designated certifiers.
- Practitioners who are providing ongoing care for patients enrolled in the medical cannabis program "agree to continue treatment for the patient's qualifying condition and report medical findings to the commissioner." This is to support the commissioner's responsibility to "conduct research and studies based on data from health records submitted to the registry program and submit reports on intermediate or final research results to the legislature and major scientific journals."

  The plan for the first year of the program (7/2015-6/2016) is to collect information only from the dispensing sites, the information collected by the pharmacists. This will be used to better understand which research questions might be addressed – either through focused studies on certain patient groups using retrospective medical record abstraction or through future specification of medical record information that must be documented.

Annotation 15: **Informational email with registration information sent to patient by MDH/OMC**

After the practitioner completes the entry, an email is generated to the patient that includes:

- Required information about the experimental nature of medical cannabis.
- A link to a listing of support groups.

  These were specified in the legislation as HCP responsibilities and MDH/OMC is expecting this to satisfy the requirement; however, opinions have differed on this. This information will also be available on the MDH/OMC Medical Cannabis website. See Patient Information Sheet. This document is available if the HCP wishes to give it to the patient, and/or use it in discussion.
- Further, registration materials must be completed within 90 days. Information about these patient requirements is available on the MDH/OMC website.

Annotation 16: **Patient visits dispensing site and receives medical cannabis**

- Once the patient has completed registration and payment has been received the patient is entered into the registry and is eligible to schedule an appointment at one of eight distribution centers to obtain medical cannabis.
- The patient will meet with a pharmacist to discuss formulations, doses and delivery methods of medical cannabis. They will be given a dosing protocol and no more than a 30-day supply of the medication.
- Each time the patient visits the distribution center for a refill, the pharmacist will collect standard information about any change in symptoms and side effects or other adverse events. This information is collected in a common registry accessible by all distribution centers.

- The pharmacist will recommend that patients share the specifics of their medical cannabis plan with their treating HCP. The packaging will include the preparation's chemical composition and dosage, along with patient identification information.

Annotation 17: **Maintaining ongoing patient treatment relationship**

- Monitor for and report serious adverse reactions.
  - Serious adverse events are defined as any unexpected or harmful physical or psychological reaction that results in death, admission to a hospital, or requires medical treatment beyond first aid.
  - Life-threatening events, or death, should be reported within three days of the HCP becoming aware of the event.
  - Non-life-threatening events should be reported within 14 days of the HCP becoming aware of the event.
  - Reports can be made through the MDH/OMC site.
- Monitor for follow-up with treatment plan schedule
- Monitor for non-compliance
  - Reporting requirements for HCPs when diversion of medical cannabis is suspected or discovered, have not yet been clarified.
- Communication with health care team to support continuity
  - There is currently no defined process for HCPs and the dispensing pharmacist to have a discussion or otherwise share patient information. The work group recommended that this be developed. This is under discussion, but will not be available at the onset of the program.

Other Information

Medical groups may need to consider standards regarding the use of problem lists and medication lists for information regarding a patient's participation in the medical cannabis program, as there are no specific ICD 9 or 10 codes for use of medical cannabis, nor complete medication names in pharmacy databases as dispensed by the distribution centers.

This document was created to support the initiation and beginning work of certification of patients for medical cannabis. When it is next in session (early 2016), the Minnesota Legislature may take actions that could significantly impact this document.

References and Other General Resources for HCPs

2014 Minnesota Session Laws: Minnesota Statute 311

Implementation of the Minnesota Medical Cannabis Program Task Force on the Therapeutic Use of Medical Cannabis *Report to the Minnesota Legislature 2015*

Minnesota Department of Health Office of Medical Cannabis
Phone: 651-201-5598, toll-free at 844-879-3381 or email health.cannabis@state.mn.us.

Leafline Labs

Minnesota Medical Solutions

Minnesota Medical Association [MMA special report supplement to Minnesota Medicine]

Minnesota Hospital Association (MHA)

Many professional societies have a policy statement on use of medical cannabis in specific population or conditions.

Horn JR, Hansten PD. Drug interactions with marijuana. 2014.

Members of this work group were not reimbursed for participation; however, support was provided to the Institute for Clinical Systems Improvement from the Minnesota Department of Health Office of Medical Cannabis to convene a work group to create materials for general guidance of practitioners in ambulatory care as medical cannabis becomes available July 1, 2015.

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Appendix A – Medical Cannabis Qualifying Condition Certification Visit

Note: This is required to be an in-person visit

[The patient must be a MN resident. There is a step in the State process to confirm this, but if the patient is known not to be a resident, there is no need to go further.]

Does the patient have one of the qualifying conditions?

If you have been providing ongoing care for this condition:

- Document the condition and the relevant history and/or tests that support the determination.
- Document the relevant physical exam findings

If this is a new patient to the practice:

- Document that records for the preceding 12 months have been reviewed.
- Document the condition and the relevant history and/or tests that support the determination.
- Document the relevant physical exam findings

Does the HCP agree with certifying the qualifying condition?

- If yes, proceed.
- If no, HCP discusses denial with the patient and documents rationale for denial of certification in medical record.

Does this patient have a disability that prevents him/her from self-administration of medications or patient is unable to acquire medical cannabis from a distribution center?

- Document the reason for this determination.

Discuss treatment options

- Review what is known about using medical cannabis for the patient's condition.
- Review other treatment options that have been tried or are available.

Create treatment plan, including follow-up plan for next 12 months

[Certifying practitioner is required to be the treating physician and agrees to continue care.]

Provide patient with after visit summary

- Must include: problem list/diagnoses and current medication list via paper document and/or Patient Portal for access to the most up-to-date medical information.

Provide Tennessen warning to patient

- Document that this was done using the Office of Medical Cannabis (OMC) form, which will include necessary information required. Or clinics can use their own Tennessen forms.
- Obtaining a signature from the patient is good practice

Enter patient into the State Registry

- Enter patient name, qualifying condition and email address (specific for medical cannabis) into the State registry.
- Include documentation of disability if appropriate.
- Note: When the patient has been certified by the state, they will receive notification directing them to the OMC MDH website to review non-profit support groups.
- NOTE: The patient application requires a copy of the certification from the HCP that is dated within 90 days prior to the submission of the application.

Add medical cannabis to the Problem List (ICD-9 and/or ICD-10 as appropriate) after pharmacist dispenses the medical cannabis