Management
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Minnesota Department of Health—Office of Medical Cannabis

Panel Recommendations on Adding Intractable Pain as a Qualifying Condition for the Minnesota Medical Cannabis Program

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Introduction

In 2014, the Minnesota legislature passed a bill allowing the use of medical cannabis for the therapeutic treatment of nine qualifying conditions and "any other medical condition or its treatment approved by the commissioner."[1] Chapter 311 Section 20 of 2014 Minnesota Laws establishes that before considering any other conditions, the Commissioner of Health must first consider whether intractable pain should be added to the list of qualifying conditions. To this end, the Minnesota Department of Health (MDH) gathered information for the Commissioner by collecting input via public testimony, reviewing current literature on the scientific knowledge available, and collecting advice from a panel of medical and mental health experts.

Advisory panel membership and process

Membership

MDH's Office of Medical Cannabis (OMC) authorized an eight-member panel to advise the Commissioner on whether intractable pain should be added as a qualifying condition for the use of medical cannabis. The advisory panel included a substance abuse treatment expert, two primary care physicians with expertise in pain management, a physical medicine and rehabilitation physician with subspecialty certification in pain medicine, a physician's assistant with a pain management specialty, an advanced practice registered nurse with pediatric pain management focus, a pharmacist, and a board certified clinical psychologist with specialty experience in pain management.

Process

The OMC convened the group, coordinated four meetings, and provided presentations to the panel. Management Analysis & Development (MAD), a division of Minnesota Management & Budget (MMB), provided facilitation and report writing.

Over the four meetings, the panel members heard presentations on chronic pain management, scientific research on the therapeutic potential of cannabinoids for chronic pain, and addiction medicine and pain management. The members also heard testimony from over a dozen members of the public on whether intractable pain should be added to the list of qualifying conditions for the use of medical cannabis. In addition to the public testimony at the advisory panel meeting, MAD compiled and shared with the panel a report on public comments gathered[2] from July through October 2015 on whether intractable pain should be added as a qualifying condition.[3]

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[1] 2015 Minnesota Statute 152.22

[2] Members of the public could provide comment in three ways: by submitting the comment on line via the MDH website, submitting written comments in paper form or via email to MAD or MDH, or providing oral testimony at public meetings.

[3] Public Comment on Adding Intractable Pain as a Qualifying Condition for the Minnesota Medical Cannabis Program, October 2015; Management Analysis & Development, Minnesota Management & Budget

The OMC also contracted with the Minnesota Evidence-based Practice Center (MPEC), to conduct a literature review and grading of evidence for studies of cannabis use for treating chronic non-cancer pain.[4] Mary Butler, PhD, co-Director of the MEPC, presented to the panel a report of that project's findings.

Advisory panel discussions

To develop their recommendations, the advisory panel responded to a series of questions provided by MAD.[5] MAD then summarized panel responses into a document which members reviewed and revised at their fourth meeting. Through this process, the panel developed principles, stipulations, and recommendations to advise the Commissioner of Health.

Guiding Principles

The advisory panel agreed on several key principles that set the context for its recommendations. These principles are:

- Medical cannabis is not a magic bullet for treating pain
- Knowledge of effects of medical cannabis as pain treatment is insufficient
- Pain is complex and requires complex solutions
- Providers are cautious to prescribe another potentially dangerous medication

Medical cannabis is not a panacea for treating pain

Panel members expressed concern that patients eligible to use medical cannabis for pain have expectations that it would provide total relief and that such a perception may lead patients to abandon other proven pain management regimens, such as physical therapy. Panel members agreed that medical cannabis should not be the first line of therapy in treating intractable pain but that it could be an option after exhausting other standard treatments. Such standard treatments include, but are not limited to, physical therapy, approved medications, and addressing psycho-social issues.

Knowledge of effects of medical cannabis as pain treatment is insufficient

Many times throughout advisory panel meetings, panel members cited the lack of scientific knowledge regarding the effectiveness and potential harmful effects of using medical cannabis, such as addiction, abuse, and adverse effects. They noted that cannabis is a Schedule 1 drug at the federal level, which limits researchers' ability to study the drug. For example, one member suggested that basic science and anecdotal evidence indicate that cannabis can have a positive effect on pain control, but existing clinical research is insufficient to provide adequate guidelines, such as appropriate dosage, for the use of medical cannabis for pain relief in humans. They also mentioned that evidence does not indicate whether the medical cannabis manufactured in Minnesota would have the same effect as cannabis obtained elsewhere. Dr. Butler's extensive review of existing literature found that the effects of

[4] Medical Cannabis for Non-Cancer Pain: A Systematic Review , Prepared for Office of Medical Cannabis Minnesota Department of Health; Prepared by Minnesota Evidence-based Practice Center, Minneapolis, Minnesota; Investigators: Mary Butler, Ph.D., M.B.A., et al

[5] See Attachment A

cannabis fall short of the standards that would be required for Food and Drug Administration (FDA) approval for any medication.

Pain is complex and requires complex solutions

Panel members stated that treating chronic pain requires an interdisciplinary bio-psycho-social model, of which medical cannabis could be one component but not the only component. Panel members mentioned that there is no way to measure pain definitively, as there is for other qualifying conditions. They noted pain is a symptom rather than a specific diagnosis and not a useful way of defining a clinical population. Additionally they mentioned that the intractable pain population includes some people for whom medical cannabis may be appropriate and others for whom it is not likely to be appropriate.

Providers are cautious to prescribe another potentially dangerous medication

Due to the lack of knowledge on the effects of medical cannabis and how to best use it to treat pain, (mentioned above) panel members said providers are wary of prescribing or certifying its use. Panel members cited the recent opioid crisis, where good medications were demonized because prescribers used it to treat pain without knowing its proper uses. Even after studying the information available on medical cannabis, panel members said providers do not feel prepared to certify patients for its use.

Recommendations

After considering the reports, anecdotal information, and presentations, and discussing reasons for or against adding intractable pain to the list of qualifying conditions, the advisory panel diverged on whether intractable pain should be added as a qualifying condition. Initially, the majority of panel members were in favor of adding intractable pain to the list of qualifying conditions, and a few members were opposed. However, after panel member met at their fourth meeting to discuss what recommendations they would send to the Commissioner of Health, the majority of panel members were in opposition of adding intractable pain to the list of qualifying conditions.

Though most panel members did not support adding intractable pain to the list of qualifying conditions, they did identify and agree on several stipulations if the Commissioner decides to add it.

Should intractable pain be added to the list of qualifying conditions?

MAD surveyed the advisory panel[6] prior to the final advisory panel meeting on their opinions about adding intractable pain to the list of qualifying conditions. With the guiding principles above, the advisory panel answered the question, "Should intractable pain be added to the list of qualifying conditions for the use of medical cannabis?" When aggregated, panel member responses were:

Five (5) panel members were **in favor** of adding intractable pain.
Two (2) panel members were **opposed** to adding intractable pain.

[6] See Attachment A

After the fourth advisory panel meeting, MAD asked panel members the same question. This time, panel members responded:

> **Three (3)** panel members were **in favor** of adding intractable pain.
> **Five (5)** panel members were **opposed** to adding intractable pain.

During the fourth advisory panel meeting, members agreed that none of them could provide a definitive answer, but that their answers reflected more of a "yes, it should be added, but…" or "no, it should not be added, but…" and followed with conditions or stipulations for the Commissioner of Health.

Stipulations for adding intractable pain to the list of qualifying conditions

Panel members added stipulations as either qualifications to being in favor of intractable pain or conditions those opposed to adding intractable pain thought should be met if intractable pain becomes a qualifying condition for medical cannabis. The advisory panel agreed on the following stipulations that the Commissioner of Health should consider if the state adds intractable pain as a qualifying condition.

Criteria for inclusion, precaution, or exclusion

Inclusion

Inclusion of a patient and certifying their condition as qualifying for the use of medical cannabis should depend on provider-established treatment goals and whether the goals are to improve function or to simply relieve pain (i.e. palliation). The panel found the potential harm of medical cannabis use less concerning if the goal for the patient is palliation due to life-limiting conditions. They noted because there is evidence that medical cannabis can impair function, the treatment may be inappropriate for patients whose goals target functional restoration.

Additionally, medical cannabis may be an option for some patients only after traditional, approved methods of treatment have been exhausted.

Precautions

The advisory panel identified patient characteristics or conditions that should cause precaution among providers:

- Patients with current or history of substance abuse disorder[7]
- Patients with problematic mental health symptoms or conditions to the extent that symptoms are made worse or brought on by the use of medical cannabis

[7] The panel discussed that while using cannabis may increase risk of abuse or adverse effects in patients with substance abuse disorder, some patients may be using substances to alleviate pain and would not have access to medical cannabis if substance abuse disorder were considered an exclusion, rather than a precaution.

Exclusions
The panel suggested that the following characteristics or conditions should disqualify patients from the use of medical cannabis to treat intractable pain:

- Patients under age 21 who are expected to live a normal life span
- Patients with current or past personal history of psychosis
- Patients who are pregnant or lactating

Patient reassessment
The advisory panel recommended that certifying providers should conduct periodic reassessments of pain and function that incorporate feedback from the patient, pain management teams, medical cannabis dispensary, and the patient's family and friends.

Definition of intractable pain
Panel members discussed components of the definition of intractable pain.[8] Topics of discussion included whether specific conditions for the use of medical cannabis should be identified or whether to limit eligible certifying providers to pain clinics. The panel ultimately decided not to add such limitations.

Research and state oversight
The panel recommended that certifying providers report to the MDH data on diagnoses and assessment of benefits and harms with use of medical cannabis for intractable pain, so that the MDH can conduct observational studies on the impact of medical cannabis for intractable pain.

Panel members further stated that providers should report to the state every six months on effectiveness and harm using a standardized data collection method. MDH should conduct a periodic review of progress, challenges, compliance with policy, and whether any specific groups are being excluded.

Additional recommendations

Support and provide for additional research
The panel recommended the following to address the need for additional clinical research. The need for additional research arose repeatedly during panel discussion, in addition to public comments and expert presentations:

- The federal government should move cannabis out of Schedule 1 in order to facilitate research on the benefits and harm of medical cannabis.
- The State of Minnesota and academic and other institutions should provide for controlled clinical trials of the effectiveness and safety of medical cannabis for treating pain and other conditions. In particular, the State of Minnesota should, to the greatest extent possible and for the highest possible standards for research:
    - Provide funding for research; and

[8] The current definition can be found at: http://www.health.state.mn.us/topics/cannabis/intractable/definition.html.

- Explore opportunities, especially in coordination with other states that allow medical cannabis, to recommend that the federal government reschedule cannabis, so there are fewer barriers to conducting research.

Provide a product according to standards that ensure uniformity and purity of its active ingredients to facilitate multi-center clinical studies The panel also identified potential topics for research, including:

- Effects of specific cannabinoids
- Effects of cannabidiol (CBD) versus tetrahydrocannabinol (THC)
- Contraindications for medical cannabis
- Drug interactions and the impact on effectiveness of other drugs when used with medical cannabis
- How cannabis is processed in the body and the different enzyme pathways through the liver
- Harm associated with medical cannabis in specific populations, such as pregnant women
- Consequences of sudden cessation of medical cannabis use, including withdrawal and its characteristics and treatment
- Long term effects of using medical cannabis to treat pain

Educate providers

Panel members noted that health care practitioners often have minimal training on pain management. They noted health care practitioners and other providers need more information about medical cannabis products, evidence of benefit and harm from using cannabis products to treat specific conditions, and strategies for responsible incorporation of medical cannabis into clinical practice. Additionally, the panel recommended providers should be informed about:

- Topics and components for research listed in the Support and Provide for Additional Research recommendation;
- What is currently known and unknown regarding medical cannabis;
- How to conduct screening for mental health issues and addiction; and
- The questions they need to ask when considering whether to certify a patient.

Adjust requirements for patient pain management, monitoring, and recertification

The advisory panel recommended narrower policies for monitoring and recertifying patients for medical cannabis. Those policies include:

- Including medical cannabis obtained through the program in the Minnesota Prescription Monitoring Program
- Requiring intractable pain patients to recertify and visit their certifying provider every six months[9] to ensure their compliance with their treatment plan
- Allowing certifying providers the ability to decertify a patient if they do not comply with their pain management regimen, including the dosage of medical cannabis and participating in other proven practices, like psychotherapy or physical therapy, as prescribed

[9]Patients using medical cannabis for other qualifying conditions are currently required to recertify annually.

- Requiring a holistic team approach to managing pain that involved interdisciplinary care providers, the patient, and the patient's family or support system to assess and monitor the patient

Appendix A

Use of Medical Cannabis for Intractable Pain

Panel Member Worksheet

DATE _____

Name (optional) _____

How would medical cannabis help in the treatment of intractable pain?

What concerns do you have about the use of medical cannabis for treating intractable pain?

What do you see as the key issues to medical cannabis use for intractable pain?

What insights helped formulate your opinion?

Should intractable pain be added to the list of qualifying conditions for the use of medical cannabis?

Yes _____ No _____

One key reason why. . .

What recommendations would you make on whether to add intractable pain to the list of qualifying conditions for the use of medical cannabis?