Minnesota Medical Cannabis Program Petition to Add a Qualifying Medical Condition

Making Your Petition

Any person may petition the Minnesota Department of Health ("the Department" or "MDH") to add a qualifying medical condition to those listed in subdivision 14 of Minnesota Statutes section 152.22. Petitions will be accepted only between June 1, 2022, and July 31, 2022. Petitions received outside of these dates will not be reviewed.

Use this online form to submit requested information.

Instructions

Complete each section of this petition and attach all supporting documents where noted in this form. Clearly indicate which section of the petition an attachment is for. You can save your submission as a PDF, which you can print or keep for your records. Each petition is limited to one proposed qualifying medical condition. If your petition includes more than one medical condition, it will be dismissed. If you are petitioning for the addition of a medical condition that was considered but not approved in a prior year's petition process, you must include new scientific evidence or research to support your petition or describe substantially different symptoms. The MDH website has the petitions for each petitioned medical condition reviewed in prior years. See Petitions to Add Qualifying Medical Conditions. Petitions that do not include new scientific evidence or research to support your petition or describe substantially different symptoms will not be considered. If the petition is accepted for consideration, MDH will send the petition documents to the Medical Cannabis Review Panel ("Review Panel"). MDH staff will also provide information to the Review Panel about the proposed qualifying condition, its prevalence, and the effectiveness of current treatments. You may withdraw your petition any time before the Review Panel's first public meeting of the year by submitting a written statement to MDH stating that you want to withdraw it.

Petition Review Process

An appointed citizens Review Panel will meet to review all eligible petitions and supporting documentation. MDH will post notice of the public meetings of the Review Panel on its medical cannabis website. After the public meeting and by Nov. 2, 2022, the Review Panel will provide the Commissioner of Health a written report of findings.

The Commissioner will approve or deny the petition by Dec. 1, 2022.

Section A: Petitioner's Information

This information has been redacted.

Section B: Medical Condition You Are Requesting Be Added

Please specify the name and provide a brief description of the proposed qualifying medical condition. Be as precise as possible in identifying the condition. Optional: Include diagnostic code(s), citing the associated ICD-9 or ICD- 10 code(s), if you know them.

Opioid Use Disorders

• Condition: Opioid Use Related Disorders ICD-10-CM F11-F11.99.

• Diagnostic Criteria:

o Opioids are taken in greater dosages and for longer periods than initially intended.

o Compulsive, continuous use.

o Patients spend a significant amount of time attempting to obtain opioids, use opioids, or recover from the effects.

o Craving or strong desire to use opioids.

o Recurrent opioid use negatively affecting social and professional lives.

O Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids

o Opioid use during potentially physically hazardous situations.

o Recurrent opioid use even if the opioids are causing or exacerbating physical or psychological complications.

o Tolerance is defined as: a need for increased amounts of opioids to induce intoxication or desired affects, or a marked diminished affect with the same continuous dosage.

o Withdrawal defined as: opioid withdrawal syndrome or opioids are taken to relieve or to avoid withdrawal symptoms (unless, under medical supervision).

Section C: Symptoms of the Proposed Medical Condition and/or Its Treatment

Describe the extent to which the proposed qualifying medical condition or the treatments cause suffering and impair a person's daily life.

• Symptoms of Opioid Use Disorders include:

Constipation, Nausea, Feeling High, Slowed breathing rate, Drowsiness, Confusion, Poor Coordination, Increased dose required for pain relief, Worsening or increased sensitivity to pain with higher doses, Stealing/forging or selling prescriptions, Taking higher doses than prescribed, Excessive mood swings or hostility, Seeking prescriptions from more than one doctor, Low blood pressure, Potential for breathing to stop, Coma, Overdose has a significant risk of death.

Treatments

• Methadone side effects include: constipation, dizziness, drowsiness, nausea or vomiting, impaired cognition or confusion, forgetfulness, impaired balance or coordination. It is much easier to overdose on methadone than other opioid drugs.

• For buprenorphine patients report severe headaches, stomach issues, constipation, trouble sleeping, back pain, and vision issues. In addition, Buprenorphine use comes with the continued risk of misuse and overdose.

• For naltrexone, patients report dizziness, nausea, headaches, anxiety, fatigue, and trouble sleeping.

Section D: Availability of Conventional Medical Therapies

Describe conventional medical therapies available and the degree to which they ease the suffering caused by the proposed qualifying medical condition or its treatment.

Medication-assisted Treatment (MAT): Use of medications in combination with counseling and behavioral therapies to provide a "whole patient" approach to treating substance use disorders.

Ultimate goal is full Recovery including the ability to live self-directed life

MAT has been clinically proven to significantly reduce need for patient detox services (SAMHSA, 2022)

Opioid dependency medications include Buprenorphine, methadone, and naltrexone, these are safe to use for months, years, or even a lifetime.

Naloxone is used to prevent opioid overdose by reversing the toxic effects.

Medications to assist in withdrawal: clonidine, buprenorphine, suboxone, or methadone may be used by physicians, under legally regulated conditions to ease symptoms of withdrawal from opioids.

Vivitrol can be given as an injection, monthly, by a healthcare provider, which may assist patients in staying off opioids early in recovery.

Long-acting opioids such as methadone or buprenorphine and gradually decreasing the dose, help the body adjust, preventing withdrawal.

Anxiety and insomnia are treated with benzodiazepines or other drugs for sedation. Clonidine or tizanidine can be used to decrease signs of autonomic overactivity, such as anxiety or piloerection caused by withdrawal.

Diarrhea, nausea, and vomiting are treated with loperamide, prochlorperazine, or both, along with electrolyte drinks and intravenous fluids.

Section E: Anticipated Benefits from Medical Cannabis

Describe the anticipated benefits from the medical use of cannabis specific to the proposed qualifying medical condition.

Symptom Relief: Medicinal cannabis may reduce the use of highly addictive opioids in Minnesota, while addressing side effects and symptoms of other medication and medical conditions that patients with Opioid Use Disorder. Utilizing cannabinoids within the endocannabinoid system shows promise in assisting with addiction cessation through symptom improvement. Cannabis has been reported to be beneficial in improving generalized pain, muscle cramps, anxiety, nausea, vomiting, and insomnia.

Reductions in opioid use: An article published in JAMA in 2018 concluded medical cannabis laws are associated with significant reductions in opioid prescribing in the Medicare Part D population (Bradford, 2018).

Reduced Hospitalizations: May lead to a reduced number of hospitalizations caused by opioid overdoses, dependence, and withdrawal symptoms.

Expanded Treatment Accessibility: Provides patients suffering from opioid dependence with a treatment option that is more widely available than medication assisted treatment or in-patient rehabilitation.

Section F (optional): Scientific Evidence of Support for Medical Cannabis Treatment

Strengthen your petition by including evidence generally accepted by the medical community and other experts supporting the use of medical cannabis to alleviate suffering caused by the proposed medical disease or its treatment. Please include citations and links (if available) to peer-reviewed published journals or other completed medical studies.

Bisaga A, Sullivan MA, Glass A, Mishlen K, Pavlicova M, Haney M, Raby WN, Levin FR, Carpenter KM, Mariani JJ, Nunes EV. The effects of dronabinol during detoxification and the initiation of treatment with extended release naltrexone. Drug Alcohol Depend. 2015 Sep 1;154:38-45. doi: 10.1016/j.drugalcdep.2015.05.013. Epub 2015 Jul 8. PMID: 26187456; PMCID: PMC4536087.

In this study investigators used a randomized controlled trial to investigate the effects of dronabinol during detox. They found she severity of opioid withdrawal during inpatient phase was lower in the dronabinol group relative to placebo group. In addition to relieving withdrawal symptoms investigators also concluded participants who elected to smoke marijuana during the trial were more likely to complete treatment regardless of treatment group assignment.

Beth Wiese and Adrianne R. Wilson-Poe.Emerging Evidence for Cannabis' Role in Opioid Use Disorder.Cannabis and Cannabinoid Research.Dec 2018.179-189. http://doi.org/10.1089/can.2018.0022

FDA-approved opioid replacement therapies and maintenance medications used to ease the severity of opioid withdrawal symptoms and aid in relapse prevention, these medications are not risk free nor are they successful for all patients. To fill the gap between efficacious OUD treatments and the widespread prevalence of misuse, relapse, and overdose, the development of novel, alternative, or adjunct OUD treatment therapies is highly warranted. After reviewing available evidence the concluded the compelling nature of thedata and the relative safety profile of cannabis warrant further exploration of cannabis as an adjunct or alternative treatment for OUD.

Reiman, A., Welty, M., & Solomon, P. (2017). Cannabis as a Substitute for Opioid-Based Pain Medication: Patient Self-Report. Cannabis and Cannabinoid Research,2(1), 160-166. doi: 10.1089/can.2017.0012

A survey sample size of 2897 participants where 81% of respondents stated they ''strongly agreed/agreed'' taking cannabis by itself was more effective at treating their condition than taking cannabis with opioids. Leading investigators to conclude, cannabis may be a viable option for medication assisted treatment for OUD.

Powell, D., Pacula, R. L., & Jacobson, M. (2015). Do Medical Marijuana Laws Reduce Addictions and Deaths Related to Pain Killers? doi: 10.3386/w21345

The research found that states with greater accessibility displayed a significant decrease (averaging 18.5%) in individuals seeking treatment for opiate misuse and addiction.

Lucas, P., & Walsh, Z. (2017). Medical cannabis access, use, and substitution for prescription opioids and other substances: A survey of authorized medical cannabis patients. International Journal of Drug Policy,42, 30-35. doi: 10.1016/j.drugpo.2017.01.011

Researchers surveyed Canadian medical cannabis patients to determine usage trends, issues of accessibility, and impacts, surrounding the issue of medication substitution. The researchers found that 63% of patients served by Canadian cannabis company Tilray use cannabis as a substitute for traditional pharmaceutical medications. Of the 63% of patients, 32% substituted cannabis for opioids, 16% for benzodiazepines, and 12% for antidepressants. The most common reason for medication substitution cited in the survey was "less adverse side effects". Respondents report that medical cannabis is incredibly effective at symptom relief, especially around pain-related conditions, with 95% reporting that medical cannabis "often" or "always" relieves their symptoms.

Bradford, A. C., & Bradford, W. D. (2016). Medical Marijuana Laws Reduce Prescription Medication Use In Medicare Part D. Health Affairs, 35(7), 1230-1236. doi: 10.1377/hlthaff.2015.1661

This research found the most significant reduction in the number of daily doses for FDA approved medications for pain management (primarily, opiate-based painkillers), with an average reduction of 1,826 daily doses prescribed per physician annually in states with medical marijuana laws. Researchers also found a significant reduction in prescriptions for treating anxiety, nausea, psychosis, and seizures, modest reductions in prescriptions for treating

depression and sleep disorders, and insignificant impacts on prescriptions for glaucoma and spasticity.

Reiman, A., Welty, M., & Solomon, P. (2017). Cannabis as a Substitute for Opioid-Based Pain Medication: Patient Self-Report. Cannabis and Cannabinoid Research,2(1), 160-166. doi: 10.1089/can.2017.0012

Due to telling results where 97% of patients taking opioids, stated they were able to decrease opioid usage while using cannabis. This study concluded future research should track clinical outcomes where cannabis is offered as a viable substitute for pain treatment and examine the outcomes of using cannabis as a medication assisted treatment for opioid dependence.

Livingston, M. D., Barnett, T. E., Delcher, C., & Wagenaar, AC. (2017). Recreational Cannabis Legalization and Opioid-Related Deaths in Colorado, 2000-2015. American Journal of Public Health, 107(11), 1827-1829. doi: 10.2105/ajph.2017.304059

After analyzing opioid deaths between 2000-2015, the investigators concluded legalization of cannabis in Colorado was associated with short-term reductions in opioid-related deaths.

Section G (optional): Letters in Support of Adding the Medical Condition

Upload letters of support for the use of medical cannabis from persons knowledgeable about the proposed qualifying medical condition, such as a licensed health care professional. (Please combine letters of support into one file before you upload.)

Attached at the end of this document.

Section H: Acknowledgment and Signature

Please note: Any individually identifiable health information relating to any past, present, or future health condition or health care contained in this petition is classified as a health record under Minnesota Statutes §144.291, and is not subject to public disclosure.

I certify that the information provided in this petition is true and accurate to the best of my knowledge.

This information has been redacted. (Submitted 07/31/2022)

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sensible changemn

Sensible policies, safer communities.

Commissioner Jan Malcolm
Minnesota Department of Health
Office of Medical Cannabis

Dear Commissioner:

We provide this letter in support of the petitions for the addition of Anxiety and Opioid Use Disorder (OUD) as qualifying conditions.

The Sensible Minnesota and Sensible Change Minnesota teams have worked extensively at chipping away at the restrictive nature of the medical cannabis program that was first passed by the Minnesota legislature in 2014. The original law was a travesty for patient access, but our teams have worked to expand the program to include Post-Traumatic Stress Disorder (2016), Autism Spectrum Disorder (2017), Alzheimer's Disease (2018), and Chronic Pain (2019) as qualifying conditions, worked on legislative expansion – including three years building support for smokable flower, and adding GI and oral dissolving edibles as allowable delivery methods.

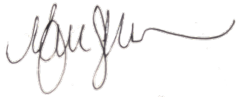
Our work accounts for nearly 100% of currently registered medical cannabis patients based on the June 2022 program data.

Previously, we have petitioned for the addition of Opioid Use Disorder and Anxiety as qualifying conditions – and continue to support their addition to the program. While these patients may find themselves qualified with other conditions, we regularly field inquiries from patients who do not qualify based on existing conditions – but would qualify should anxiety (especially) and OUD be added as qualifying conditions. We strongly believe Minnesota should begin leading with its medical cannabis program – especially considering its research component – and one way of doing that is to collect data on these conditions that have a scientific rationale for efficacy in treatment.

Additionally, the legal protections afforded to medical cannabis patients are crucial to keeping people out of the criminal justice system, employed, and in their homes. Without the protection of the medical cannabis program, those who are self-medicating for these conditions face interactions with police, arrest, eviction, and job loss.

We owe it to our fellow Minnesotans to add Anxiety and OUD as qualifying conditions in Minnesota and urge you to do so this year.

Respectfully,



Maren Schroeder
Policy Director, Sensible Change Minnesota

Vireo

July 28, 2022

To: Minnesota Department of Health
Office of Medical Cannabis
P.O. Box 64882
St. Paul, MN 55164-0882

I am a board-certified practicing family physician, the Chief Medical Officer of Vireo Health of Minnesota, and I have been involved directly in the Minnesota Cannabis Program for nearly seven years supporting education, research, and pharmacovigilance.

My decision to dedicate a portion of my career to medical cannabis was due to the strong potential I saw in this plant to support health via the Endocannabinoid System coupled with the obvious need for harm reduction related to rampant illicit market use of questionable products and no medical guidance.

The Minnesota Medical Program offers a trusted approach to oversight and administration of this complex plant. This patient-centric program has, for seven years, proudly offered quality third-party tested products dispensed under the guidance of licensed pharmacists with oversight from a patient's healthcare team and transparency on consumption coupled with pharmacovigilance monitoring to further support safety.

Last year I had the honor of participating in the work group assembled to assess anxiety as a potential qualifying condition. I attempted to showcase the existing literature and harm reduction approach that a strong, patient-centric medical program offers for those both using and exploring cannabis as a therapeutic modality. I listened carefully to the thoughtful and appropriate criticisms from colleagues concerned about the lack of data and potential for harm.

I am even more vocal this year with the recent allowance of intoxicating edibles in Minnesota. Imagine a world where anti-depressants and anxiolytics were offered in the corner store yet withheld from physicians. Calling for more evidence before decision making only pushes our patients more to unbridled access, without medical guidance, of

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the same substances criticized in the past for their lack of research and potential for harm.

I support the addition of anxiety and opioid use disorder to the list of qualifying conditions. I have witnessed first-hand with our own patients the positive impact of medical cannabis on these conditions. I have also successfully advocated in the past for eligible health professionals to certify patients for *any condition* where their own professional discretion determines that benefits outweigh risks for any individual patient. This is current standard practice for other pharmaceuticals.

Now more than ever, adjunct therapies are needed to address the issues and challenges facing society, specifically those triggered by the COVID-19 pandemic. Overdose deaths from benzodiazapines, a class of drugs FDA approved for treatment of various anxiety disorders, rose again to 12,290 in 2020. Allow the medical program a path to utilize medical cannabis for these conditions and the benefits afforded by that path – quality, tested products dispensed under the guidance of medical health professionals trained and knowledgeable in guiding patients towards best practice use specific to their own nuanced medical history. This path is imperative to the many Minnesotans looking to minimize harm while exploring medical cannabis as an option for their own health.

I appreciate the opportunity to express my opinion on the matter.

Sincerely,

Stephen Dahmer, MD
Chief Medical Officer, Vireo Health
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Vireo

goodness growth holdings

The Power of Plants

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