

MN Office of Medical Cannabis Petition Process

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PROTECTING, MAINTAINING AND IMPROVING THE HEALTH OF ALL MINNESOTANS

Objectives

- Briefly explain the Minnesota Medical Cannabis Program
- Detail the Petition Process
- Review Lessons Learned
- PTSD findings
- Q & A

MN Milestones

Legislation for Medical Program May 2014

Medical cannabis legislation was signed into law in Minnesota on May 29, 2014.

Program launch

Medical cannabis products became available for patients on the state's Medical Cannabis Registry on July 1, 2015.

Patient enrollment

2016: less than 1,000 patients

2023: 40,000 patients

Legislation for Adult Recreational Use May 2023

Currently legal to possess; home grow up to 8 plants; Tribal Nations can sell at their own dispensaries; State-regulated dispensaries in 2025

Qualifying Medical Conditions

Cancer or its treatment, with severe or chronic pain, or severe nausea, or severe wasting

Glaucoma

HIV/AIDS

Tourette Syndrome

Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's Disease)

Seizures, including those characteristic of epilepsy

Severe and persistent muscle spasms, including those characteristic of multiple sclerosis

Inflammatory Bowel Disease, including Crohn's Disease

Terminal Illness with life-expectancy < 1 year - with severe or chronic pain, or severe nausea, or severe wasting)

Intractable Pain (2016)

PTSD (2017)

Autism (2018)

Obstructive Sleep Apnea (2018)

Alzheimer's Disease (2019)

Chronic Pain (2020)

Sickle Cell Disease (2021)

Vocal or Motor Tic Disorder (2021)

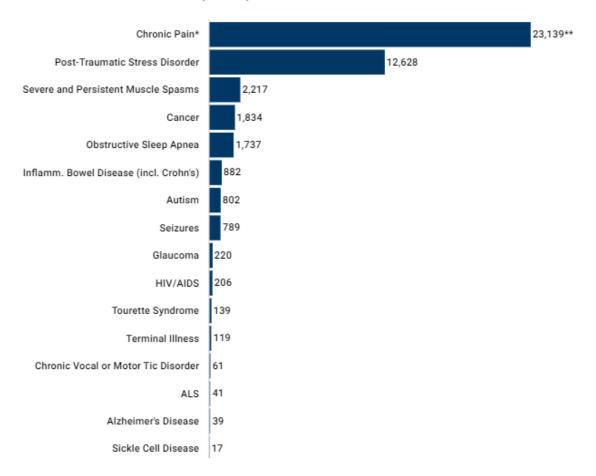
Obsessive-Compulsive Disorder (Aug 1, 2023)

Irritable Bowel Syndrome (Aug 1, 2023)

Medical Cannabis Program

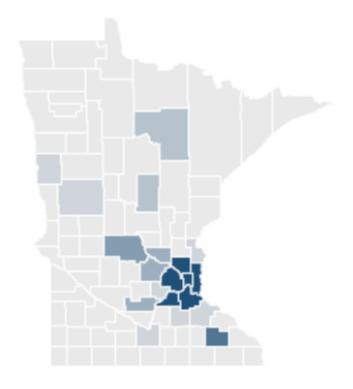
QUALIFYING MEDICAL CONDITIONS

The top two qualifying medical conditions are chronic pain (59.3%) and post-traumatic stress disorder (32.3%).



WHERE OUR PATIENTS LIVE

All Minnesota counties are represented in the program, with the majority of enrolled patients (50.0%) living in the seven-county Twin Cities metropolitan area.



Download data

Any county with a count of 0 represents a county with fewer than 17 patients. N=40,345. Data updated quarterly. Last updated March 31, 2023.

Minnesota Program Details

- Previously only extracted products, including liquids and oils in capsule/tablet, topical, tincture, vaporized form, lozenge, or watersoluble particulates
 - Added dried raw cannabis (combustible flower) March 2022
 - Added gummies August 2022
- Pharmacist dispensing consultation required for dosage and product recommendation
- Limited to two vertically-integrated manufacturers
 - Cultivation -> production -> distribution supply chain
 - Requires pharmacist dispensing
- Commitment to learning from experience with the program
 - Reports and observational studies on effectiveness, side effects, etc.



Health Care Practitioners - who can act

Minnesota-licensed doctor of medicine.

•Minnesota-licensed physician assistant acting within the scope of an authorized practice.

•Minnesota-licensed advanced practice registered nurse who has the primary responsibility for the care and treatment of the qualifying medical condition of a person diagnosed with a qualifying condition.

Health Care Practitioners - Duties

- Participation is voluntary
- Certify diagnosis
- Initial certification can be via tele-medicine as of August 1, 2023
- Agree to provide ongoing treatment
- Allow MDH access to health records upon request
- Recertify patients annually

Annual Petition Process

The Minnesota Department of Health accepts petitions from the public every year from June 1 through July 31 to add:

A qualifying medical condition

A delivery method (the form in which a medication is taken).

Review Panel

Legislation enacted 2016

- The Health 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.
- Seven members including: one medical cannabis patient advocate; one health care practitioner; one pediatric health care practitioner; and four at-large members.
- Members serve a three-year term or until a successor is appointed and qualified, and members can serve more than one term.

Electronic Petition Form

- 1. Medical condition to be added
- 2. Symptoms of the condition and its treatment
- 3. Availability of conventional medical therapies
- 4. Anticipated benefits
- 5. Scientific evidence of support (optional)

Issue Briefs

Research Unit writes up Issue Briefs

- Primary focus is on clinical trials and observational studies
- Also pre-clinical studies (typically laboratory and animal model studies)
- Interpretation of surveys published in peer-reviewed journals. This is usually difficult because it is unclear whether responders represent the population of interest and because of unknown validity of responses
- Recommendations or opinions of national organizations / medical organizations will be included, if found

Petition Review Process

- Gather requests and post Notice of Public Meeting and Comment
- Review Panel meets to review all eligible petitions and supporting documentation
- Provide the Commissioner of Health a written report of findings
- Commissioner will approve or deny the petition by December 1
- Approved conditions/delivery methods go into effect August of the following year
- NOTE: Legislative Session January-May can provide "input"

Lessons Learned

- As more conditions were added, annual Petitions are too often
- Composition of Panel is important
 - Impartial medical knowledge, including mental health, pharmacy
 - Patients in the program (or caregivers) were important participants
- Include guidance for if/when same conditions can be repetitioned

Anxiety Disorder Work Group

- Physicians
- Mental Health Professionals (physicians, therapists, drug counselors)
- University of Minnesota (M.D., Pharmacy)
- Office of Medical Cannabis Staff
- Manufacturer Chief Medical Officers (Vireo, Leafline Labs)

3 Anxiety Disorder Work Group Meetings

Anxiety Review

Program Background and Statistics

Manufacturer's Experience

Experience of Other States

Current state of anxiety and cannabis research

Decision: Anxiety NOT accepted as a new qualifying condition*.

*PTSD and OCD are qualifying conditions.

PTSD Report Background

- 751 patients enrolled in the program with PTSD between August 1 December 31, 2017.
- PTSD Checklist for DSM-5 (PCL-5): At enrollment and in patient surveys, patients complete a 20-item self-report symptom measure.
- Primary cause of PTSD
 - 71% was non-military in nature
 - 13% military
 - 6% both military and non-military
 - 10% preferred not to answer
- Each patient's medical cannabis purchasing transactions during their first enrollment year were analyzed. A total of 15,538 products were purchased through 9,529 transactions.
- Products for inhalation (vaporized oil) accounted for 71% of products purchased
- THC:CBD ratios for (all) products purchased:
 - 55% of products were Very High THC:CBD ratio
 - 9% High THC:CBD
 - 27% were balanced products
 - 9% High CBD:THC
 - <1% Very High CBD:THC



PTSD Report Findings

- At enrollment, 96% of patients scored above 33 points (cut-point for provisional PTSD diagnosis)
- Comparing PCL-5 score at enrollment and at 3 months: Clinically meaningful difference in PCL-5 scores measured at different times amounts to a difference of 10-20 points. Between 50% and 71% (depending on whether a reduction of 20 points or 10 points is used) of respondents saw a clinically meaningful improvement in PTSD symptoms
- Change in PCL-5 score appeared to be similar across groups based on primary cause of PTSD
- Patient Survey: How much benefit have you received from using medical cannabis on a scale from 1 (no benefit) to 7 (great deal of benefit)
 - 76% indicated a benefit rating of 6 or 7
 - Most important benefit: 23% indicated anxiety reduction, 16% improved sleep, 13% improved mood and/or emotional regulation, and 12% pain reduction

PTSD Report Findings, cont.

The most common adverse effects were mild-moderate

- dry mouth,
- increased appetite,
- anxiety, drowsiness, and fatigue.

No serious adverse events (life threatening or requiring hospitalization)

Quotes from Patients

"Fewer periods of dissociation due to increased mindfulness, being able to tolerate processing trauma in therapy without dissociating, improved sleep, improved transition from sleeping to wakefulness, decreased body pain, eating more, not isolating from friends and family as much, being able to tend to my house more."

Quotes from Patients

"Controlled doses. I used cannabis before this program in such an uncontrolled dosage that it affected my other medications. The control of the cartridge has been extremely helpful."

Quotes from Patients

"Since starting medical cannabis it's like I've been given a fair chance to treat my PTSD symptoms I've struggled with over a decade now. My family sees a night and day difference and it's easier to communicate with them. I've since found a part-time job with flexible hours to work around starting college in January, 2018. The only hope I have is that it becomes more affordable as I'm barely able to afford it now."

Websites

Post-Traumatic Stress Disorder Patients
 in the Minnesota Medical Cannabis
 Program - MN Dept. of Health
 (state.mn.us)

 Medical Cannabis - MN Dept. of Health (state.mn.us)





Questions & Discussion

https://www.health.state.mn.us/speakerrequest

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