

MEDICAL CANNABIS

Six years in, Minnesota's program is growing and changing

BY LINDA PICONE

Minnesota's medical cannabis program started just a little more than six years ago and has grown, as expected, in the number of qualifying medical conditions covered, the number of patients registered, the number of healthcare providers participating and the number of medical cannabis units sold and product sales made by the state's two authorized manufacturers.

It also has grown in terms of the knowledge base about medical cannabis.

"We continue to be one of the only states in the nation collecting patient experience data," says Chris Tholkes, MA, director of the Office of Medical Cannabis. "What we're learning from the data is that patients are seeing tremendous benefit from participating in the program. We hear story after story about not just a reduction in symptoms but being able to get off other medications."

The Office of Medical Cannabis has commissioned and performed several studies on use of medical cannabis for specific conditions—and will do more in the future. "There have been so many restrictions on cannabis research (because marijuana/cannabis is still a Schedule I illegal drug under federal law). I really have a great love for what we can contribute to research," says Tholkes.

Upcoming changes in Minnesota's medical cannabis program

Although the Minnesota Legislature did not legalize recreational marijuana in the 2021 session (the House passed a bill, but it was not taken up by the Senate), it did make several significant changes to the medical cannabis program.

The biggest change allows medical cannabis patients who are 21 or older to access medical cannabis flower—which means smokable cannabis. Currently, Minnesota is one of only a few states with medical cannabis access that prohibits use of flower products. Medical cannabis flower products will be allowed once policy is developed by the Minnesota Department of Health's Office of Medical Cannabis, no later than March 1, 2022.

With smokable products, Tholkes says, there likely will be a reduction in cost to the patient—and cost of the current products is a complaint of many in the program and likely keeps others who could benefit out of the program.

"Other states have seen a reduction in costs with smokable cannabis," Tholkes says. "The biggest cost now is that the manufacturers have to extract the oil, so smokable should in theory be less expensive."

The regulations for smokable cannabis will be designed to make sure that the

product is stable and consistent in dosage, as are the non-smokable products.

Recreational cannabis would be "a whole different ballgame," Tholkes says. "Most other states have seen a decline in the medical side when they go to recreational, but lots of folks, I think, would continue in the medical program. People really value that conversation with pharmacists and there is some comfort in knowing how it is processed."

Other 2021 legislative changes to the medical cannabis program:

- Allow curbside pickup of medical cannabis products.
- Allow a single designated caregiver to pick up medical cannabis products for up to six registered patients (it has been restricted to one).
- Make it possible for the Commissioner of MDH to remove a health condition from the list of those qualified for medical cannabis, after receiving a petition from the public or a task force. Until now, the Commissioner has only been able to add or modify conditions.
- Allow pharmacist-patient consultations by phone or other remote means, in addition to videoconference.
- Remove the requirement for a pharmacist-patient consultation when there is no change in dosage or product.
- Remove the requirement that a healthcare practitioner determine whether a

patient is disabled and needs caregiver assistance with medical cannabis because of that disability.

The curbside visit and telephone consultation came about through executive order during the pandemic shut-down, says Tholkes

Medical cannabis numbers

The Office of Medical Cannabis posts updated registration data on its site <https://www.health.state.mn.us/people/cannabis/about/medicalcannabisstats.html> on Fridays.

The cumulative statistics from the beginning of the program on June 1, 2015 through August 5, 2021 are:

- 1,946 healthcare practitioners registered and authorized to certify patients for medical cannabis.
- 50,482 patients who were approved for medical cannabis (since the program started).
- 23,772 patients currently active in the medical cannabis registry.

- 1,130 patient caregivers who have received background checks and are approved.

The price of medical cannabis

Prices of most medical cannabis products dropped by 20–24 percent from 2016 to 2019. For example: 120 ml Heather oral suspension, cherry vanilla flavor, sold by LeafLine, cost \$207 in October 2016 and \$158.28 in December 2019 (and today).

The average 30-day “spend” for a patient with one qualifying condition was \$355 in 2016 and \$311 in 2019. In 2019, the average ranged from \$189 for a person with terminal illness to \$364 for someone with seizures.

In 2019, 10,755 patients with intractable pain spent an average of \$314 every 30 days on medical cannabis products. The next largest group was 3,008 with PTSD, who spent an average of \$320. Some 1,223 patients with cancer spent an average of \$236.

The number of units sold by both medical cannabis manufacturers went from 17,691 in the fourth quarter of 2016 to

113,832 in the fourth quarter of 2019, with net sales of \$1.6 million in the last quarter of 2016 to \$7.2 million in the last quarter of 2019—an increase of \$5.6 million or 350 percent.

By the end of 2019, Minnesota’s authorized medical cannabis dispensary companies, LeafLine and Green Goods, had sold:

- 503,980 vape oil units at a total of \$37.8 million.
- 174,981 oral suspension units at a total of \$16.8 million.
- 177,978 capsule units at a total of \$8.2 million.
- 26,376 topical units at a total of \$1.2 million.

Report on Medical Cannabis Price Study May 2020 by BerryDunn of Portland, Maine, for Minnesota Department of Health, Office of Medical Cannabis

Medical cannabis and PTSD

Post-traumatic stress disorder (PTSD) was added to the list of qualifying conditions

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for medical cannabis effective August 1, 2017.

In the first year after PTSD was added, 15,538 products were purchased by those who were certified because they had a PTSD diagnosis as a qualifying condition.

Patients who responded to a survey about their use of medical cannabis ranked the benefit they felt they had received from 1 (no benefit) to 7 (great deal of benefit); 76 percent of responding patients rated benefit 6 or 7, 4 percent rated benefit 1, 2 or 3.

The most important benefits, patients said, were anxiety reduction (23 percent), improved sleep (16 percent), improved mood and/or emotional regulation (13 percent) and pain reduction (12 percent).

Comments from patients who responded included:

- *"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."*
- *"Sleeping has been AMAZING, pain is way down, not helping my anxiety as much as I would like, but nothing is perfect."*
- *"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."*
- *"Being able to go to work with less anxiety and feeling like I can function. No more night terrors and screaming in my sleep."*
- *"Feeling less anxious and having to deal with less chronic pain has overall improved my quality of life a great deal. I have more moments of happiness and it's opened up many doors to me that I have had shut for a long time."*

- *"Better sleep, better appetite, I'm not so angry all the time. My memories don't seem to bother me like they used to. This has been a life changer for me!"*
- *"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."*

About 25 percent of the patients who responded reported physical or mental side effects related to medical cannabis use. The most common adverse side effects were dry mouth, increased appetite, anxiety, drowsiness and fatigue. No serious adverse events were reported during the observation period.

Post-Traumatic Stress Disorder Patients in the Minnesota Medical Cannabis Program: Experiences of Enrollees During the First Five Months July 2019, report of the Minnesota Department of Health, Office of Medical Cannabis

Medical cannabis and intractable pain

From August 1, 2016 through December 31, 2016, 2,290 patients were enrolled under the qualifying condition of intractable pain (45 of them were already enrolled for another condition).

According to the Patient Self-Evaluation (PSE) completed by patients prior to each medical cannabis purchase, from patient and healthcare practitioner surveys and from pain scale information at certification, about half of those certified for intractable pain saw a high degree of benefit from medical cannabis (61 percent of patients who responded and 43 percent of healthcare practitioners) or a score of 6 or 7 on a seven-point scale. About 10 percent of patients and 24 percent of healthcare

practitioners said medical cannabis was of little or no benefit (score of 1, 2 or 3).

The most-mentioned benefits included reduction in pain severity (64 percent) and improved sleep (27 percent). Patient comments included:

- *"This program has opened up a world for me I thought I lost. I started on this just a few short months ago and am totally off my narco's and nictin. I also have had less spasms and cramping throughout my body. I even chanced getting on a motorcycle and going for a short ride with a friend before it snowed. Thought never do that again. It has also helped me gain weight. And silence some demons in my head from my PTSD. So, thank you. Now all I ask is make it affordable to stay on."*
- *"At first, when I began using the medical cannabis for pain, I Definitely noticed a Drastic Relief in my pain levels - that was So Wonderful - I was So Hopeful. Then, unfortunately, after the first week of using the cannabis regularly, the efficacy for the pain relief I had been receiving began to steadily wane..., to the point of no noticeable pain relief at all within a 6 to 8 week period - even though I carefully "upped" the dosage and the frequency of dosing, etc... I'm so disheartened..., but I know others with the same type of pain that I have that are experiencing and sustaining far better pain relief."*
- *"Medical cannabis has not made a difference for me. I have never used it before and was a little hesitant to try. When I did I found that I had no relief of pain and I didn't like the way I felt so I discontinued use."*
- *"Reduction in migraine occurrence and severity, improved sleep, less overall muscle aching and cramping, pain relief from arthritic joints, reduction in GI reflux which also aids sleep."*
- *"I have fibromyalgia. I lived my life in constant pain my daily pain on an average was an 8. I started taking medical cannabis in August. I now have a daily pain average between 2 and 3. After 2 weeks of cannabis I cooked my first meal in 15 years. My husband was doing all of the cooking and housework I am now able to help with it."*

Nearly 60 percent said they were able to reduce their use of other pain medications while on medical cannabis.

The most common adverse side effects were dry mouth, drowsiness, fatigue and

mental clouding/“foggy brain.” About 35-40 percent reported experiencing at least one mental or physical adverse effect, with about 90 percent saying the adverse effect was mild to moderate in severity. No

serious adverse events were reported during the observation period. **MM**

Intractable Pain Patients in the Minnesota Medical Cannabis Program: Experience of Enrollees During the First Five Months, report of the Minnesota Department of Health, Office of Medical Cannabis

Medical cannabis for **ANXIETY DISORDER?**

Physician working group takes a closer look

BY ANDY STEINER

Nearly every year since medical cannabis was legalized in Minnesota, the Minnesota Department of Health’s Office of Medical Cannabis has received petitions requesting that anxiety disorder be included in the list of conditions eligible to be certified for medical cannabis treatment. Every year the petitions have been rejected.

This year, in what may be a small step toward certification, a working group of physicians and other mental health and addiction professionals were recruited by the office to discuss medical cannabis and its efficacy in the treatment of anxiety disorders. (MDH is accepting public written comments on medical cannabis and anxiety disorders through October 1. Send comments to health.cannabis.addmedicalcondition@state.mn.us.)

Chris Tholkes, MA, director of the Office of Medical Cannabis, explained that the group of seven, which included five physicians in a range of specialties, met this spring in three two-hour-long virtual sessions.

While her department is well aware of the level of public interest in adding anxiety to the list of qualifying conditions, Tholkes says she and her colleagues are

also aware of valid concern that’s been expressed by members of the state’s medical community.

“There’s obviously tremendous interest in adding this condition,” Tholkes says. “It didn’t feel fair to ask people to just keep submitting petitions every year. We felt like we weren’t elevating the discussion with the passive approach we were taking. We weren’t hearing from the medical community.”

The relative silence from physicians needed to be addressed, Tholkes says: The petitions of support felt troublingly uneven, with laypeople clearly on the side of certification and physicians uncharacteristically reluctant to weigh in on the issue.

“We got hundreds of letters from individuals,” Tholkes says. “We got one letter from a psychiatrist who raised some very valid concerns about the use of cannabis in treating anxiety.” Minnesota’s medical cannabis system requires a physician, physician assistant or advanced practice registered nurse to certify a patient for treatment, she explains, and because of this fact, staff wanted to fully address this concern and further test the waters with members of the medical community before diving in.

The work group was her office’s attempt at getting a better sense of where physicians stood on the issue, Tholkes says: “Support was there from patients or regular people in our program or people who want to be patients in our program.” After much review and consideration, she adds, “Where we landed was, ‘It feels like we have to go back out and try to do a deeper engagement with the medical community.’”

Recruiting a diverse group of physicians to take a deeper look at the issues felt like an important step. Because a warning flag had been raised about the safety of cannabis in treating anxiety, Tholkes and her colleagues believed it was important to measure physicians’ collective pulse: Minnesota’s medical cannabis program can’t work without physician support.

“We think it is important to engage the medical community on these issues,” she says. “We want the guard rails up. We want medical input on these decisions.”

A diversity of opinion

To assemble members of the working group, Tholkes and her staff set out to find a group of physicians who represented a range of backgrounds, opinions and experience treating patients with anxiety—as well as physicians who’ve worked with patients who self-medicate for anxiety with cannabis.

To assemble a list of possible working group members, Tholkes and her staff started with a blank slate. “We did a ton of outreach,” she says. “We brainstormed. We did internet research on who is working in this space. We reached out to the

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