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Minnesota Medical Cannabis Program: Patient Experiences from the First Program Year Executive Summary

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Minnesota Department of Health
Office of Medical Cannabis
St. Paul, MN
(phone) 651-201-5598
health.cannabis@state.mn.us

Executive Summary

In May 2014, Minnesota became the 22nd state to create a medical cannabis program. Distribution of extracted cannabis products in liquid or oil form to qualified, enrolled patients began July 1, 2015. Minnesota's medical cannabis program is distinct from those in nearly all other states as the Minnesota Department of Health's Office of Medical Cannabis is required to study and learn from the experience of participants. This report draws on data from enrollment, purchasing and related health information, and survey results to describe the experience of patients who enrolled during the first year of the program's operation: July 1, 2015 through June 30, 2016.

The Office of Medical Cannabis anticipates performing additional analyses of data for the first year cohort of enrolled patients, as well as initiating analyses of data from patients who enrolled in the program later. Of particular interest are patients who enrolled after intractable pain became a qualifying condition on August 1, 2016. A report is planned for the end of 2017 that will give a preliminary look at the experience of the first several hundred patients certified for intractable pain. It is possible that focused projects will be developed in the future that will draw on medical record information to answer specific questions raised by analyses of the kinds of program data described in this report.

Participation

Between July 1, 2015 and June 30, 2016 a total of 1660 patients enrolled in the program and 577 health care practitioners registered themselves in order to certify that patients have a medical condition that qualifies them for the program. The most common qualifying conditions were severe and persistent muscle spasms (43%), cancer (28%), and seizures (20%). Each of the remaining six qualifying conditions during the first year – Crohn's Disease, Terminal illness, HIV/AIDS, Tourette Syndrome, glaucoma, and ALS – accounted for less than 10% of patients. Ten percent (167 patients) were certified for more than one qualifying condition. Most patients were middle-aged (56% between ages 36-64), 11% were <18, and 11% were ≥65. Distribution by race/ethnicity generally matched the state's demographics, with 90% of patients describing themselves as white.

The legislation that established the program specified there would be one location for purchasing medical cannabis (called Cannabis Patient Centers; CPCs) in each of the state's eight congressional districts. Patients who enrolled in the program during the first year came from throughout the state, with the average distance from the patient's home to the nearest CPC 29 miles (median distance=16 miles). Some patients were a considerable distance from the nearest CPC, however, with 13% over 60 miles from the nearest one. The program allows patients to have one or more parents or non-parent caregivers who register with the program, who are then are allowed to transport and administer a patient's medical cannabis. Only 11% of patients had a registered caregiver, 17% had a registered parent or guardian, and 26% had either a registered parent/legal guardian or a registered caregiver.

Among the 577 health care practitioners who registered with the program 82% were physicians, 13% were advanced practice registered nurses, and 5% were physician assistants.

Medical Cannabis Purchasing Patterns

Most patients make their first medical cannabis purchase within 14 days of program approval. Subsequent purchases typically follow a roughly monthly periodicity. However, intervals between purchases are sometimes less than a month, especially during the first months of program participation as the patient experiments with small amounts of different products. And intervals between purchases are sometimes much longer than a month. Using a cutoff of six months without any medical cannabis purchases as a surrogate for program discontinuation, 51% of patients who enrolled and made a purchase within the first six months of the program discontinued participation in the program as of December 31, 2016.

Medical Cannabis Use Patterns

Each patient's medical cannabis purchasing transactions during their first enrollment year (or through early March if still within their first enrollment year) were analyzed. A total of 16,238 products were purchased during 10,898 transactions, with 38% of all transactions consisting of two or more products. For analytic purposes, products were classified according to the ratio of delta-9-tetrahydrocannabinol (THC) to cannabidiol (CBD) as follows: Very High THC:CBD (100:1 or higher), High THC:CBD (>4:1 up to 99:1), Balanced THC:CBD (1:1 up to 4:1), High CBD:THC (≥1:1 up to 99:1), and Very High CBD:THC (100:1 or higher).

Products for enteral administration (swallowed – includes capsules and oral solutions) and products for inhalation (vaporized oil) each accounted for 45% of product purchases. Products for oromucosal administration (absorption through cheek) accounted for 9%. Nearly 50% of all purchases were Very High THC:CBD products, followed by Balanced THC:CBD (30%) and High CBD-THC (15%). Very High THC:CBD products were most commonly oil for vaporization or for oromucosal absorption, while Balanced THC:CBD and High CBD:THC products were most often for enteral administration.

Examining purchasing history across all patients is very complex for reasons that include experimentation with different products over time. As a first approach to assessing routine use of products, most frequently purchased products were examined for each patient. For 28% of patients, two or more products were purchased the same number of times. The product types that emerged as most frequently purchased were Very High THC vaporization oil (25%), High CBD:THC enteral preparations (14%), and Balanced enteral preparations (13%). Most frequently purchased product types varied considerably across medical conditions.

Benefits

Information on patient benefits comes from the Patient Self-Evaluations (PSE) completed by patients prior to each medical cannabis purchase and from patient and health care practitioner

surveys. Results of analysis of PSE and survey data indicate perceptions of a high degree of benefit for most patients.

Patients responded to a survey question asking them how much benefit they believe they received from using medical cannabis on a scale from 1 (no benefit) to 7 (great deal of benefit). Across all patients 64% indicated a benefit rating of 6 or 7 and this degree of benefit was indicated by at least half of the patients with each medical condition. A small but important proportion of patients indicated little or no benefit: 9% gave a rating of 1, 2, or 3. Benefit ratings varied somewhat by qualifying medical condition. When patients were asked what the most important benefit was for them, two-thirds indicated a reduction in symptoms directly related to their qualifying medical condition and most of the remainder indicated more general quality of life benefits.

An important part of this report is the verbatim comments written by patients, and the reader is encouraged to review these comments, presented in an Appendix. Examples of these comments include:

- "Almost all muscle spasm and pain associated with spasms are gone. I used to have constant nerve triggered pain that is minimal now. Results were almost immediate. I am sleeping way better now also."
- "[NAME] has passed away. I am her daughter and was her care giver. She was open to trying medical cannabis and we got the liquid form. It was a saving grace. She was in a lot of pain and when prescribed medications did NOT work – we started this and it kept her calm and relaxed. I am very thankful that we were able to have this option available. It helped to make her last months more bearable and truly it would have been miserable without it."
- "I am getting enough sleep for the first time since about 2011. My absence seizures have gone from 3-4 a day to almost 0. It also has lessened the severity of grand mal seizures. The recovery time after has gone from around 12 hours to around 4."
- "At first it helped a lot but my seizures have returned."
- "Spasms – only a little better."

Health care practitioners were somewhat more conservative in assessment of benefit to their patients. Across all the benefit ratings by health care practitioners, 38% indicated a rating of 6 or 7 and 23% indicated little or no benefit (rating of 1, 2, or 3). Similarity in benefit assessment between health care practitioners and patients appears to vary by medical condition, with highest discrepancy among seizure patients. Descriptive comments suggest at least part of the difference is driven by perspective of what constitutes benefit. The patients cite quality of life benefits more often than the health care practitioners, who appear to focus more on objective measures such as seizure counts.

The symptom scores provided in the Patient Self-Evaluation data have the advantage of completeness, since they are required prior to each medical cannabis purchase. In this report a reduction of ≥30% was applied to most symptoms to indicate clinically meaningful symptom reduction. Results show patterns similar to those in the survey benefits rating, but usually

somewhat smaller in size. For most symptoms between half and two-thirds of patients who achieve clinically meaningful improvement retained that degree of improvement over the next four months.

Examples of proportion of patients achieving and retaining ≥30% symptom reduction include:

- Among seizure patients, 68% reported ≥30% reduction in seizure frequency and 49% both achieved that level of reduction and retained it, on average, for at least four months
- Among patients with Tourette syndrome, 61% reported ≥30% reduction in tic frequency and 46% both achieved that level of reduction and retained it, on average, for at least four months
- Among patients with Crohn's disease, 51% reported ≥30% reduction in number of liquid stools per day and 29% both achieved that level of reduction and retained it, on average, for at least four months
- Among patients with severe, persistent muscle spasms, 48% reported ≥30% reduction in spasm frequency and 28% both achieved that level of reduction and retained it, on average, for at least four months

Moderate to severe levels of non-disease-specific symptoms such as fatigue, anxiety, and sleep difficulties were common across all the medical conditions. And the reductions in these symptoms was often quite large. These findings support the understanding that some of the benefit perceived by patients is expressed as improved quality of life.

The type(s) of medical cannabis used at the time patients achieved clinically significant improvement was analyzed for each symptom assessed within each category of medical condition. Full results of these analyses are presented in an Appendix and summaries are in the Benefits chapter.

Adverse Side Effects

At this point, the safety profile of the medical cannabis products available through the Minnesota program seems quite favorable. Approximately 20-25% of enrolled patients report negative physical or mental side effects of some kind, with the majority – around 60% - reporting only one and 90% reporting three or fewer. The vast majority of adverse side effects, around 90%, are mild to moderate in severity. An assessment of the 30 patients reporting severe side effects, meaning “interrupts usual daily activities,” found no apparent pattern of patient age, medical condition, or type of medical cannabis used. The most common adverse side effects are dry mouth, drowsiness, and fatigue. Fortunately, up to the present no serious adverse events (life threatening or requiring hospitalization) have been reported.

Affordability and Suggestions for Improving the Program

Unlike traditional pharmaceuticals whose costs are often covered through insurance reimbursement, medical cannabis purchased through the Minnesota program is currently not covered by insurance and must be purchased out of pocket. The patient survey asked for a rating of product affordability on a scale of 1 (very affordable) to 7 (very prohibitive). More than half (51%) responded with a 6 or a 7 and 86% responded with a score of 4 or higher. "Bring the costs down" was a frequent response when patients and certifying health care practitioners were asked how the program could be improved. Some patients indicated on surveys they used less medical cannabis than they knew was helpful to them because they could not afford it.