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

MDH Minnesota Department *of* Health
OFFICE OF MEDICAL CANNABIS

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

Minnesota Department of Health
Office of Medical Cannabis
PO Box 64882
St. Paul, MN 55164-0882
651-201-5598 (Metro) or 844-879-3381 (Non-metro, toll-free)
Health.Cannabis@state.mn.us
www.health.state.mn.us

As requested by Minnesota Statute 3.197: This report cost approximately $58,500 to prepare, including staff time, printing and mailing expenses.

Upon request, this material will be made available in an alternative format such as large print, Braille or audio recording. Printed on recycled paper.

Table of Contents

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
- Among cancer patients with at least moderate levels of nausea when they started using medical cannabis, 38% reported ≥30% reduction of nausea and 23% both achieved that level of reduction and retained it, on average, for at least four months
- Among cancer patients with at least moderate levels of pain when they started using medical cannabis, 29% reported ≥30% reduction of pain and 12% 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.

1. Introduction

In May 2014, Minnesota became the 22nd state to create a medical cannabis program. Distribution of cannabis products to qualified, enrolled patients began July 1, 2015. Minnesota's medical cannabis program is distinct from those in nearly all other states due to the fact that the Minnesota Department of Health's Office of Medical Cannabis is required to study and learn from the experience of participants. Minnesota's online registry, which integrates information from patients, certifying health care practitioners and manufacturers, continuously captures program data. Data elements from the Registry have been selected to create a de-identified research data set for reporting and research. This report draws on aspects of that research data set to describe the experience of patients who enrolled during the first year of the program's operation: July 1, 2015 through June 30, 2016.

Data in this report come from several aspects of the program's operations:

- Information from registration or enrollment of patients, health care practitioners, and caregivers;
- Information patients provide each time they visit a cannabis patient center for purchase of cannabis products, including information on symptom severity and side effects;
- Details about each cannabis product purchased; and
- Information is derived from responses to periodic surveys of patients and their certifying health care practitioners.

Though there is certainly imprecision in some of the data collected by the program, this report provides important details that can be found in few other states. A notable part of the report is a set of statements regarding benefits, negative effects, and comments about the program made by patients and health care practitioners. These are redacted to protect privacy, but otherwise presented as was written on the surveys. The comments have been coded by type but the verbatim comments have a power of their own, reminding us that each enrollee is a unique individual, not just a number. A few comments are included elsewhere, but the reader is encouraged to spend time reviewing the full listing of responses in the appendices.

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 data derived from the program registry.

2. Patients and Caregivers Registered in the First Program Year

DESCRIPTION OF PATIENTS ENROLLED IN THE FIRST PROGRAM YEAR

Qualifying Condition

During the first year of the Minnesota Medical Cannabis program (July 2015-June 2016), 1,660 patients were certified by registered healthcare practitioners and subsequently enrolled in the program (Figure 2.1). The healthcare practitioners certified the patients as having one or more of the following qualifying conditions: severe and persistent muscle spasms (n=713), cancer (n=468), seizures, including those characteristic of epilepsy (n=328), Crohn's disease (n=108), terminal illness (n=94), HIV/AIDS (n=54), Tourette syndrome (n=30), glaucoma (n=24), and amyotrophic lateral sclerosis (ALS) also known as Lou Gehrig's disease (n=22) (Table 2.1, Figure 2.2). Of the 1660 patients from the first program year, 167 (10.1%) were certified as having more than one qualifying condition; these patients are represented more than once in Table 2.1 and Figure 2.2.

Figure 2.1. Patient enrollment in the first program year.

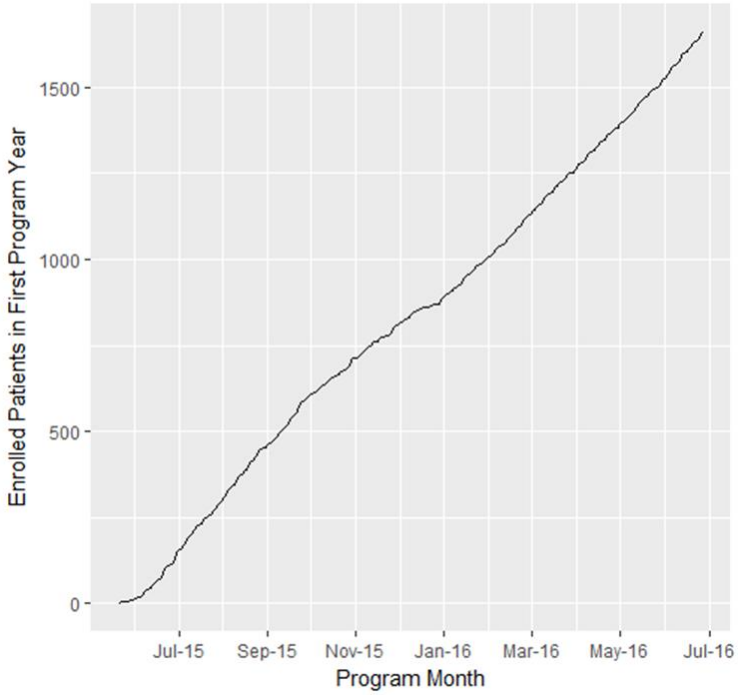
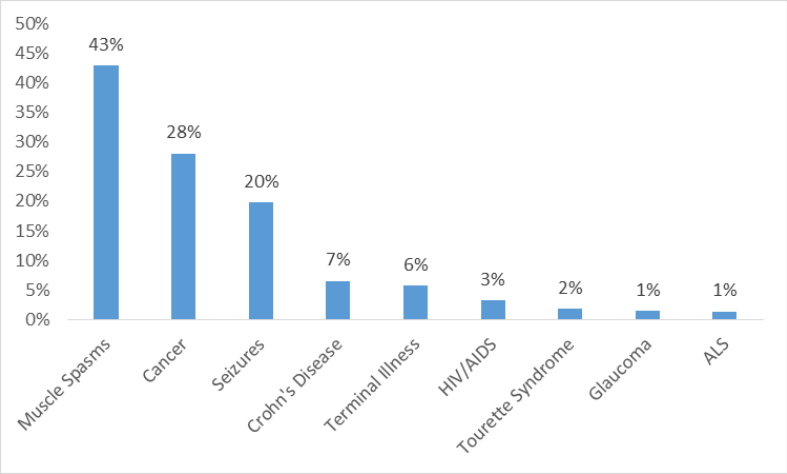


Table 2.1. Patient counts by qualifying condition.

Condition	Count	%
Muscle Spasms	713	43%
Cancer	466	28%
Seizures	328	20%
Crohn's Disease	108	7%
Terminal Illness	94	6%
HIV/AIDS	54	3%
Tourette Syndrome	30	2%
Glaucoma	24	1%
ALS	22	1%

Note: Percentages sum to more than 100 percent because among the 1660 patients enrolled during the first year, 167 (10.1%) were certified for more than one qualifying condition.

Figure 2.2. First year cohort patients by qualifying medical condition.



Note: Percentages sum to more than 100 percent because among the 1660 patients enrolled during the first year, 167 (10.1%) were certified for more than one qualifying condition.

Age and Gender

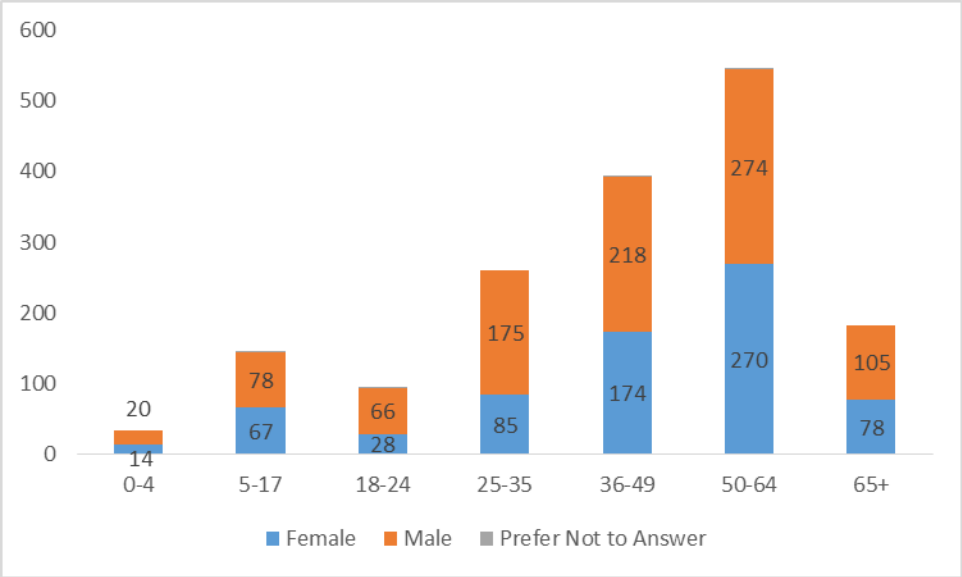
At the time of certifying that a patient has a medical condition qualifying them for the medical cannabis program, the certifying healthcare practitioner enters the patient's date of birth. Additionally, during registration, patients are asked to report gender and race/ethnicity but are not required to do so. Table 2.2 shows the breakdown of patients by age category and gender at the time of initial program enrollment. The gender breakdown of patients in the first program year was 57% male and 43% female, with <1% of patients declining to report gender. Patients tended to be middle-aged, with 56.3% of the cohort falling between ages 36-64. However, the cohort also included a notable proportion of pediatric patients (10.7%) and patients over 65 years (11.0%).

Table 2.2. Patient counts by age and gender.

	0-4	5-17	18-24	25-35	36-49	50-64	65+
Female	14 (41%)	67 (46%)	28 (29%)	85 (33%)	174 (44%)	270 (49%)	78 (43%)
Male	20 (59%)	78 (53%)	66 (69%)	175 (67%)	218 (55%)	274 (50%)	105 (57%)
Prefer Not to Answer	0 (0%)	1 (1%)	2 (2%)	0 (0%)	2 (1%)	3 (1%)	0 (0%)
Total	34 (2%)	146 (9%)	96 (6%)	260 (16%)	394 (24%)	547 (33%)	183 (11%)

Note: Percentages are calculated based on the total count of patients in each age category.

Figure 2.3. Age and gender breakdown of first year cohort.



Age by Qualifying Condition

Breakdown of age category within each qualifying condition is shown in Table 2.3. Among the first year cohort, average age was 44.3 ± 18.9 years. Age distribution varied substantially across qualifying medical condition groups; patients certified for glaucoma or ALS tended to be older in general (average age of 60.4 ± 14.0 and 61.5 ± 9.6, respectively); patients certified for seizure disorders or Tourette syndrome generally were younger (23.4 ± 16.0 and 25.3 ± 11.7, respectively).

Table 2.3. Patient age by qualifying medical condition.

	0-4	5-17	18-24	25-35	36-49	50-64	65+	Mean Age (SD)	Total
Muscle Spasms	3 (0%)	6 (1%)	33 (5%)	124 (17%)	216 (30%)	268 (38%)	63 (9%)	47.3 (14.5)	713
Cancer	3 (1%)	15 (3%)	11 (2%)	33 (7%)	83 (18%)	217 (47%)	104 (23%)	54.6 (16.2)	466
Pain	1 (0%)	3 (1%)	8 (3%)	26 (8%)	65 (20%)	151 (47%)	66 (21%)	54.3 (15.3)	320

	0-4	5-17	18-24	25-35	36-49	50-64	65+	Mean Age (SD)	Total
Nausea/Vomiting	1 (0%)	12 (4%)	10 (4%)	18 (7%)	50 (18%)	130 (48%)	52 (19%)	53.4 (16.5)	273
Cachexia/Wasting	1 (1%)	6 (3%)	5 (3%)	8 (4%)	16 (9%)	90 (50%)	54 (30%)	57.9 (16.5)	180
Seizures	30 (9%)	114 (35%)	43 (13%)	68 (21%)	52 (16%)	18 (6%)	3 (1%)	23.4 (16.0)	328
Crohn's Disease	0 (0%)	0 (0%)	9 (8%)	35 (32%)	35 (32%)	22 (20%)	7 (7%)	41.4 (13.8)	108
Terminal Illness	2 (2%)	9 (10%)	3 (3%)	8 (9%)	20 (21%)	38 (40%)	14 (15%)	48.7 (20.1)	94
Pain	0 (0%)	7 (11%)	1 (2%)	6 (9%)	16 (24%)	27 (41%)	9 (14%)	48.7 (20.1)	66
Nausea/Vomiting	1 (2%)	4 (9%)	2 (4%)	3 (7%)	9 (20%)	21 (47%)	5 (11%)	48.7 (20.3)	45
Cachexia/Wasting	1 (3%)	4 (11%)	2 (5%)	1 (3%)	3 (8%)	19 (50%)	8 (21%)	48.9 (20.3)	38
HIV/AIDS	0 (0%)	0 (0%)	0 (0%)	8 (15%)	20 (37%)	26 (48%)	0 (0%)	47.0 (9.7)	54
Tourette Syndrome	0 (0%)	11 (37%)	3 (10%)	12 (40%)	3 (10%)	1 (3%)	0 (0%)	25.3 (11.7)	30
Glaucoma	0 (0%)	0 (0%)	1 (4%)	0 (0%)	4 (17%)	11 (46%)	8 (33%)	60.4 (14.0)	24
ALS	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (9%)	12 (55%)	8 (36%)	61.5 (9.6)	22

Race and Ethnicity

Table 2.4 shows patient-reported race and ethnicity. Patients were given the option to select multiple race and ethnicity categories, so the counts reflect some patients more than once. Ninety-one patients selected more than one race/ethnicity and 95 patients declined the question. Compared to 2014 Census Bureau estimates of race/ethnicity in Minnesota, the distribution of responding members of the first program year cohort is generally similar, with a slightly higher proportion of American Indians (2.7% versus 1.9%) and lower proportion of Hispanics (2.4% versus 4.9%) and Asians (1.7% versus 5.0%).

Table 2.4. One-year cohort patient race and ethnicity compared to overall state demographics.

Race/Ethnicity	Medical Cannabis Registry	2014 Census Bureau Estimates
American Indian	42 (2.7%)	1.9%
Asian	27 (1.7%)	5.0%
Black	101 (6.5%)	6.5%
Hawaiian	3 (0.2%)	0.1%
White	1410 (90.1%)	87.5%
Hispanic	37 (2.4%)	4.9%
Other	26 (1.7%)	1.7%

Race and ethnicity estimates for Minnesota can be found at the following website: http://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml

Registered Caregivers and Parents/Legal Guardians

If a patient is unable to pick up their medication from a cannabis patient center or is unable to administer the medication, their certifying health care practitioner may also certify the patient's need for a designated caregiver. This allows the enrolled patient to have a caregiver who then undergoes a background check and registers with the program. Registered caregivers can then legally obtain and possess the patient's medical cannabis on their behalf. Additionally, parents or legal guardians of patients can register with the program to act as caregiver and pick up or possess medication on behalf of the patient. Table 2.5 shows the proportion within each

qualifying condition group of patients who have registered caregivers or parents or legal guardians registered to pick up medication on behalf of the patient. Patients certified for ALS, cancer, or terminal illness have the highest proportions of patients with registered caregivers (32%, 15% and 15%, respectively). Patient certified for seizure disorders or Tourette syndrome, who are also generally younger than the cohort at large, have the highest proportion of patients with registered parents or legal guardians in the program (65% and 53%, respectively). Patients with seizures or Tourette syndrome also have the highest proportion of either registered caregivers or registered parents/legal guardians. Table 2.6 shows the absolute number of registered caregivers associated with a patient in the first year cohort, reported by condition. Most patients with registered caregivers have only one caregiver able to pick up medication on their behalf (n=157); 21 patients have two caregivers and one patient has three caregivers.

Table 2.5. Proportion of patients with registered caregivers, parents or legal guardians authorized to pick up medication, or both.

CONDITION	Number of Enrolled Patients	Patients with Registered Caregiver(s)	Patients with Registered Parent(s)/Legal Guardian(s)	Patients with Registered Caregiver(s) or Parent(s)/Legal Guardian(s)
All Conditions	1660	179 (11%)	279 (17%)	430 (26%)
Cancer	466	71 (15%)	23 (5%)	92 (20%)
Terminal Illness	94	14 (15%)	10 (11%)	22 (23%)
Glaucoma	24	3 (13%)	0 (0%)	3 (13%)
HIV/AIDS	54	1 (2%)	0 (0%)	1 (2%)
Tourette Syndrome	30	2 (7%)	16 (53%)	16 (53%)
ALS	22	7 (32%)	1 (5%)	8 (36%)
Seizures	328	32 (10%)	213 (65%)	225 (69%)
Muscle Spasms	713	72 (10%)	26 (4%)	96 (13%)
Crohn's Disease	108	6 (6%)	3 (3%)	8 (7%)

Table 2.6. Count of registered caregivers associated with patients enrolled in the first program year, by qualifying condition.

Condition	Registered Caregiver Count
All Conditions	202
Cancer	83
Terminal Illness	19
Glaucoma	4
HIV/AIDS	1
Tourette Syndrome	2
ALS	7
Seizures	37
Muscle Spasms	79
Crohn's Disease	6

Geographic Distribution and Distance to Nearest Cannabis Patient Center

At the time of registration, patients provide their home address for verification of Minnesota residency. Home addresses are retained in the patient's online registry account but are not retained in the research database; in lieu of home address, patient ZIP codes and calculated distances from each address to the nearest cannabis patient center are accessible for research purposes. The general geographic distribution of patients was examined using patient-reported ZIP codes; the first three digits of ZIP codes compose a prefix which corresponds to an approximate geographic region[1]. The U.S. Postal Service assigns to each prefix labels that match

[1] http://pe.usps.com/Archive/HTML/DMMArchive20050106/print/L002.htm

the major city within the region and approximate surrounding cities; these region labels are shown in Table 2.7, along with the count of patients living in the corresponding ZIP codes.

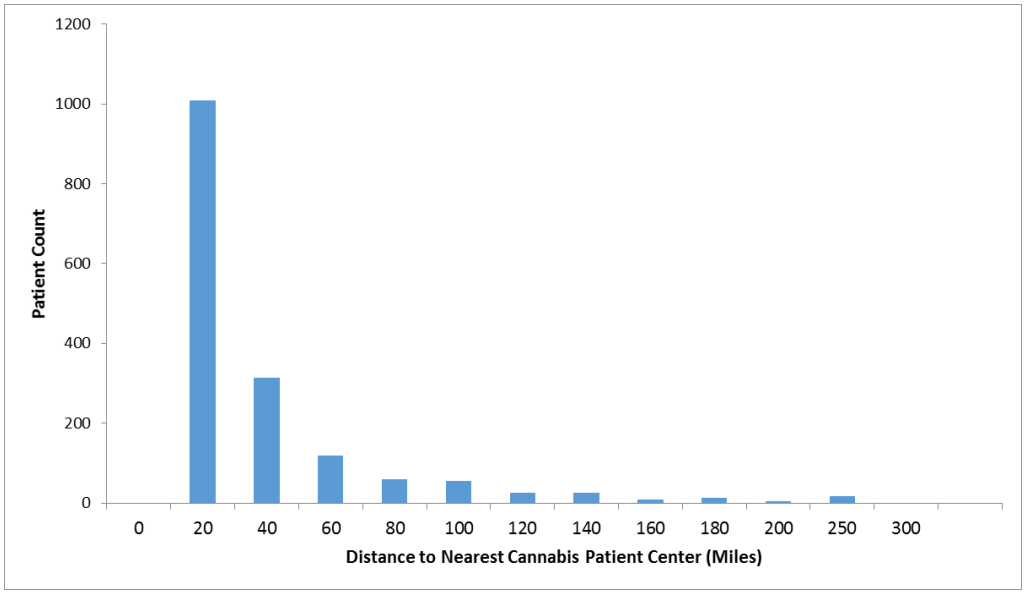
Table 2.7. Geographic distribution of patients by ZIP code prefix.

Region	ZIP Code Range	Patient Count (%)
St Paul	55000-55199	561 (34%)
Minneapolis	55300-55599	671 (40%)
Duluth	55600-55899	59 (4%)
Rochester	55900-55999	104 (6%)
Mankato	56000-56199	63 (4%)
Willmar	56200-56299	49 (3%)
St Cloud	56300-56399	80 (5%)
Brainerd	56400-56499	27 (2%)
Detroit Lakes	56500-56599	28 (2%)
Bemidji	56600-56699	11 (1%)
Grand Forks*	56700-56799	7 (0%)

Note: The Grand Forks region, corresponding to ZIP codes with a 567 prefix, refers to a region including Grand Forks, South Dakota, as well as several ZIP codes located in Minnesota near the western border. Patients living in this region reside in Minnesota.

Two medical cannabis manufacturers each operate four cannabis patient centers where patients can purchase medical cannabis following consultation with pharmacy staff at the center. Minnesota law required that one cannabis patient center be open in each of Minnesota's eight legislative districts by July 1, 2016 (one year after the program start date). Figure 2.4 shows the distribution of calculated one-way distance from each patient's home address to the nearest cannabis patient center location as of July 1, 2016, when all eight centers were operational. Average one-way distance is 28.9 ± 36.9 miles; median one-way distance is 15.5 miles. The majority of patients (n=1441; 86.8%) live within 60 miles of the nearest cannabis patient center.

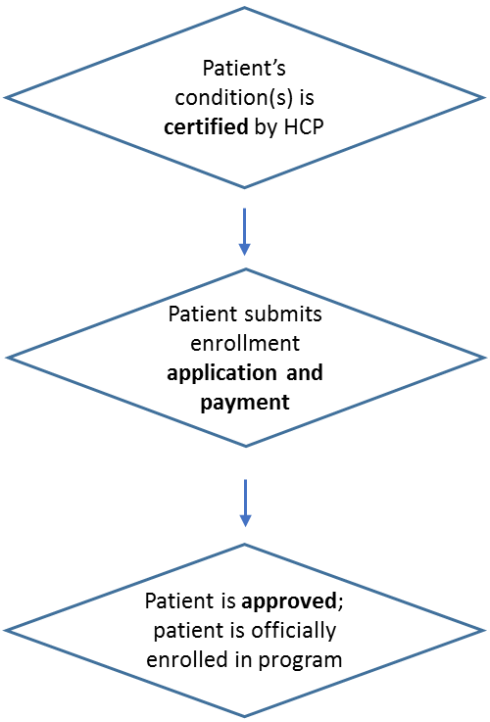
Figure 2.4. Distribution of one-way distance from patient home to nearest cannabis patient center.



From Certification to Program Approval: How Long Does it Take for Patients?

A sequential series of steps are followed in order to move patients from certification by a healthcare practitioner to their enrollment in Minnesota's Medical Cannabis program. First, patients must have at least one medical condition that qualifies for the program and must have that condition certified by a registered health care practitioner (HCP). After their medical condition is certified, patients have 90 days to submit a complete application to enroll in the program. Patients must also submit payment to cover the annual enrollment fee along with their application materials. Once the application and enrollment fee are submitted, Office of Medical Cannabis (OMC) staff reviews and verifies all submitted materials and can approve the patient for the program. Figure 2.5 depicts the process flow from certification to program approval:

Figure 2.5. Flow chart of enrollment events.



To give current and prospective patients some idea of the time it takes to go from certification to program approval, records from patients in the first program year cohort (n = 1660) were analyzed at different time points: 1) time between certification to program approval, 2) time between certification to enrollment payment, and 3) time between enrollment payment and program approval.

Time from Certification to Program Approval

Just over half of all patients (54.7%) in the cohort (n = 1660) were approved/enrolled in the program within 3 days of having their condition(s) certified. Close to 90% (1484 out of 1660 patients) were enrolled in the program within a month of being certified.

Time from Certification to Annual Enrollment Fee Payment

Records of enrollment fee payments were unavailable for patients who did not make an electronic payment; therefore, calculations of time between certification and enrollment fee payment was restricted to 1579 patients (95.1% of patients in the cohort represented) who paid the enrollment fee electronically. Of these patients, 57.2% of them (n = 903) submitted payment within 1 day of getting their qualifying condition(s) certified by their HCP. More than 90% of patients (n = 1452) submitted payment within one month of certification.

Time from Annual Enrollment Fee Payment and Program Approval

Records of enrollment fee payments were not available for all patients in the cohort; therefore, calculations of time between enrollment fee payment and program approval was restricted to 1579 patients (95.1% of patients in the cohort represented). Of these patients, 72.7% of them (n = 1148) were approved for the program (officially enrolled in the program) within a day of submitting their annual enrollment fees. Close to all patients (99.3%) were enrolled in the program within a month of submitting their annual enrollment fees. The small proportion of patients who do not get approved within a month of their fee submission generally reflects patients who submitted inadequate or incomplete information during the enrollment submission process (meaning that the Office of Medical Cannabis is waiting for additional information to approve them for the program).

From Certification to Program Approval: Conclusions

Just over half of all patients in the cohort were officially enrolled in the program within three days of being certified. Within a week of certification, 70% of patients were enrolled in the program. This suggests that the majority of patients move relatively quickly from certification to enrollment in the program.

When breaking down the process flow between certification and program approval, it typically took longer for patients to move from certification to paying the enrollment fee than it did from their paying the enrollment fee to getting approved. This generally reflects the nature of the process flow going from certification to paying the enrollment fee: after patients are certified, the patient must self-initiate and complete the submission of all application materials along with payment (involves variable amounts of time to gather all materials and to ensure sufficient funds to make fee payment). This is in contrast to the step between enrollment fee payment and getting approved for the program: patient has submitted all materials and payment by this

point and – unless they are directed otherwise by OMC staff – will get approved for the program in the order their materials were received in the queue.

Re-Enrollment

The Minnesota medical cannabis program requires by statute that once a patient becomes certified as having a qualifying condition and enrolled in the program, the patient's enrollment lasts for one year; therefore each year a patient must be re-certified as having at least one qualifying condition and must re-enroll in the program and pay an annual enrollment fee. If a patient is not re-certified as having a qualifying condition and does not re-enroll in the program by the anniversary date of the most recent enrollment, their account is deactivated and they are no longer able to purchase medical cannabis from a cannabis patient center or retain the protections of the program. To investigate the rate at which enrolled patients who approach their expiration dates re-enroll in the program, patients who enrolled in the program during the first program month (including those who were approved early, prior to the program start in July 2015) were examined. A total of 253 patients were enrolled in the first program month; these patients' enrollments expired in July 2016. Re-enrollment activity for these patients was examined six months following expiration of the first enrollment year. Within six months following the expiration of the first year of enrollment, 115 (45%) among these patients re-enrolled in the program. Of the remaining 138 patients who did not re-enroll during this period, 24 patients (17%) died within 18 months of initial enrollment. Additionally, patients can re-enroll at any time following expiration, and some patients who did not re-enroll immediately may do so at a later time.

Most patients who re-enrolled within six months of expiration did so prior to expiration (44%) or within the first month after enrollment expiration (40%). Only 3% of these patients re-enrolled beyond three months post expiration. Timing of re-enrollment for patients who initially enrolled during the first program month are shown in Table 2.8.

Table 2.8. Timing of program re-enrollment for patients enrolled in the first program month.

Time Re-Enrollment Occurred	Patient Count (%)
Prior to Expiration	51 (44%)
1st Month After Expiration	46 (40%)
2nd Month After Expiration	0 (0%)
3rd Month After Expiration	15 (13%)
4th Month After Expiration	1 (1%)
5th Month After Expiration	2 (2%)
6th Month After Expiration	0 (0%)
Total Count of Patients Re-enrolled Within 6 Months of Annual Expiration Date	*115*

Note: Among the 253 patients who enrolled in the program in July 2015, 115 (45%) re-enrolled within six months of expiration. Percentages are based on a total number of re-enrollments within this period (n=115).

At the time of enrollment expiration, a patient can allow their enrollment to lapse without any action or communication with the Office of Medical Cannabis. Currently OMC does not collect information systematically on why patients chose to either re-enroll or let their current enrollment expire. However, some insight into program discontinuation is available from a Continued Use survey, which asks patients who have not purchased medical cannabis for 60 days whether they have decided to stop the treatment, whether they received any benefits from the treatment, and what their reasons are for either stopping or pausing the treatment. Early results looking at patients who purchased medical cannabis within the first three program months but discontinued purchasing for 60 days showed that 62% (n=10) of patients who indicated they planned to stop using medical cannabis (n=16) found little or no benefit from the treatment. Among 59 patients who indicated they were unsure of whether they would continue or that they intended to continue the treatment, 35 (73%) cited cost as a barrier to continuing. These results do not directly answer the question of why some patients do not re-enroll but give some indication of potential reasons for doing so. (For methodology and preliminary results from the Continued Use survey, see "Early Results of Office of Medical Cannabis Surveys: May 2016" on the Office of Medical Cannabis website).

3. Health Care Practitioners Registered in the First Program Year

The Minnesota Medical Cannabis program outlines a set of qualifying medical conditions which make a patient eligible for enrollment in the program. By Minnesota statute, a patient must be certified by a Minnesota-licensed physician, physician assistant (PA), or advanced practice registered nurse (APRN) as having one or more of the qualifying conditions. A Minnesota practitioner with appropriate credentials must first register with the Minnesota Medical Cannabis program before they can certify patients for the program: practitioners complete a short online form with their name and clinic information to register. Office of Medical Cannabis staff verify the provider's entered information and their Drug Enforcement Agency (DEA) license prior to approving the practitioner to certify patients. This chapter will describe the certifying healthcare practitioners who registered in the first program year.

Healthcare Practitioner Count, Age and Gender

From July 2015- June 2016, 577 healthcare practitioners licensed in Minnesota registered in the medical cannabis program, including 473 physicians (82%), 77 APRNs (13%) and 27 PAs (5%). Table 3.1 shows the breakdown of healthcare practitioner (HCP) type, gender and average age, based on publicly available data from the Boards of Medical Practice and Nursing. Physicians registered in the program were predominantly male (72%) and were generally older than registered APRNs and PAs, who were predominantly female (88% and 78%, respectively).

Figure 3.1. Count of registered healthcare practitioners during the first program year.

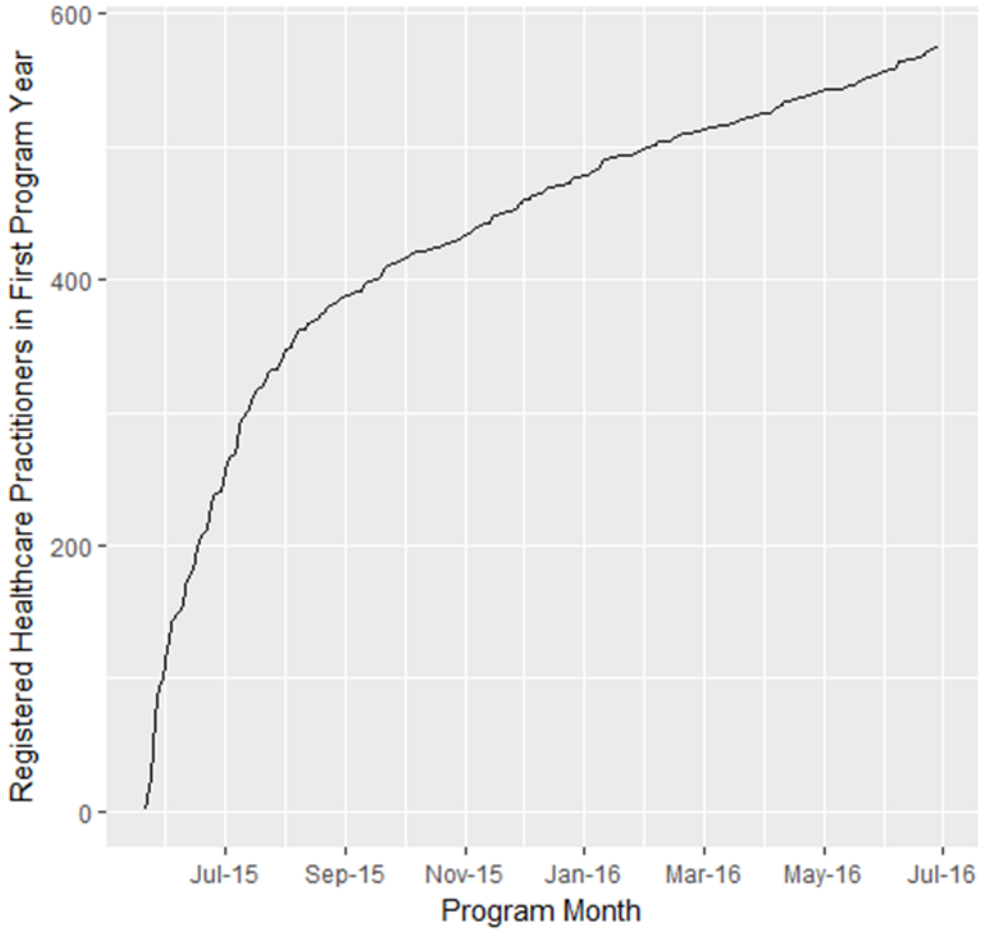


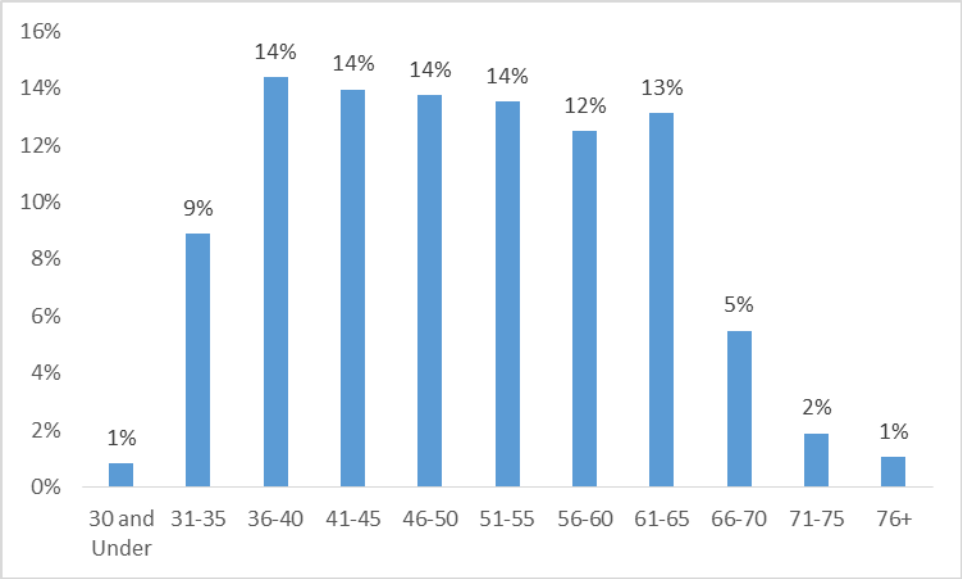
Table 3.1. Healthcare practitioner by type, with gender and average age.

HCP TYPE	N	%	MALE: N (%)	MEAN AGE (SD)
Physician	473	82%	341 (72%)	50.3 (11.3)
APRN	77	13%	9 (12%)	47.0 (9.4)
PA	27	5%	6 (22%)	39.9 (9.5)
Total	577	100%	356 (62%)	49.4 (11.2)

Note: Age data was unavailable for 17 APRNs and three physicians.

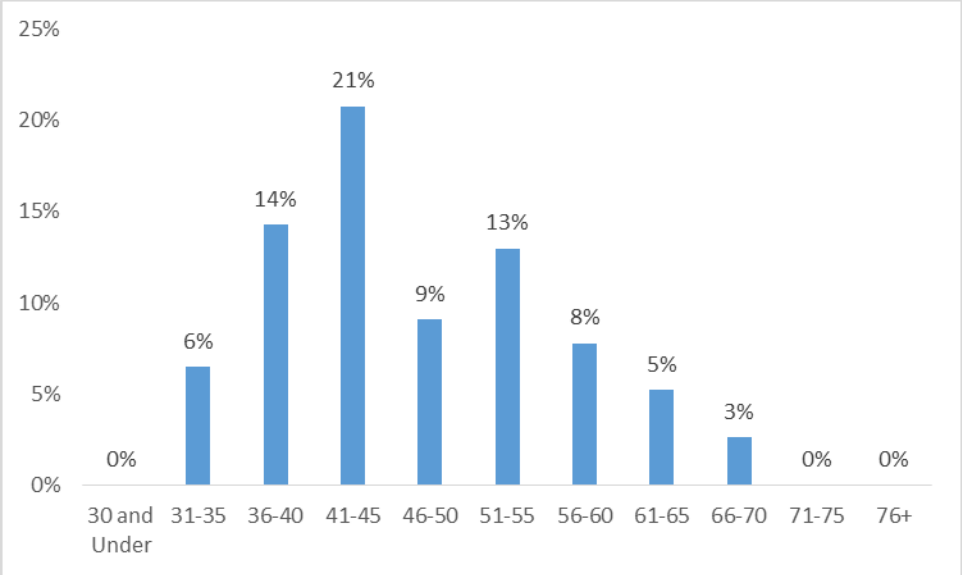
More detailed representations of age distribution among registered physicians, PAs and APRNs are available in Figures 3.2-3.4. Figure 3.2 shows the age distribution in 5 year increments of physicians enrolled in the first program year; most physicians fall between ages 36-65 years (81%) with relatively even distribution of numbers across this range. Figure 3.3 shows the age distribution for APRNs; 51% of APRNs are 50 years or under. Figure 3.4 shows the age distribution for PAs registered in the program; most PAs fall between ages 31-45 (78%).

Figure 3.2. Age distribution of physicians registered in the medical cannabis program (n=473).



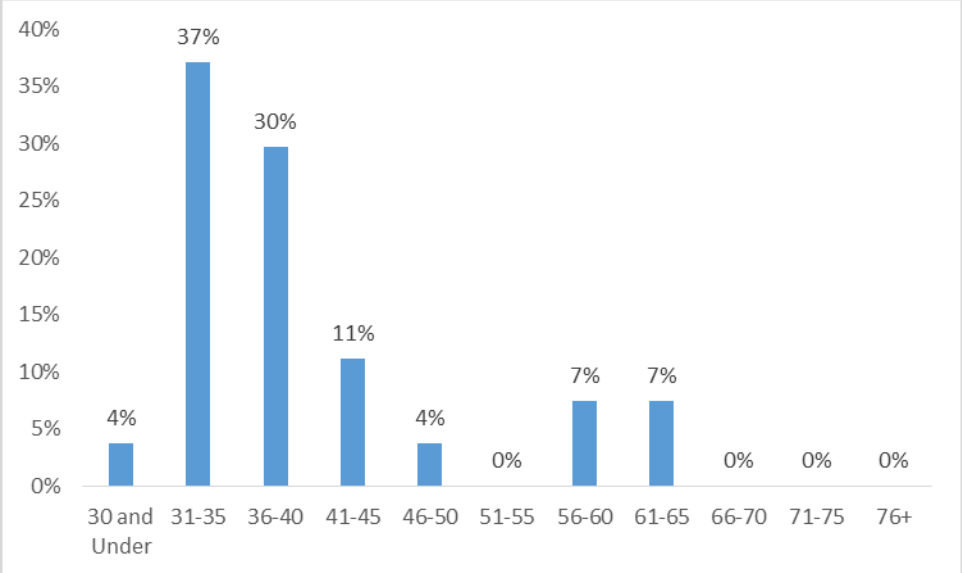
Note: Age data was not publicly available for three physicians registered in the first program year.

Figure 3.3. Age distribution of advanced practice registered nurses registered in the medical cannabis program (n=77).



Note: Age data was not publicly available for 17 APRNs registered in the first program year.

Figure 3.4. Age distribution of physician assistants registered in the medical cannabis program (n=27).



Registered Physician Specialties and Licensures

The Minnesota Board of Medical Practice lists information on Minnesota-licensed physicians and physician assistants. Included is self-reported "Area of Specialty" information indicating a physician's (or physician assistant's) certifications from the American Board of Medical Specialties or American Osteopathic Specialty Boards. While physician assistant specialty information is infrequently provided, physicians often list certifications in more than one area of specialty. For example, physicians practicing as oncologists may list certifications in the areas of Internal Medicine, Hematology, and Medical Oncology. A variety of specialties were represented among physicians registered in the first program year, including subspecialties of neurology (neurology with special qualifications in child neurology, clinical neurophysiology, and epilepsy), pediatrics (pediatric hematology-oncology) and internal medicine or family medicine (gastroenterology, geriatric medicine, hospice and palliative medicine, sports medicine, nephrology, and infectious disease). Specialties including ophthalmology, dermatology, radiology and surgery were also represented. In cases where a physician listed an area of specialty and subspecialty, such as Internal Medicine and Gastroenterology, the subspecialty was chosen to represent the physician's practice (in this case, Gastroenterology). Table 3.2 shows the distribution of physician specialties; each physician is represented only once. Two physicians who are licensed in Minnesota and registered in the program do not have any listed specialties with the Board of Medical Practice; they are therefore excluded from Table 3.2. The most common specialty category for physicians registered in the first program year was primary care (38%), which included internal medicine (13%), family medicine (23%) and pediatrics (2%). Physicians with specialization in oncology (17%) and neurology (14%) were also common.

Table 3.2. Registered physician specialty categories.

Registered Physician Specialties	**N (%)**
Primary Care	179 (38%)
Internal Medicine	*61 (13%)*
Family Medicine	*109 (23%)*
Pediatrics	*8 (2%)*
Oncology	81 (17%)
Neurology	65 (14%)
Pediatric Specialty	29 (6%)
Hospice/Palliative Medicine	25 (5%)
Physical Medicine and Rehabilitation	21 (4%)
Gastroenterology	11 (2%)
Psychiatry	10 (2%)
Ophthalmology	9 (2%)
Surgery	8 (2%)
Infectious Disease	6 (1%)
Radiology/Radiation Oncology	5 (1%)
Pain Medicine	5 (1%)
Nephrology	3 (1%)
Geriatric Medicine	3 (1%)
Emergency Medicine	2 (0%)
Rheumatology	2 (0%)

Obstetrics and Gynecology	2 (0%)
Sports Medicine	2 (0%)
Anesthesiology	2 (0%)
Dermatology	1 (0%)
Public Health and Preventive Medicine	1 (0%)
Pulmonary Disease	1 (0%)
Sleep Medicine	1 (0%)

Advanced Practice Registered Nurse Licensures

Advanced practice RNs include licensed Clinical Nurse Specialists (CNS), Certified Registered Nurse Anesthetists (CRNA), Certified Nurse-Midwives (CNM) or Certified Nurse Practitioners (CNP). Among the 77 APRNs who registered in the first program year, 75 held CNP certification, 1 held CNS certification, and 1 held both CNP and CNS certifications.

Summary

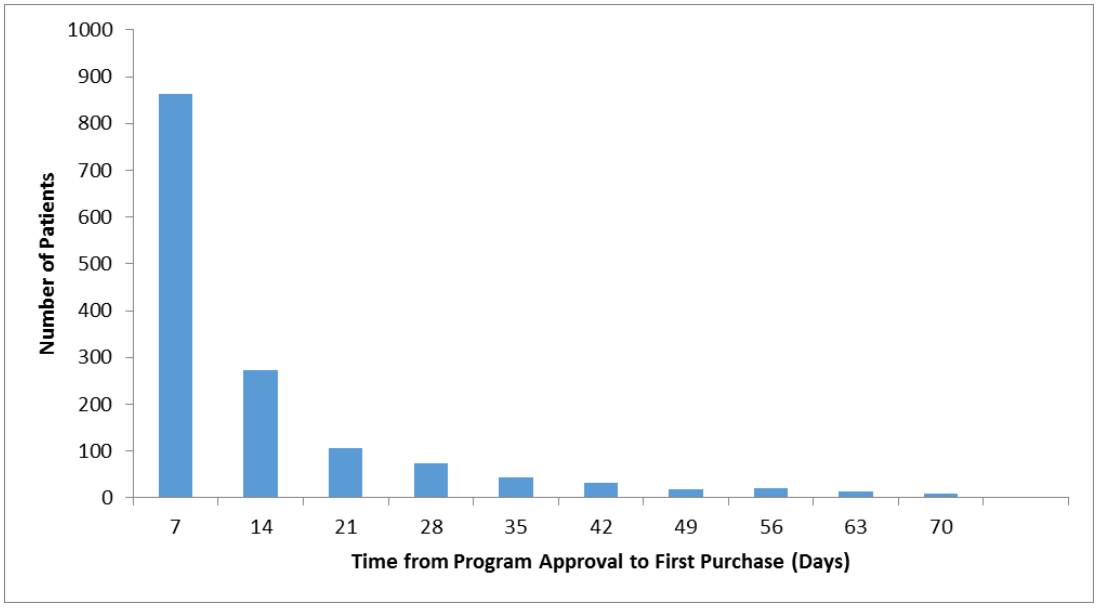
In the first year of the Minnesota Medical Cannabis program, 577 licensed healthcare practitioners registered as certifying providers with the program, predominantly physicians (82%). There were age and gender differences across the HCP types; physicians tended to be older and male; PAs and APRNs tended to be younger and female. Physician licensure information showed that physicians from a diversity of clinical practices are involved in certifying patients for the medical cannabis program, but the majority of these providers are primary care providers or specialties that typically manage patients with the Minnesota program's qualifying conditions (i.e. severe muscle spasms, seizure disorders, Tourette syndrome and ALS are typically managed by neurologists; cancer is often managed by oncologists).

4. Frequency and Duration of Medical Cannabis Purchases

Time from Program Approval to First Medical Cannabis Purchase

Once a patient is approved for the medical cannabis program, the patient and/or their registered caregiver(s) or parent(s)/legal guardian(s) can visit any of the eight cannabis patient centers and purchase medical cannabis. Figure 4.1 shows the distribution of time from program approval to first medical cannabis purchase for patients enrolled during the first program year who purchased medical cannabis before December 31, 2016 (n=1528). Many patients (n=196; 13%) made a first purchase within one day of program approval; over half (n=864; 57%) made a first purchase within seven days and most patients (n=1137; 74%) made a first purchase within 14 days of program approval.

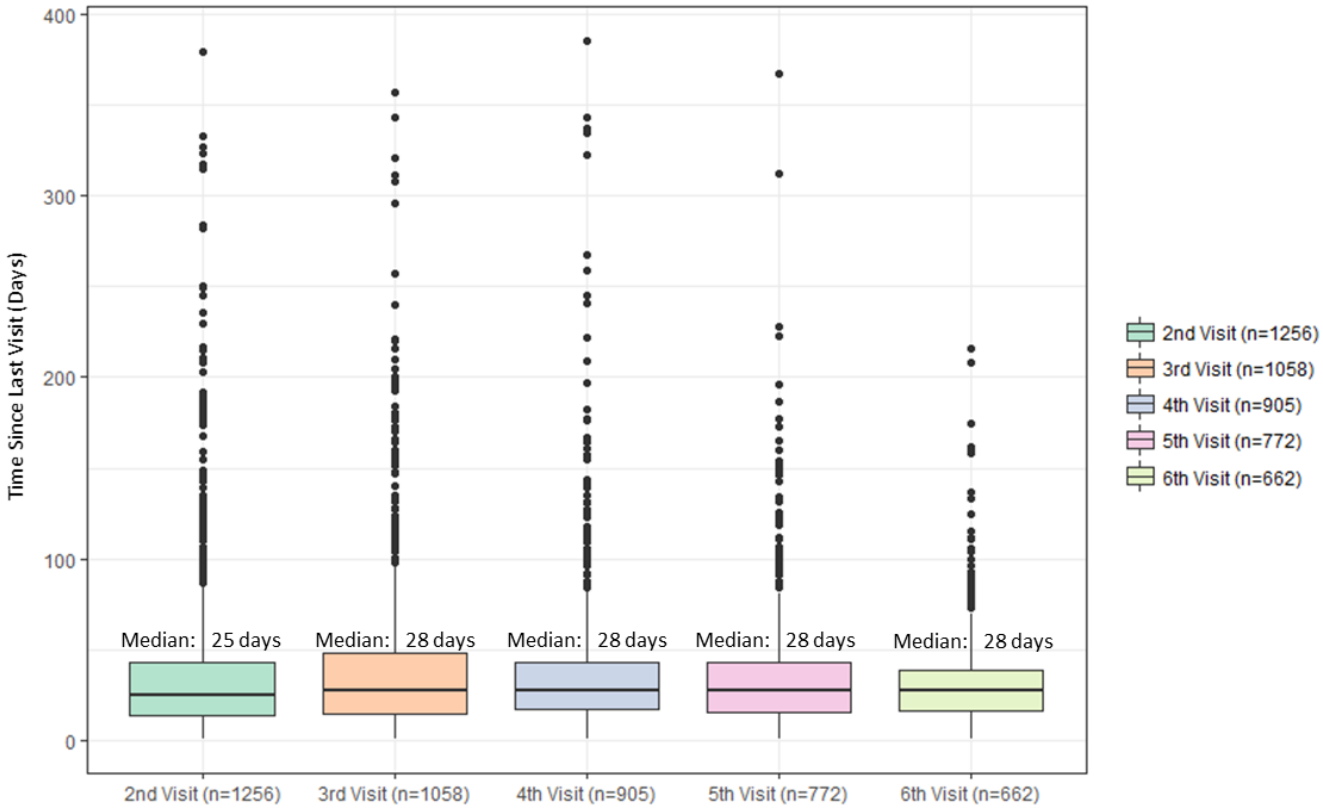
Figure 4.1. Time from patient approval to first medical cannabis purchase.



Time Between Purchases

According to Minnesota statute, patients can purchase up to a 30-day supply of medicine at a cannabis patient center. However, visits to a cannabis patient center vary from 30-day intervals for several reasons. Figure 4.2 shows the intervals between purchases for patients from the one-year cohort with at least two purchases (n=1256). Patients must purchase medical cannabis with cash and many patients report that the medicine's cost is prohibitive; for these reasons, patients may purchase smaller quantities than a month's supply and visit cannabis patient centers more frequently than once a month. On the other hand, many patient responses to the Continued Use Survey (see "Early Results of Office of Medical Cannabis Surveys: May 2016" on the Office of Medical Cannabis website) indicated a quantity of medicine intended to be a 30-day supply lasted longer than 30 days, or the patient chose to use the medicine sparingly as a cost-saving measure and therefore the supply lasted longer than anticipated. However, the median times between visits for the first consecutive six visits were close to the expected interval of one month (median time since last visit: 25, 28, 28, 28, and 28 days for the second, third, fourth, fifth and sixth visits, respectively).

Figure 4.2. Time between visits for patients with two or more visits from July 2015-December 2016.



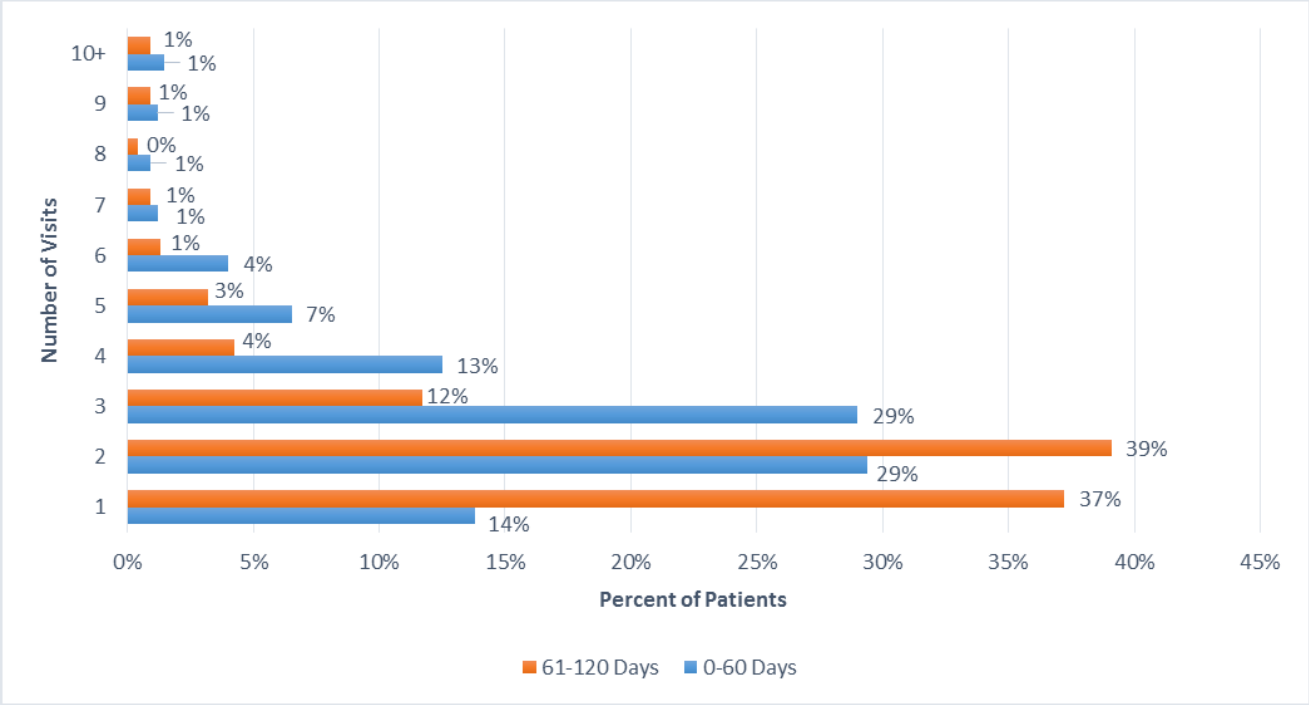
Note on boxplots: upper and lower hinges for each boxplot correspond to the 75th and 25th percentiles of each distribution, respectively. The upper and lower whiskers extend to the highest and lowest values that are within 1.5 x the interquartile range from the upper and lower hinges, respectively. Data beyond the whiskers, plotted as individual points, are outliers.

Purchasing Activity in First Four Months of Program Participation

Patients beginning medical cannabis treatment often try different types of products with varying ratios of THC:CBD and routes of administration to achieve optimal symptom management; therefore patients may be more likely to make more visits to cannabis patient centers at the beginning of treatment and fewer visits in later times once the patient's regimen had been established. As seen in Figure 4.2, frequency of visits (represented as time between consecutive visits) varies widely across patients. To compare purchasing activity in the first two months versus the second two months of program activity, the number of visits for each patient with continuous enrollment was examined in the first and second 60 days of program activity (day 0 defined as the date of first medical cannabis purchase). Patients who made no

purchases between days 61 and 120 or beyond day 120 were excluded to eliminate patients who had atypical purchasing activity or quit the program during this time window. Figure 4.3 shows the distribution of number of visits per patient which occurred in the first and second 60 days of program activity (n=752). During the first 60 days of program activity, median number of visits was 3 and 543 of 752 patients in this group (72%) made three or fewer purchases. During days 61-120 of program activity, median number of visits was 2 and 662 of 752 patients (88%) made three purchases or less. While the distributions of purchasing activity in the first 60 days and second 60 days is roughly similar, they indicate that purchasing activity is slightly greater during the first 60 days of program activity.

Figure 4.3. Number of visits in first 60 days and second 60 days of program activity, for patients with one or more purchases in both 60 day intervals.

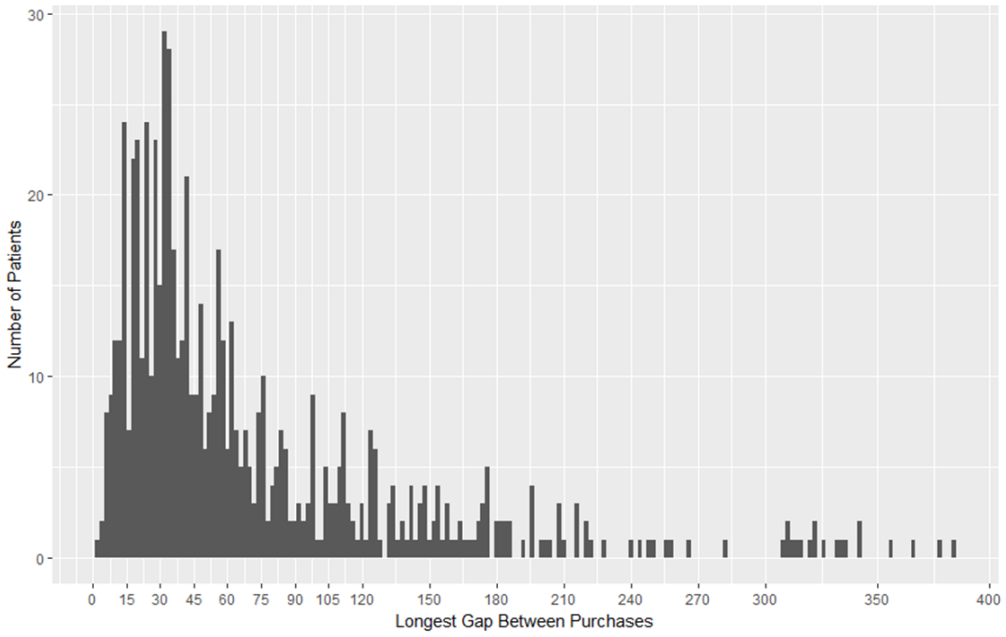


Patients Who Stopped Purchasing Medical Cannabis

Since patients make an annual payment to be enrolled in the medical cannabis program, if they decide at some point during the following year to discontinue medical cannabis treatment, it is unlikely they will request to be withdrawn from the program, as there is no financial incentive to do so. Therefore, to understand discontinuation in the program, a functional definition was created based on purchasing patterns. For each patient in the one year cohort enrolled with a first purchase prior to December 31, 2015 and making at least two purchases before December 31, 2016 (n=669), the longest gap between consecutive purchases from July 2015-December 2016 is shown in Figure 4.4; median longest gap in this group was 47 days. Among these

patients, 546 (82%) had a longest gap between purchases of 120 days or less; 616 (92%) had a longest gap between purchases of 180 days or less. Median longest gap for each patient is significantly longer than median time between visits for patient's first six visits; this suggests that there may be a great deal of variability within a patient's inter-visit times. Early patient responses to the Continued Use survey point to factors which may impact purchasing frequency: unexpectedly low rate of product usage, cost-motivated reduction or temporary cessation of product usage, unrelated medical treatment changes which interfered with cannabis usage, or out-of-state travel.

Figure 4.4. Distribution of longest gap between visits per patient, July 2015-December 2016.



Since most patients (92%) enrolled and purchasing within the first six program months who made two or more purchases by December 31, 2016 had no inter-visit gaps longer than 180 days, program discontinuation was defined for this analysis as ceasing purchasing activity for six months or longer during the period included in this analysis (July 2015-December 2016). This definition was applied to all patients enrolled in the first six program months who made at least one purchase (n=774) to find the proportion of patients (regardless of duration enrolled in the program) who did not make any purchases for at least six months, through the end of 2016. Of these 774 patients making at least one medical cannabis purchase, 398 patients (51%) made no purchases for at least six months, as of December 2016. Based on the distribution of longest gaps between purchases in this subset of the one-year cohort, it is likely that this proportion is

a rough estimate of the proportion of patients who quit the program within 18 months after trying medical cannabis.

Using a six month window with no purchases as a surrogate for program discontinuation has limitations. For example, our analysis did not account for duration of enrollment and any effect it may have on purchasing patterns. However, it gives an approximation of patients who abandon medical cannabis treatment and roughly aligns with the re-enrollment rate of 45% in patients enrolled in the first program month (see “Re-Enrollment” in Chapter 2: Description of Patients and Designated Caregivers).

Frequency and Duration of Medical Cannabis Purchases: Conclusions

Most patients make their first medical cannabis purchase within 14 days of program approval. Subsequent purchases often follow a roughly monthly periodicity, with median inter-visit gap at 25 days for the gap between the first and second visit and 28 days for the next four inter-visit gaps. Additionally, patients tend to make purchases slightly more frequently in the first 60 days of program activity compared to the second 60 days of program activity (median number of visits is 3 from 0-60 days and 2 from 61-120 days). Finally, most patients (92%) do not have an inter-visit gap longer than 180 days; using 6 months or more of no purchasing activity as a surrogate for program discontinuation, 51% of patients who enrolled and made a purchase within the first six months of the program ceased purchasing medical cannabis as of December 31, 2016.

5. Medical Cannabis Use Patterns

Medical cannabis purchasing records were extracted from the registry in early March 2017 for patients enrolled in the 1st program year. From this data, all transactions that occurred within a patient's first enrollment year were retained. For those patients whose first enrollment year had not yet ended at the time of data extraction, all purchasing transactions were retained. This resulted in a dataset with the following:

- 10,898 purchasing transactions consisting of:
- 16,238 products within these transactions (37.9% of all purchasing transactions consisted of two or more products), which
- Represented 1529 patients (92.1% of the first program year cohort).

For analytical purposes, all 16,238 product transactions were classified according to the ratio of delta-9-tetrahydrocannabinol (THC) to cannabidiol (CBD) found in the medical cannabis products. Products ranged from containing very high THC to CBD content to those with very high CBD to THC, as well as everything in between (products with relatively balanced amounts of THC and CBD). For definitions on THC:CBD ratio classifications, see Box 5.1.

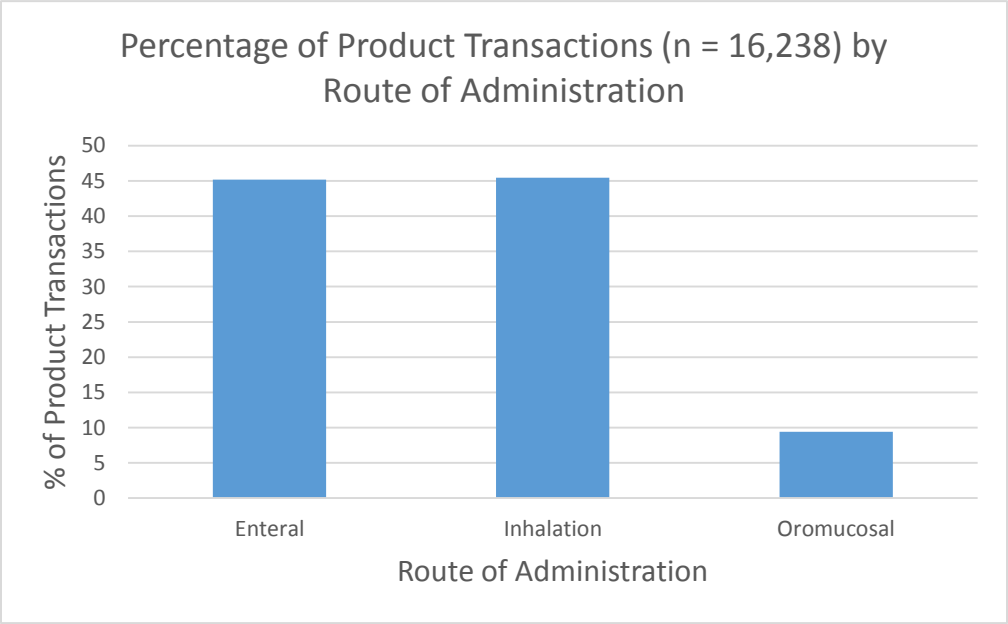
Box 5.1. Definitions to classify medical cannabis products by THC:CBD ratios.

Product Classifications Based on THC to CBD content:

- **Very High THC to CBD** = 100:1 or higher
- **High THC to CBD** = >4:1 up to 99:1
- **Balanced** = 1:1 up to 4:1
- **High CBD to THC** = ≥1:1 up to 99:1
- **Very High CBD to THC** = 100:1 or higher

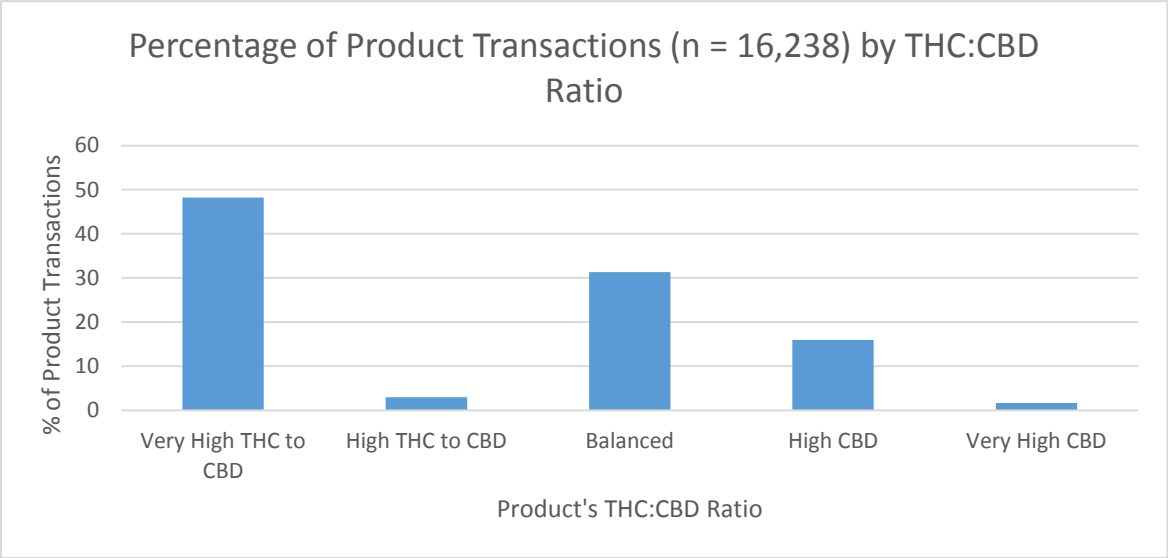
Products purchased for enteral administration (swallowed – includes capsules and oral solutions) and inhalation (vaporized oil) represented the majority of the products purchased (90.6% of all product transactions) with significantly fewer products purchased for oromucosal absorption (oil absorbed through cheek; 9.4% of all product transactions). In fact, products for enteral administration and inhalation were roughly equally purchased by patients, respectively representing 45.2% (n = 7333) and 45.4% (n = 7376) of all products dispensed. See Figure 5.1.

Figure 5.1. Purchasing transactions categorized by the product's intended route of administration (out of 16,238 products dispensed).



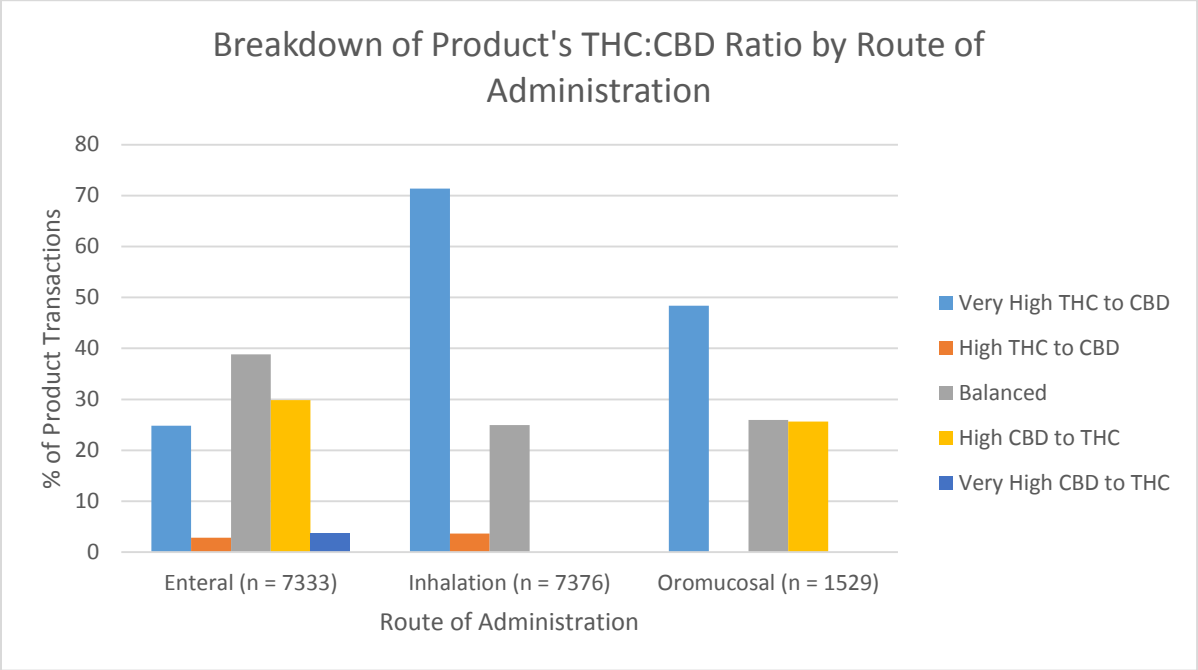
When products were classified by the ratio of THC to CBD present in the product, the following patterns emerged. Firstly, 48.2% of all product transactions were for products with very high THC amounts compared to CBD (hundreds to one). Balanced products (roughly equal amounts of THC to CBD) represented the next biggest group of products purchased, representing 31.3% of products dispensed. This was followed by high CBD to THC products which represented 15.9% of all product transactions. See Figure 5.2.

Figure 5.2. Product transactions represented by the THC to CBD ratio available in the product.



Product transactions were also examined by the products' THC:CBD ratios as a function of their routes of administration (see Figure 5.3). Of all product transactions intended for enteral administration, close to 39% of them were for products with relatively balanced THC:CBD ratios followed by products with high CBD:THC (29.9%) and very high THC:CBD products (24.8%). Product transactions for inhalation predominately had very high THC to CBD (71.4%). Lastly, close to half (48.4%) of all oromucosal product transactions were for very high THC:CBD products, with roughly a quarter each constituting balanced and high CBD to THC products (respectively 26.0% and 25.6%).

Figure 5.3. A percentage breakdown of product transactions by the THC:CBD product ratio types as a function of route of administration.



Most Frequently Purchased Product(s)

Examining purchasing history across all patients is very complex. For example, patients may experiment with different products as they explore what works best for them, and some may establish a pattern of using more than one product. Additionally, those using more than one product do not always purchase all of those products at each purchasing transaction. As a first approach to assessing routine use of products, we report here the product(s) most frequently purchased by each patient. Table 5.1 shows the product(s) that were identified as the most frequently purchased by patients (indicated by "X"), as well as the percentage of patients it represents from the 1529 patients included in this analysis. Additionally, the table displays the average daily THC and CBD dose across patients for the product(s) purchased most frequently based on THC/CBD content information (provided by the medical cannabis manufacturers) as well as pharmacist-entered information regarding the length of time the product supply should last. Omitted from display in Table 5.1 are cases where two or less people had the same combination of most frequently purchased product(s)—this was done for ease of interpretation, as some of those cases seemed to be indicative of a wider range of experimentation across multiple products and/or indicative of patients with a shorter purchasing history.

Table 5.1 shows that roughly 72% of all patients most frequently purchased a single product that falls under 1) a specific THC:CBD ratio and 2) is intended for a particular route of administration (note the rows that have a single "X" in Table 5.1). Roughly a quarter of all patients most frequently purchased a very high THC to CBD product intended for vaporization followed by relatively similar numbers of patients most frequently purchasing a single, balanced-enteral product or a single, high CBD:THC-enteral product (respectively 12.6% and 13.7%). For patients most frequently purchasing two or more products an equal number of times, the most common combination was for an enteral-balanced product and an inhaled-very high THC:CBD product, accounting for 3% of all patients.

While the subsequent portions of this section will be devoted to stratifying routine product use by qualifying condition, the following statement should be made: the method for determining routine product use in this report (most frequently purchased) is relatively simple and, therefore, poses limitations for understanding the complexities in medication usage. Future endeavors will include a further discussion and potential refinement in methodology to better capture medical cannabis use in program participants

Table 5.1. Product(s) most frequently purchased by each patient (out of 1529 patients), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 1529 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
					X										25.4 (389)	83.2 mg / 0.4 mg
			X												13.7 (209)	8.5 mg / 174.2 mg
		X													12.6 (193)	38.8 mg / 29.7 mg
							X								5.8 (88)	39.5 mg / 17.2 mg
X															5.0 (77)	70.8 mg / 0.3 mg
										X					4.3 (66)	39.8 mg / 0.2 mg
		X			X										3.0 (46)	99.2 mg / 47.5 mg
					X		X								2.7 (41)	84.9 mg / 14.0 mg
X					X										2.4 (36)	69.5 mg / 0.4 mg
												X			2.2 (34)	46.3 mg / 33.0 mg
		X					X								2.1 (32)	44.0 mg / 26.5 mg
X		X													1.4 (21)	48.0 mg / 15.0 mg
				X											1.3 (20)	6.9 mg / 1225.3 mg
		X								X					1.2 (19)	82.5 mg / 30.8 mg
					X					X					1.2 (18)	91.3 mg / 0.5 mg
													X		1.2 (18)	2.9 mg / 121.6 mg
X										X					1.0 (15)	46.8 mg / 0.2 mg
X		X					X								0.9 (14)	65.6 mg / 18.2 mg
X		X			X		X								0.7 (11)	164.8 mg / 54.1 mg
X		X			X										0.7 (10)	137.0 mg / 21.9 mg
		X			X		X								0.6 (9)	838.8 mg / 211.5 mg
						X									0.6 (9)	963.5 mg / 56.7 mg
		X	X												0.5 (8)	18.4 mg / 121.9 mg
X					X					X					0.5 (7)	119.6 mg / 0.6 mg
	X														0.5 (7)	873.5 mg / 19.2 mg
		X	X				X								0.4 (6)	37.0 mg / 105.6 mg
			X	X											0.3 (5)	10.9 mg / 539.0 mg
			X		X										0.3 (5)	56.8 mg / 224.2 mg
			X				X								0.3 (5)	66.7 mg / 663.6 mg
					X	X									0.3 (5)	205.7 mg / 8.8 mg
										X		X			0.3 (5)	46.6 mg / 10.4 mg
		X										X			0.3 (4)	63.9 mg / 45.8 mg
			X							X					0.3 (4)	32.3 mg / 78.8 mg

Table 5.1 Continued. Product(s) most frequently purchased by each patient (out of 1529 patients), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 1529 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
X		X	X												0.2 (3)	110.4 mg / 125.2 mg
X		X								X					0.2 (3)	54.1 mg / 8.7 mg
X					X		X								0.2 (3)	122.7 mg / 25.1 mg
	X	X			X										0.2 (3)	94.4 mg / 11.3 mg
							X					X			0.2 (3)	52.2 mg / 23.4 mg
							X						X		0.2 (3)	30.5 mg / 133.2 mg
												X	X		0.2 (3)	31.5 mg / 134.4 mg

Severe and Persistent Muscle Spasm Patients

Of the 1529 patients represented in this analysis, 44.3% (677) of them were certified as having Severe and Persistent Muscle Spasms, including those Characteristic of Multiple Sclerosis. Table 5.2 shows the product(s) that were identified as the most frequently purchased by muscle spasm patients (indicated by “X”), as well as the percentage of patients it represents from the 677 patients included in this analysis.

The most frequently purchased product for the majority of patients (70.2%) was a single product with a specific THC:CBD ratio and route of administration. The most common product purchased was a very high THC:CBD-inhaled product (32.3% of all patients) followed by a balanced-enteral and balanced-inhaled product (16.7% and 7.2%, respectively). For patients who purchased multiple products most frequently an equal number of times, the most common combination purchased was for a very high THC:CBD-inhaled product and a balanced-enteral product, accounting for 4.3% of all patients.

Table 5.2. Product(s) most frequently purchased by each muscle spasm patient (out of 677 patients), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 677 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
					X										32.3 (219)	95.2 mg / 0.4 mg
		X													16.7 (113)	37.8 mg / 31.4 mg
							X								7.2 (49)	34.1 mg / 16.9 mg
X															5.3 (36)	69.0 mg / 0.3 mg
		X			X										4.3 (29)	115.7 mg / 64.8 mg
					X		X								4.0 (27)	89.2 mg / 15.0 mg
			X												2.8 (19)	9.9 mg / 190.1 mg
										X					2.8 (19)	41.0 mg / 0.2 mg
		X					X								2.4 (16)	46.3 mg / 27.9 mg
X					X										1.9 (13)	72.9 mg / 0.4 mg
												X			1.9 (13)	19.7 mg / 14.2 mg
X		X													1.5 (10)	57.0 mg / 18.4 mg
X		X			X										1.0 (7)	167.3 mg / 24.2 mg
X		X					X								1.0 (7)	67.2 mg / 18.3 mg
		X								X					1.0 (7)	60.0 mg / 23.8 mg
X		X			X		X								0.9 (6)	219.9 mg / 77.3 mg
		X	X												0.7 (5)	16.8 mg / 102.8 mg
		X			X		X								0.7 (5)	1449.9 mg / 370.4 mg
						X									0.7 (5)	150.9 mg / 8.9 mg
					X					X					0.6 (4)	111.8 mg / 0.6 mg
X										X					0.4 (3)	54.9 mg / 0.2 mg
		X	X				X								0.4 (3)	50.7 mg / 121.2 mg
	X				X										0.3 (2)	170.3 mg / 4.5 mg
			X		X										0.3 (2)	56.3 mg / 90.6 mg
			X				X								0.3 (2)	30.3 mg / 80.0 mg
					X	X									0.3 (2)	184.2 mg / 7.9 mg
										X		X			0.3 (2)	39.7 mg / 15.1 mg
X		X	X												0.3 (2)	38.1 mg / 89.9 mg
X					X					X					0.3 (2)	193.1 mg / 1.0 mg
X		X			X					X					0.3 (2)	107.6 mg / 14.2 mg

Table 5.2 Continued. Product(s) most frequently purchased by each muscle spasm patient (out of 677 patients), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 677 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
	X														0.1 (1)	166.7 mg / 15.7 mg
				X											0.1 (1)	1.0 mg / 182.6 mg
X							X								0.1 (1)	131.4 mg / 18.2 mg
		X		X											0.1 (1)	10.1 mg / 205.5 mg
		X				X									0.1 (1)	80.7 mg / 24.3 mg
		X										X			0.1 (1)	37.4 mg / 37.4 mg
		X											X		0.1 (1)	12.8 mg / 153.4 mg
			X							X					0.1 (1)	16.2 mg / 40.0 mg
			X									X			0.1 (1)	153.9 mg / 919.7 mg
			X										X		0.1 (1)	33.9 mg / 644.0 mg
					X								X		0.1 (1)	88.5 mg / 99.2 mg
							X					X			0.1 (1)	59.0 mg / 41.0 mg
							X						X		0.1 (1)	34.2 mg / 67.2 mg
												X	X		0.1 (1)	39.7 mg / 146.9 mg
X	X	X													0.1 (1)	65.8 mg / 8.0 mg
X	X			X											0.1 (1)	106.1 mg / 201.4 mg
X	X				X										0.1 (1)	111.3 mg / 6.1 mg
X			X		X										0.1 (1)	113.8 mg / 47.7 mg
X					X		X								0.1 (1)	118.8 mg / 36.9 mg
	X				X		X								0.1 (1)	146.1 mg / 18.2 mg
		X	X							X					0.1 (1)	42.3 mg / 113.4 mg
		X	X									X			0.1 (1)	107.4 mg / 108.7 mg
		X			X					X					0.1 (1)	138.5 mg / 43.4 mg
		X			X							X			0.1 (1)	86.4 mg / 44.6 mg
		X					X			X					0.1 (1)	76.5 mg / 32.6 mg
		X								X		X			0.1 (1)	81.1 mg / 51.2 mg
			X	X			X								0.1 (1)	34.7 mg / 302.1 mg
			X		X		X								0.1 (1)	91.7 mg / 742.3 mg
					X		X			X					0.1 (1)	314.3 mg / 25.7 mg
					X		X					X			0.1 (1)	232.5 mg / 127.7 mg

Table 5.2 Continued. Product(s) most frequently purchased by each muscle spasm patient (out of 677 patients), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 677 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
					X		X						X		0.1 (1)	117.1 mg / 112.0 mg
					X					X			X		0.1 (1)	88.3 mg / 47.9 mg
X		X	X				X								0.1 (1)	44.7 mg / 117.0 mg
	X	X			X		X								0.1 (1)	121.6 mg / 31.4 mg
		X	X		X		X								0.1 (1)	70.4 mg / 111.2 mg
		X	X				X					X			0.1 (1)	53.1 mg / 129.1 mg
		X			X		X			X					0.1 (1)	138.2 mg / 21.4 mg
		X				X	X					X			0.1 (1)	258.3 mg / 98.3 mg
			X	X	X					X					0.1 (1)	692.0 mg / 248.8 mg
X		X	X	X			X								0.1 (1)	86.0 mg / 6117.0 mg
X		X			X		X			X					0.1 (1)	135.6 mg / 10.6 mg
		X	X				X			X		X			0.1 (1)	65.8 mg / 69.9 mg
X		X	X	X	X		X								0.1 (1)	139.1 mg / 304.6 mg
X		X			X	X	X			X					0.1 (1)	303.9 mg / 27.8 mg
		X	X		X	X						X	X		0.1 (1)	189.7 mg / 130.6 mg
		X	X		X		X			X		X			0.1 (1)	161.6 mg / 848.6 mg

Cancer Patients

Of the 1529 patients represented in this analysis, 26.6% (406) of them were certified for Cancer. Table 5.3 shows the product(s) that were identified as the most frequently purchased by cancer patients (indicated by “X”), as well as the percentage of patients it represents from the 406 patients included in this analysis.

The majority of patients (61.6%) most frequently purchased a single product with a specific THC:CBD ratio and route of administration. Most commonly purchased products were a very high THC:CBD-inhaled product (23.9% of all patients) followed by a balanced-enteral and very high THC:CBD-oromucosal product (10.3% and 9.6%, respectively). For patients who purchased multiple products most frequently an equal number of times, the most common combination purchased was for a very high THC:CBD product – one for enteral administration and one for inhalation (accounted for 5.4% of all patients).

Table 5.3. Product(s) most frequently purchased by each cancer patient (out of 406 patients), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 406 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
					X										23.9 (97)	81.4 mg / 0.4 mg
		X													10.3 (42)	46.4 mg / 28.4 mg
										X					9.6 (39)	37.3 mg / 0.2 mg
X															5.9 (24)	108.0 mg / 0.5 mg
X					X										5.4 (22)	62.9 mg / 0.4 mg
							X								3.7 (15)	69.2 mg / 22.6 mg
					X					X					3.2 (13)	87.0 mg / 0.4 mg
		X					X								3.0 (12)	37.7 mg / 21.9 mg
												X			2.7 (11)	58.5 mg / 54.2 mg
		X			X										2.7 (11)	70.6 mg / 17.3 mg
			X												2.5 (10)	9.6 mg / 239.3 mg
X										X					2.2 (9)	45.5 mg / 0.2 mg
		X								X					2.2 (9)	111.8 mg / 39.0 mg
					X		X								1.7 (7)	68.7 mg / 13.7 mg
X		X					X								1.7 (7)	82.8 mg / 22.8 mg
				X											1.5 (6)	3.8 mg / 666.5 mg
X		X													1.5 (6)	47.6 mg / 9.5 mg
X					X					X					1.2 (5)	90.3 mg / 0.5 mg
	X														1.0 (4)	28.6 mg / 5.4 mg
X		X			X		X								1.0 (4)	102.0 mg / 25.3 mg
		X										X			0.7 (3)	72.7 mg / 48.6 mg
										X		X			0.7 (3)	51.2 mg / 7.2 mg
X		X			X										0.7 (3)	64.4 mg / 11.3 mg
X		X								X					0.7 (3)	54.1 mg / 8.7 mg
	X	X			X										0.7 (3)	94.4 mg / 11.3 mg
		X	X				X								0.7 (3)	24.2 mg / 92.5 mg
		X			X		X								0.7 (3)	80.9 mg / 13.3 mg
						X									0.5 (2)	3812.7 mg / 224.3 mg
		X	X												0.5 (2)	20.1 mg / 200.4 mg
			X							X					0.5 (2)	43.0 mg / 97.6 mg
					X	X									0.5 (2)	227.9 mg / 10.4 mg
							X					X			0.5 (2)	48.8 mg / 14.5 mg

Table 5.3 Continued. Product(s) most frequently purchased by each cancer patient (out of 406 patients), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 406 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
													X		0.2 (1)	3.4 mg / 64.8 mg
X			X												0.2 (1)	33.1 mg / 150.1 mg
X												X			0.2 (1)	18.7 mg / 8.8 mg
	X	X													0.2 (1)	181.3 mg / 35.6 mg
	X		X												0.2 (1)	282.1 mg / 525.9 mg
			X		X										0.2 (1)	47.6 mg / 150.2 mg
					X							X			0.2 (1)	97.9 mg / 31.4 mg
					X								X		0.2 (1)	60.8 mg / 117.1 mg
												X	X		0.2 (1)	32.7 mg / 135.4 mg
X	X			X											0.2 (1)	106.1 mg / 201.4 mg
X		X	X												0.2 (1)	13.0 mg / 49.5 mg
X					X		X								0.2 (1)	185.0 mg / 20.5 mg
X					X							X			0.2 (1)	94.5 mg / 24.7 mg
		X			X					X					0.2 (1)	125.6 mg / 50.4 mg
					X		X					X			0.2 (1)	232.5 mg / 127.7 mg
X		X			X	X									0.2 (1)	427.4 mg / 64.7 mg
			X	X	X					X					0.2 (1)	692.0 mg / 248.8 mg
X	X	X	X		X										0.2 (1)	278.3 mg / 302.9 mg
X		X	X		X					X					0.2 (1)	135.4 mg / 296.4 mg
		X	X	X	X		X								0.2 (1)	184.5 mg / 237.7 mg
		X			X		X			X		X			0.2 (1)	128.8 mg / 16.4 mg
		X			X		X					X	X		0.2 (1)	154.6 mg / 139.8 mg

Seizure Patients

Of the 1529 patients represented in this analysis, 19.8% (303) of them were certified for Seizures, including those Characteristic of Epilepsy. Table 5.4 shows the product(s) that were identified as the most frequently purchased by seizure patients (indicated by “X”), as well as the percentage of patients it represents from the 303 patients included in this analysis.

89.1% of all patients most frequently purchased a single product with a specific THC:CBD ratio and route of administration. Most commonly used products were a high CBD:THC-enteral product (59.7% of all patients) followed by a very high THC:CBD-inhaled product and high CBD:THC-oromucosal product (7.9% and 5.0%, respectively).

Table 5.4. Product(s) most frequently purchased by each seizure patient (out of 303), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 303 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
			X												59.7 (181)	8.3 mg / 170.6 mg
					X										7.9 (24)	75.2 mg / 0.4 mg
													X		5.0 (15)	2.7 mg / 130.4 mg
		X													4.6 (14)	31.1 mg / 24.8 mg
				X											4.3 (13)	7.9 mg / 1394.4 mg
							X								3.6 (11)	36.3 mg / 14.7 mg
												X			2.0 (6)	96.7 mg / 43.3 mg
			X	X											1.7 (5)	10.9 mg / 539.0 mg
X															1.3 (4)	7.8 mg / 0.0 mg
			X				X								1.3 (4)	72.7 mg / 815.1 mg
X		X													0.7 (2)	46.5 mg / 16.6 mg
		X	X												0.7 (2)	22.1 mg / 64.1 mg
		X					X								0.7 (2)	56.7 mg / 46.0 mg
					X		X								0.7 (2)	151.4 mg / 27.6 mg
							X						X		0.7 (2)	32.7 mg / 89.4 mg
X	X	X	X		X										0.3 (1)	278.3 mg / 302.9 mg
X		X	X												0.3 (1)	63.2 mg / 130.4 mg
X		X			X										0.3 (1)	55.3 mg / 3.2 mg
X		X					X								0.3 (1)	36.1 mg / 9.7 mg
X					X		X								0.3 (1)	64.3 mg / 17.7 mg
		X		X											0.3 (1)	10.1 mg / 205.5 mg
		X											X		0.3 (1)	10.0 mg / 100.0 mg
			X	X									X		0.3 (1)	16.5 mg / 492.9 mg
			X		X										0.3 (1)	75.2 mg / 723.6 mg
			X										X		0.3 (1)	33.9 mg / 644.0 mg
				X			X								0.3 (1)	19.0 mg / 217.9 mg
					X	X									0.3 (1)	204.3 mg / 7.3 mg
					X								X		0.3 (1)	88.5 mg / 99.2 mg
						X									0.3 (1)	170.0 mg / 10.0 mg
										X					0.3 (1)	18.0 mg / 0.1 mg
												X	X		0.3 (1)	39.7 mg / 146.9 mg

Crohn's Disease Patients

Of the 1529 patients represented in this analysis, 6.7% (103) of them were certified for Crohn's Disease. Table 5.5 shows the product(s) that were identified as the most frequently purchased by Crohn's patients (indicated by "X"), as well as the percentage of patients it represents from the 103 patients included in this analysis.

71.8% of all patients most frequently purchased a single product with a specific THC:CBD ratio and route of administration. Most commonly used products were a very high THC:CBD-inhaled product (28.2% of all patients) followed by a balanced-enteral and balanced-inhaled product (16.5% and 8.7%, respectively). For patients who purchased multiple products most frequently an equal number of times, the most common combination identified was for a balanced-enteral product and a very high THC:CBD-inhaled product, accounting for 4.9% of all patients.

Table 5.5. Product(s) most frequently purchased by each Crohn's Disease patient (out of 103 patients), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 103 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
					X										28.2 (29)	70.0 mg / 0.4 mg
		X													16.5 (17)	31.9 mg / 31.5 mg
							X								8.7 (9)	28.5 mg / 12.5 mg
			X												5.8 (6)	15.6 mg / 297.4 mg
		X			X										4.9 (5)	68.9 mg / 16.9 mg
										X					3.9 (4)	35.8 mg / 0.2 mg
						X									2.9 (3)	153.8 mg / 9.0 mg
X					X										2.9 (3)	81.9 mg / 0.6 mg
X															1.9 (2)	15.3 mg / 0.0 mg
												X			1.9 (2)	21.3 mg / 14.5 mg
													X		1.9 (2)	4.4 mg / 83.7 mg
X		X													1.9 (2)	27.8 mg / 13.2 mg
		X					X								1.9 (2)	42.5 mg / 27.9 mg
					X		X								1.9 (2)	68.5 mg / 7.3 mg
		X								X					1.0 (1)	31.2 mg / 15.1 mg
			X		X										1.0 (1)	48.9 mg / 65.8 mg
					X					X					1.0 (1)	65.3 mg / 0.4 mg
X		X			X										1.0 (1)	64.6 mg / 3.3 mg
X										X		X			1.0 (1)	80.0 mg / 25.8 mg
	X				X		X								1.0 (1)	146.1 mg / 18.2 mg
		X	X				X								1.0 (1)	27.5 mg / 57.5 mg
		X			X		X								1.0 (1)	57.0 mg / 11.6 mg
		X					X					X			1.0 (1)	137.5 mg / 87.5 mg
					X		X					X			1.0 (1)	112.1 mg / 35.9 mg
	X	X	X		X										1.0 (1)	112.6 mg / 47.1 mg
		X	X		X		X								1.0 (1)	97.8 mg / 109.5 mg
		X				X	X					X			1.0 (1)	258.3 mg / 98.3 mg
X		X	X	X			X								1.0 (1)	86.0 mg / 6117.0 mg
X		X			X		X			X		X			1.0 (1)	299.4 mg / 152.0 mg

Terminal Illness Patients

Of the 1529 patients represented in this analysis, 5.4% (82) of them were certified for Terminal Illness. Table 5.6 shows the product(s) that were identified as the most frequently purchased by terminal illness patients (indicated by “X”), as well as the percentage of patients it represents from the 82 patients included in this analysis.

68.3% of all patients most frequently purchased a single product with a specific THC:CBD ratio and route of administration. Most commonly used products were a very high THC:CBD-inhaled product (26.8% of all patients) followed by a balanced-enteral and balanced-oromucosal product (both respectively accounting for 8.5% of all patients). For patients who purchased multiple products most frequently an equal number of times, the most common combination identified was for a very high THC:CBD product – one for enteral administration and the other for oromucosal absorption (accounted for 3.7% of all patients).

Table 5.6. Product(s) most frequently purchased by each terminal illness patient (out of 82 patients), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 82 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
					X										26.8 (22)	62.7 mg / 0.4 mg
		X													8.5 (7)	18.9 mg / 18.9 mg
												X			8.5 (7)	24.5 mg / 20.0 mg
										X					7.3 (6)	36.5 mg / 0.1 mg
X															6.1 (5)	17.2 mg / 0.0 mg
			X												6.1 (5)	9.8 mg / 188.2 mg
X										X					3.7 (3)	46.1 mg / 0.1 mg
		X					X								3.7 (3)	47.5 mg / 28.2 mg
						X									2.4 (2)	3812.7 mg / 224.3 mg
X					X										2.4 (2)	57.5 mg / 0.4 mg
		X			X										2.4 (2)	43.0 mg / 2.9 mg
					X					X					2.4 (2)	123.3 mg / 0.5 mg
X		X					X								2.4 (2)	104.5 mg / 25.7 mg
				X											1.2 (1)	5.2 mg / 925.0 mg
							X								1.2 (1)	36.4 mg / 9.1 mg
X		X													1.2 (1)	10.0 mg / 5.0 mg
	X	X													1.2 (1)	37.5 mg / 8.1 mg
		X	X												1.2 (1)	30.6 mg / 293.4 mg
					X		X								1.2 (1)	23.9 mg / 8.8 mg
					X								X		1.2 (1)	60.8 mg / 117.1 mg
							X			X					1.2 (1)	108.5 mg / 11.1 mg
X		X			X										1.2 (1)	66.0 mg / 20.3 mg
X					X					X					1.2 (1)	79.6 mg / 0.4 mg
		X			X		X								1.2 (1)	98.0 mg / 17.9 mg
			X	X	X					X					1.2 (1)	692.0 mg / 248.8 mg
X		X	X		X					X					1.2 (1)	135.4 mg / 296.4 mg
		X			X		X			X		X			1.2 (1)	128.8 mg / 16.4 mg

HIV/AIDS Patients

Of the 1529 patients represented in this analysis, 3.2% (49) of them were certified for Human Immunodeficiency Virus and/or Acquired Immune Deficiency Syndrome (HIV/AIDS). Table 5.7 shows the product(s) that were identified as the most frequently purchased by HIV/AIDS patients (indicated by “X”), as well as the percentage of patients it represents from the 49 patients included in this analysis.

75.5% of all patients most frequently purchased a single product with a specific THC:CBD ratio and route of administration. Most commonly used products were a very high THC:CBD-inhaled product (51.0% of all patients) followed by a balanced-enteral product (12.2% of patients). For patients who purchased multiple products most frequently an equal number of times, the most common combination identified was for two inhaled products – one of a very high THC:CBD ratio and the other a balanced THC:CBD ratio (accounted for 10.2% of all patients).

Table 5.7. Product(s) most frequently purchased by each HIV/AIDS patient (out of 49 patients), along with average daily THC/CBD dose (mg).

Enteral			Inhalation			Oromucosal				
Very High THC to CBD	High THC to CBD	Balanced	Very High THC to CBD	High THC to CBD	Balanced	Very High THC to CBD	High THC to CBD	Balanced	% of Patients out of 49 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
			X						51.0 (25)	93.4 mg / 0.6 mg
		X							12.2 (6)	45.4 mg / 35.9 mg
			X		X				10.2 (5)	76.8 mg / 13.7 mg
X									6.1 (3)	13.4 mg / 0.1 mg
					X				6.1 (3)	30.0 mg / 18.7 mg
		X	X						4.1 (2)	61.3 mg / 16.1 mg
X		X							2.0 (1)	20.0 mg / 15.0 mg
X						X			2.0 (1)	38.4 mg / 0.1 mg
		X			X				2.0 (1)	70.0 mg / 40.0 mg
		X				X			2.0 (1)	53.3 mg / 20.1 mg
			X	X					2.0 (1)	135.0 mg / 5.3 mg

Tourette Syndrome Patients

Of the 1529 patients represented in this analysis, 1.9% (29) of them were certified for Tourette Syndrome. Table 5.8 shows the product(s) that were identified as the most frequently purchased by Tourette Syndrome patients (indicated by “X”), as well as the percentage of patients it represents from the 29 patients included in this analysis.

93.1% of all patients most frequently purchased a single product with a specific THC:CBD ratio and route of administration. Most commonly used products were a balanced-enteral product (20.7% of all patients) followed by a very high THC:CBD-inhaled product and a very high THC:CBD-oromucosal product (respectively at 20.7% and 13.8% of all patients).

Table 5.8. Product(s) most frequently purchased by each Tourette Syndrome patient (out of 29 patients), along with average daily THC/CBD dose (mg).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 29 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
		X													20.7 (6)	37.4 mg / 20.3 mg
					X										20.7 (6)	78.4 mg / 0.3 mg
										X					13.8 (4)	52.0 mg / 0.2 mg
X															10.3 (3)	21.2 mg / 0.1 mg
							X								10.3 (3)	51.8 mg / 20.1 mg
			X												6.9 (2)	33.4 mg / 633.7 mg
X		X			X		X								3.4 (1)	85.0 mg / 30.3 mg
	X									X					3.4 (1)	178.6 mg / 10.0 mg
	X														3.4 (1)	5812.5 mg / 93.0 mg
				X											3.4 (1)	13.4 mg / 2378.6 mg
												X			3.4 (1)	24.2 mg / 24.2 mg

Glaucoma Patients

Of the 1529 patients represented in this analysis, 1.5% (23) of them were certified for Glaucoma. Table 5.9 shows the product(s) that were identified as the most frequently purchased by glaucoma patients (indicated by “X”), as well as the percentage of patients it represents from the 23 patients included in this analysis.

56.5% of all patients most frequently purchased a single product with a specific THC:CBD ratio and route of administration. Most commonly used products were a very high THC:CBD-inhaled product (21.7% of all patients) followed by a very high THC:CBD-enteral product and a balanced-enteral product (respectively at 17.4% and 13.0% of all patients).

Table 5.9. Product(s) most frequently purchased by each glaucoma patient (out of 23 patients), along with average daily THC/CBD dose (mg).

Enteral			Inhalation			Oromucosal				
Very High THC to CBD	Balanced	High CBD to THC	Very High THC to CBD	Balanced	High CBD to THC	Very High THC to CBD	Balanced	High CBD to THC	% of Patients out of 23 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
			X						21.7 (5)	60.1 mg / 0.4 mg
X									17.4 (4)	54.5 mg / 0.3 mg
	X								13.0 (3)	7.1 mg / 3.2 mg
X	X								8.7 (2)	111.8 mg / 21.9 mg
			X	X					8.7 (2)	99.2 mg / 22.6 mg
X	X	X							4.3 (1)	255.0 mg / 195.8 mg
X						X	X		4.3 (1)	71.1 mg / 31.3 mg
X						X			4.3 (1)	61.7 mg / 0.3 mg
	X	X				X			4.3 (1)	42.3 mg / 113.4 mg
	X			X					4.3 (1)	32.0 mg / 8.0 mg
			X	X		X			4.3 (1)	115.9 mg / 31.6 mg
				X					4.3 (1)	40.0 mg / 10.0 mg

ALS Patients

Of the 1529 patients represented in this analysis, 1.4% (21) of them were certified for Amyotrophic Lateral Sclerosis (ALS). Table 5.10 shows the product(s) that were identified as the most frequently purchased by ALS patients (indicated by “X”), as well as the percentage of patients it represents from the 21 patients included in this analysis.

57.1% of all patients most frequently purchased a single product with a specific THC:CBD ratio and route of administration. Most commonly used product was a very high THC:CBD-inhaled product (14.3% of all patients).

Table 5.10. Product(s) most frequently purchased by each ALS patient (out of 21 patients), along with average daily THC/CBD dose (mg).

Enteral				Inhalation				Oromucosal					
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	% of Patients out of 21 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
				X								14.3 (3)	44.8 mg / 0.3 mg
		X						X				9.5 (2)	54.9 mg / 26.6 mg
		X										9.5 (2)	16.1 mg / 7.5 mg
						X						9.5 (2)	25.6 mg / 18.1 mg
								X				9.5 (2)	29.8 mg / 0.1 mg
X								X				4.8 (1)	40.0 mg / 0.1 mg
X												4.8 (1)	16.0 mg / 0.0 mg
	X	X		X	X	X						4.8 (1)	205.5 mg / 24.4 mg
	X											4.8 (1)	20.8 mg / 3.9 mg
		X						X		X		4.8 (1)	81.1 mg / 51.2 mg
			X					X				4.8 (1)	27.1 mg / 80.1 mg
				X						X		4.8 (1)	101.2 mg / 8.7 mg
						X					X	4.8 (1)	26.1 mg / 220.8 mg
										X	X	4.8 (1)	22.2 mg / 120.8 mg
										X		4.8 (1)	28.4 mg / 28.4 mg

Medical Cannabis Use Patterns: Conclusions

To establish medication use patterns in program participants, a total of 16,238 product transactions were analyzed from 1529 patients in the 1st program year cohort. When product transactions were examined by each product's intended route of administration and THC:CBD content, the following patterns emerged. Firstly, roughly 90% of all products were purchased for enteral administration (through mouth via capsules or oral solutions) and inhalation (vaporized oil). Secondly, approximately 50% of all product transactions were for products very high in THC relative to CBD followed by balanced THC:CBD products (~30%) and high CBD:THC products (~15%). Very high THC:CBD products were most commonly purchased for inhalation or oromucosal absorption, while balanced and high CBD:THC products were most commonly used for enteral administration.

For this report, the most frequently purchased product(s) were identified for each patient as one method for understanding routine purchasing patterns. 72.5% of all patients most frequently purchased one type of product, with the most frequently purchased single product being a very high THC:CBD-inhaled product followed by a high CBD:THC-enteral and balanced-enteral product. For specific differences in the most frequently purchased products among qualifying conditions, the reader is encouraged to refer back to those specific sections.

6. Benefits

Summary

Information on patient benefits comes from the Patient Self-Evaluation (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 (see Table 6.1). A small but important proportion of patients indicated little or no benefit: 9% gave a rating of 1, 2, or 3. 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 in *Appendix A: Patient-Reported Benefits from Surveys*. 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."

Table 6.1. Patient-perceived benefit (n=792).

	No Response	1	2 or 3	4 or 5	6 or 7
All Patients	4%	4%	5%	23%	64%
Muscle Spasms	2%	3%	3%	22%	69%
Cancer	5%	5%	6%	21%	64%
Seizures	5%	5%	9%	29%	51%
Crohn's Disease	0%	2%	5%	22%	71%
Terminal Illness	11%	3%	3%	13%	71%
HIV/AIDS	4%	0%	8%	8%	79%
Tourette Syndrome	6%	0%	0%	25%	69%
Glaucoma	23%	8%	0%	0%	69%
ALS	9%	9%	0%	18%	64%

Patient responses about degree of benefit experienced: 1=no benefit; 7=great deal of benefit.

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. In the text of the report, we present results for the more conservative of the two methods used to calculate ≥30% symptom reduction. However, *Appendix D: Symptom Results*

from the Patient Self-Evaluation shows results for both methods (details can be found in this chapter). Results show patterns similar to those in the survey benefits rating, but usually somewhat smaller in size. For example, among patients with muscle spasms, weekly muscle spasm frequency was reduced ≥30% within the first four months of medical cannabis use in 48% of patients (see Table 6.2). Importantly, in the four months after first achieving this degree of spasm reduction, more than half the patients retained this degree of improvement. That is, of all patients with muscle spasms, 48% achieved ≥30% reduction in spasm frequency and 28% both achieved that degree of improvement and retained it over the next four months. Full results for symptom improvement analyses and for persistence of improvements are in *Appendix D: Symptom Results from the Patient Self-Evaluation*. Results for selected symptoms are presented in Table 6.2. 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
- Among cancer patients with at least moderate levels of nausea when they started using medical cannabis, 38% reported ≥30% reduction of nausea and 23% both achieved that level of reduction and retained it, on average, for at least four months
- Among cancer patients with at least moderate levels of pain when they started using medical cannabis, 29% reported ≥30% reduction of pain and 12% 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 meaningful improvement was analyzed for each symptom assessed within each category of medical condition. Full results of those analyses are in *Appendix D: Symptom Results from the Patient Self-Evaluation* and summaries are presented in this chapter. In most cases, a few combinations

of product types were purchased more frequently than others when analyzing data by patient condition

Table 6.2 Symptom improvement for selected symptoms. Note: for spasticity, pain, appetite, nausea, and vomiting the analysis was conducted on patients with moderate to severe symptoms at baseline.

	% of Patients who Achieved Threshold Symptom Improvement (≥30% Improvement Unless Otherwise Noted)	% of All Patients that Both Achieved Threshold Symptom Improvement and Retained that Degree of Improvement for at Least 4 Months
MUSCLE SPASMS		
Weekly spasm frequency (n = 629)	48%	28%
Spasticity (n = 618)	36%	17%
Pain (n = 640)	34%	17%
CANCER		
Pain (n = 356)	29%	12%
Appetite (n = 321)	39%	22%
Nausea (n = 283)	38%	23%
Vomiting (n = 168)	48%	27%
SEIZURES		
Weekly seizure frequency (n = 262)	68%	49%
CROHN'S DISEASE		
# Liquid stools/day (n = 41)	51%	29%
Abdominal pain (details in text; n = 73)	53%	19%
General well-being (details in text; n = 15)	47%	13%
Measures Combined (details in text; n = 102)	51%	22%
Weight (≥ 3 pound gain; n = 102)	21%	12%
TERMINAL ILLNESS		
Pain (n = 72)	19%	10%
Appetite (n = 64)	38%	17%
Nausea (n = 56)	45%	29%
Vomiting (n = 35)	57%	29%
HIV/AIDS		
Pain (n = 45)	40%	20%
Appetite (n = 39)	49%	31%
Weight (≥ 3 pound gain; n = 48)	15%	6%
TOURETTE SYNDROME		
Weekly tic frequency (n = 28)	61%	46%
GLAUCOMA (see text)		
ALS		
Weekly spasm frequency (n = 18)	33%	22%
Spasticity (n = 15)	20%	20%
Pain (n = 17)	47%	12%

Benefits Reported on Surveys

In addition to collecting data on severity of symptoms related to each patient's qualifying condition or conditions before each medical cannabis purchase, the Office of Medical Cannabis sought to gain a qualitative understanding of patient-reported benefits and harms of program participation. Utilizing expertise within the Minnesota Department of Health, the Office of Medical Cannabis developed a Patient Experience survey, which captures information on benefits and harms of program participation. A parallel survey was developed for each patient's certifying health care practitioner, which captures similar information from the clinician's perspective. The surveys include scaled response and open-response questions; health care practitioners were also asked to provide any clinical observations they noted about the patient's experience with medical cannabis. Healthcare providers familiar with the program provided feedback as part of the development process.

Survey Methodology and Data Preparation

The surveys are provided through an online platform with a hard copy alternative. The Patient Experience survey is sent three months after the patient's first medical cannabis purchase, six months after the first purchase and every six months thereafter. Healthcare practitioner surveys are sent six months after the patient's first purchase and every six months thereafter. Surveys are accessible through the patient or healthcare practitioner's registry page and through introductory emails containing unique links. To maximize survey submission rates, the survey can be submitted with incomplete responses to any of the questions. Each of the surveys is available online to the recipient for 45 days. Patient recipients receive reminder emails after one week; after two weeks with no response, paper copies of surveys are mailed to the recipient. For patients without online access the full process is accomplished by mail.

Initially, patient and healthcare practitioners (HCPs) were sent one survey three months after the patient's first purchase, without recurrence. This schedule was revised to include recurring surveys roughly every six months to provide patients and their HCPs an opportunity to report ongoing progress or changes to the patient's condition; however the HCP survey sent three months after the first purchase was eliminated based on feedback that three months may not allow enough time for the provider to see their patient following initial certification. These changes were implemented in April 2016; as a result, HCP survey data collected three months after the first purchase is only available for the first six months of the program (this includes patients who enrolled and made a first purchase between July 1, 2015 and December 31, 2015). All survey data presented in this chapter are from the patient and health care practitioner surveys sent three months after the patient's first medical cannabis purchase.

Patients and their certifying HCPs were asked to report the "most important benefit" and "most important negative effect" related to medical cannabis treatment. Survey responses from patients and health care practitioners on perceived benefits and perceived negative effects

were reported in free-text format; each response was individually reviewed and classified into a category of benefit or negative effects. Reported benefits typically included either direct improvement of symptoms related to the patient's qualifying condition or more general improvements in health or quality of life, referred to in this report as global health benefits. Additionally, many responses included more than one type of benefit; in these cases, the first reported benefit was presumed to be the most important benefit. In this report, we examine both overall perceptions of benefit, as well as type of reported benefit.

Patient Experience Survey Results

Patient Experience Survey Response Rate

Of 1491 patients who were approved and made their first medical cannabis purchase in the first year of the program (July 1, 2015- June 30, 2016), 792 patients (53%) submitted a survey three months after making the first purchase. As of December 31, 2016, 90 patients (5%) were known to be deceased since enrolling in the program. These patients were included in this report, as in some cases caregivers or relatives and HCPs completed surveys, reflecting on the patient's experience for the period of time the patient did use medical cannabis.

Table 6.3. Patient survey response rates by age group.

	Total	Patient Responses
0-4	62	17 (53%)
5-17	129	76 (59%)
18-24	89	51 (57%)
25-35	234	132 (56%)
36-49	355	192 (54%)
50-64	462	258 (56%)
65+	160	66 (41%)
Total	1491	792 (53%)

Table 6.4. Patient total counts and patient response rates by qualifying medical condition.

	Total	Patient Responses
Muscle Spasms	653	373 (57%)
Cancer	386	157 (41%)
Seizures	287	182 (63%)
Crohn's Disease	99	55 (56%)
Terminal Illness	79	38 (48%)
HIV/AIDS	46	24 (52%)
Tourette Syndrome	28	16 (57%)
Glaucoma	21	13 (62%)
ALS	21	11 (52%)

Table 6.5. Patient survey response rates by race and ethnicity.

	Total	Patient Responses
American Indian	37	14 (38%)
Asian	24	8 (33%)
Black	86	35 (41%)
Hawaiian	3	0 (0%)
White	1249	712 (57%)
Other	24	9 (38%)
Hispanic	35	14 (40%)

Patient response rates varied across age group, qualifying condition and race and ethnicity (Tables 6.3-6.5). Elderly patients (ages 65 and over) had the lowest response rate (41%); patients certified for cancer and terminal illness also had low response rates relative to other certified condition groups (41% and 48%, respectively). In general, racial and ethnic minorities were under-represented in survey responses.

Patient Perceptions of Benefits from Medical Cannabis

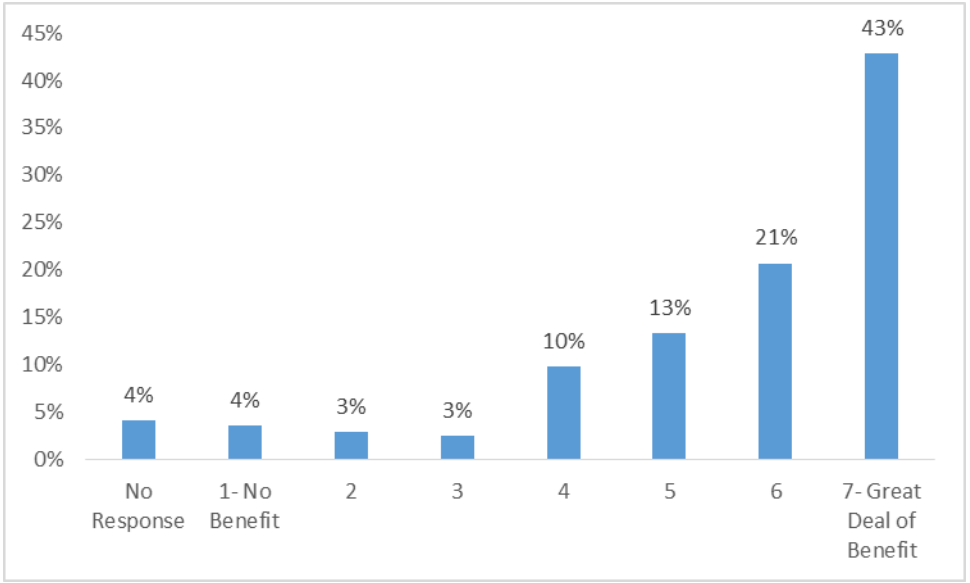
The Patient Experience and HCP surveys both ask respondents to report how much benefit they believe the patient received from using medical cannabis, on a scale from 1 (no benefit) to 7 (a great deal of benefit). Figures 6.1-6.10 show the distribution of benefit scores on this scale, as reported by patients, for all patients and by patients with each qualifying condition.

The percentages in Figures 6.1-6.10 are based on the total number of patient responses in each condition group and not the number of complete benefit scores for each group (33 patients submitted surveys without completing the benefit score question, but were included in the denominators).

ALL QUALIFYING CONDITIONS

Figure 6.1 below shows all patient responses about degree of benefit experienced. Among patient respondents, 43% report the highest degree of benefit from medical cannabis: “a great deal of benefit” or a score of 7 on a scale from 1-7.

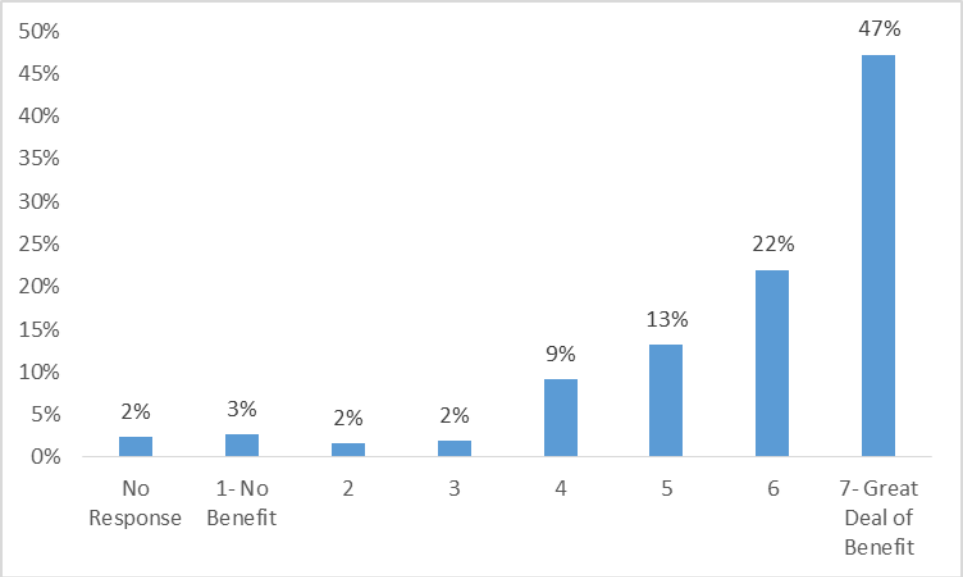
Figure 6.1. Patient-Perceived Benefit: All Conditions (N=792).



SEVERE AND PERSISTENT MUSCLE SPASMS

Figure 6.2 shows responses from patients certified for severe and persistent muscle spasms regarding degree of benefit experienced. Among respondents, 47% report a score of 7 on a scale from 1-7.

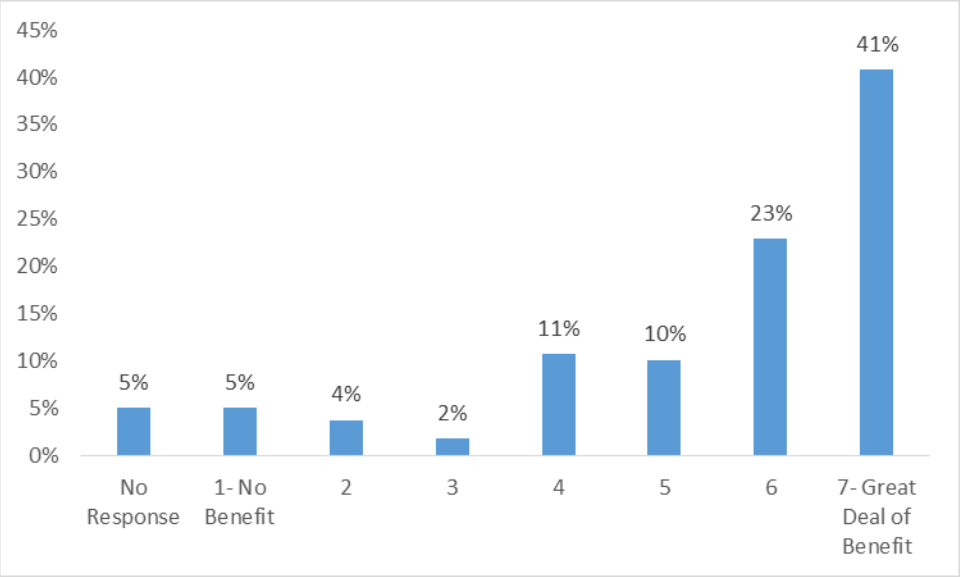
Figure 6.2. Patient-Perceived Benefit: Muscle Spasms (N=373)



CANCER

Figure 6.3 shows responses from patients certified for cancer regarding degree of benefit experienced. Among respondents, 41% report a score of 7 on a scale from 1-7.

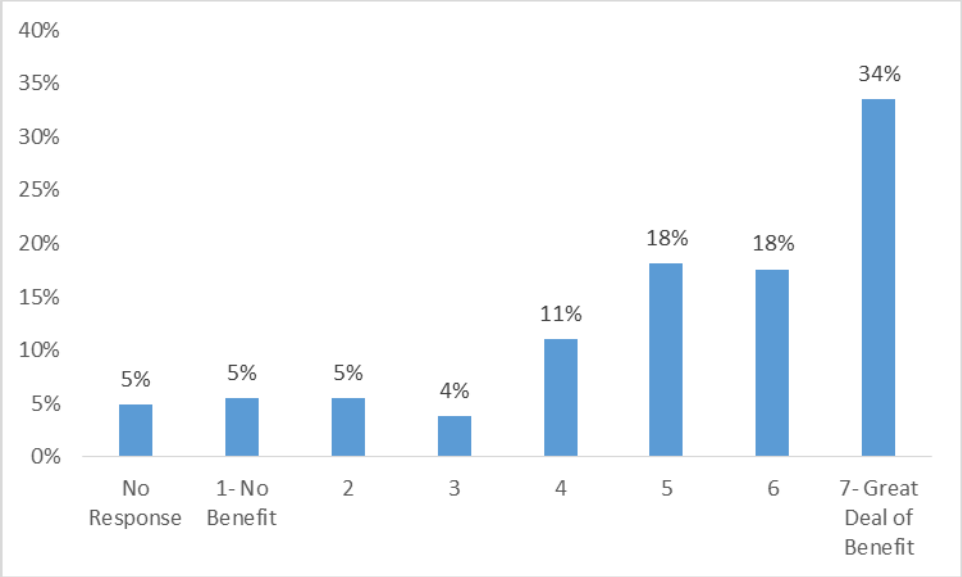
Figure 6.3. Patient-Perceived Benefit: Cancer (N=157)



SEIZURES

Figure 6.4 shows responses from patients certified for seizure disorders regarding degree of benefit experienced. Among respondents, 34% report a score of 7 on a scale from 1-7.

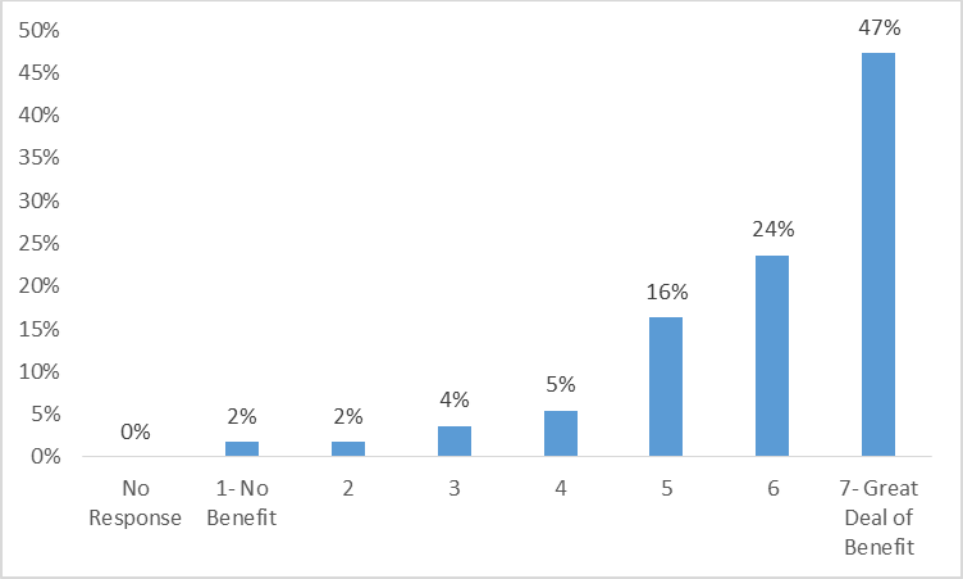
Figure 6.4. Patient-Perceived Benefit: Seizures (N=182)



CROHN'S DISEASE

Figure 6.5 shows responses from patients certified for Crohn's disease regarding degree of benefit experienced. Among respondents, 47% report a score of 7 on a scale from 1-7.

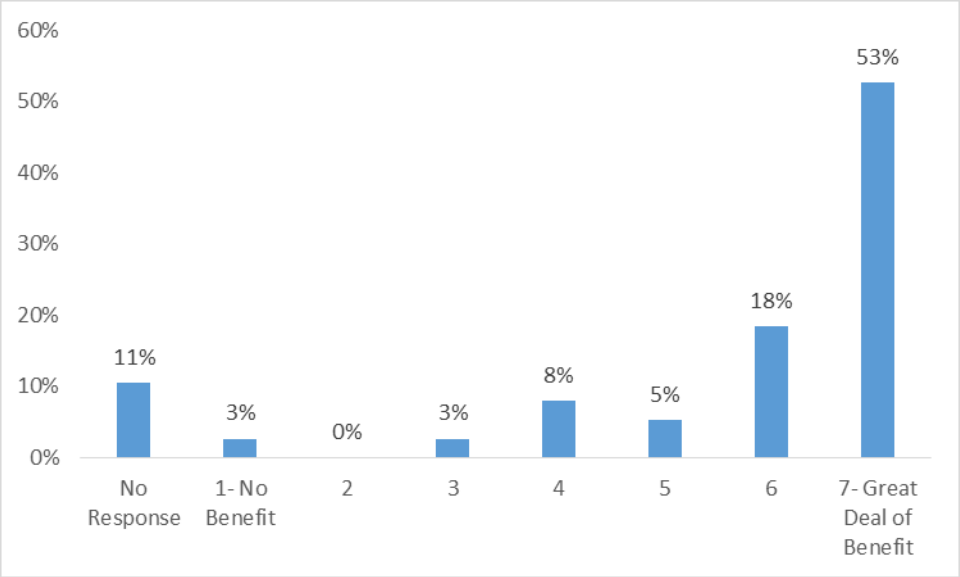
Figure 6.5. Patient-Perceived Benefit: Crohn's Disease (N=55)



TERMINAL ILLNESS

Figure 6.6 shows responses from patients certified for terminal illness regarding degree of benefit experienced. Among respondents, 53% report a score of 7 on a scale from 1-7.

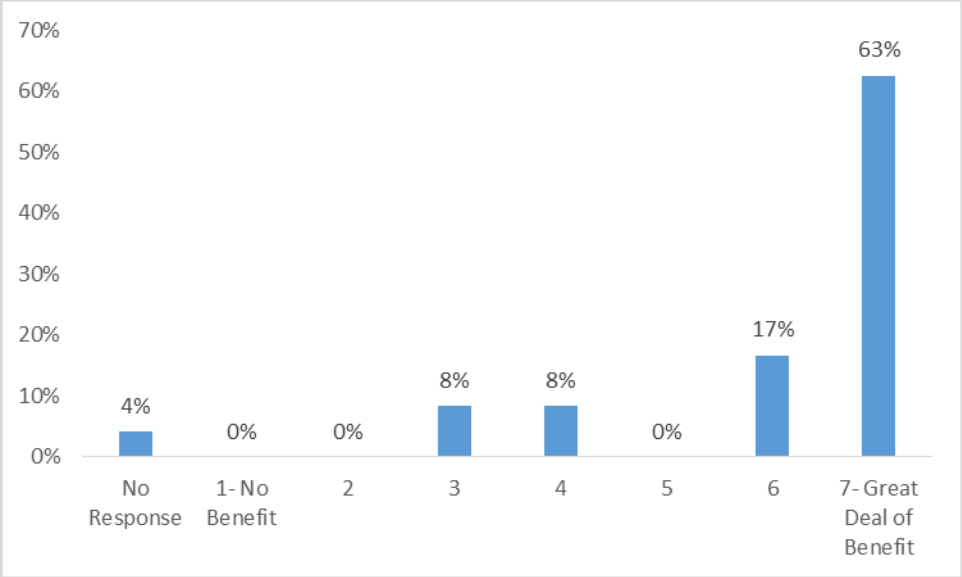
Figure 6.6. Patient-Perceived Benefit: Terminal Illness (N=38)



HIV/AIDS

Figure 6.7 shows responses from patients certified for HIV/AIDS regarding degree of benefit experienced. Among respondents, 63% report a score of 7 on a scale from 1-7.

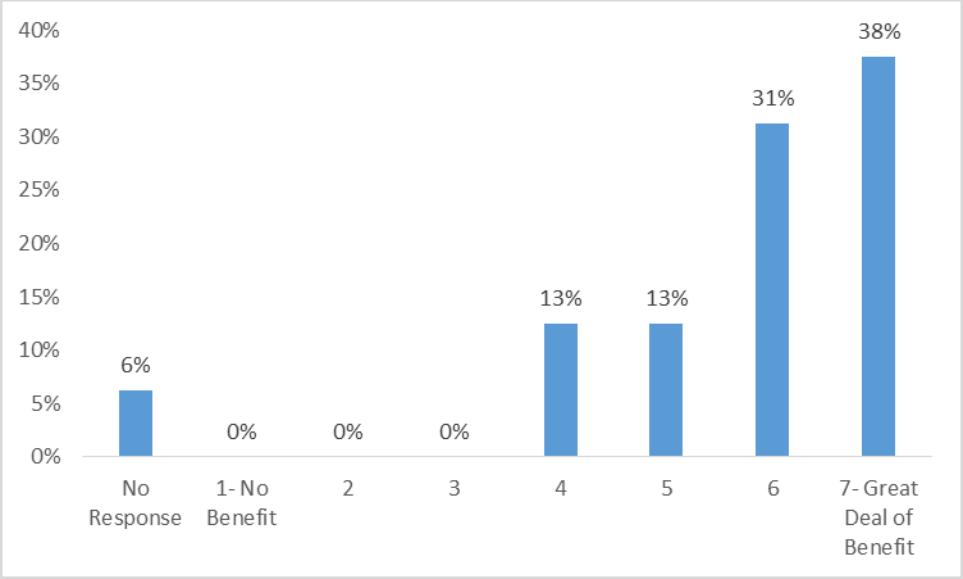
Figure 6.7. Patient-Perceived Benefit: HIV/AIDS (N=24)



TOURETTE SYNDROME

Figure 6.8 shows responses from patients certified for Tourette syndrome regarding degree of benefit experienced. Among respondents, 38% report a score of 7 on a scale from 1-7.

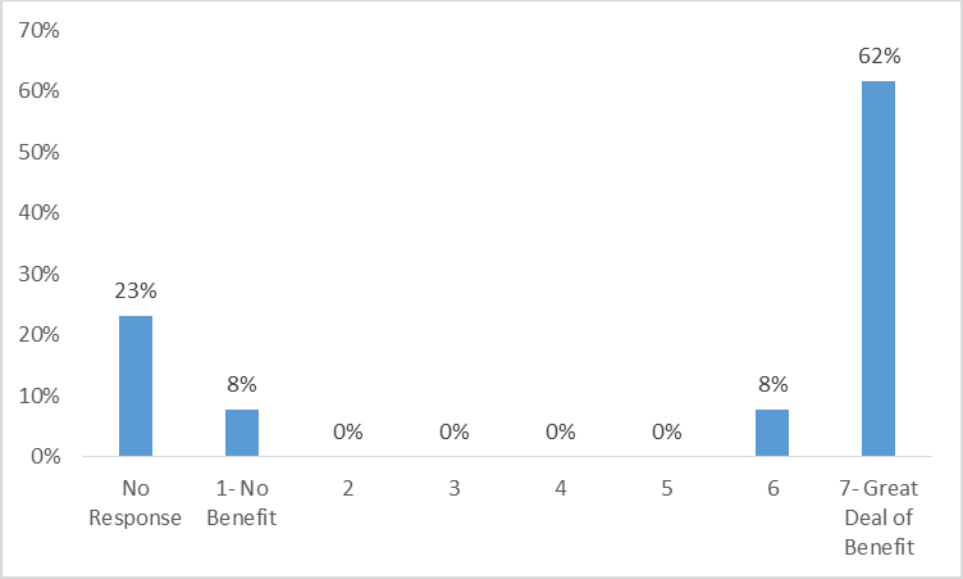
Figure 6.8. Patient-Perceived Benefit: Tourette Syndrome (N=16)



GLAUCOMA

Figure 6.9 shows responses from patients certified for glaucoma regarding degree of benefit experienced. Among respondents, 62% report a score of 7 on a scale from 1-7.

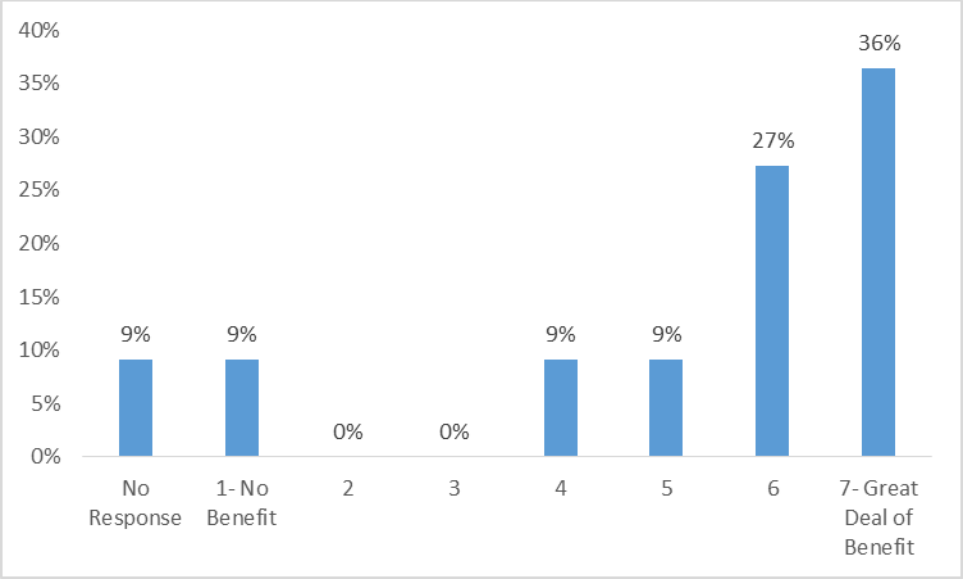
Figure 6.9. Patient-Perceived Benefit: Glaucoma (N=13)



ALS

Figure 6.10 shows responses from patients certified for ALS regarding degree of benefit experienced. Among respondents, 36% report a score of 7 on a scale from 1-7.

Figure 6.10. Patient-Perceived Benefit: ALS (N=11)



Patient Perceptions of Types of Benefits from Medical Cannabis Treatment

In both the Patient Experience and HCP surveys, patients and their certifying HCPs had an opportunity to describe the most significant benefit to the patient that was associated with medical cannabis treatment. Each response was reviewed and classified as symptom improvement (based on qualifying condition), or global health benefit, which included all health benefits not specifically related to the relief of symptoms directly associated with the patient's qualifying medical condition(s). Note that not all completed surveys had a response for this question; 86% of the Patient Experience surveys did and 66% of the HCP surveys did. Among the 681 completed Patient Experience survey responses that indicated a most significant benefit, 64% classified the benefit as symptom improvement and 25% classified it as a global health benefit; the remaining comments regarding benefit were improvement of symptoms other than those related to the qualifying condition or global health benefits. Tabulation of those responses is reported below, but the reader is also encouraged to read the verbatim responses in *Appendix A: Patient-Reported Benefits from Surveys*. Reading the words written by the patient gives a more nuanced understanding of the benefits and provides a reminder that each of the respondents is an individual person. The following is a selection of the comments, chosen to reflect the full range of benefits perceived:

- “Almost all muscle spasms 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.”
- “A large reduction in symptoms, allowing me to participate in my daily life without a large number of limits my symptoms would place on me – stools decreased from over 8 a day to about 2 with much less blood and mucous in stools. Pain has reduced to a tolerable amount”
- “[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.”
- “Has eased my muscle spasms and cramping. Has helped my visual issues. Has helped me to maintain healthy weight. Have been able to sleep much better and have cut other pain prescriptions way back. Seems to take pain away enough that I have been more active and am able to function on household tasks to a somewhat normal level. My brain seems to be working better as well ie. concentration/focusing and remembering.”
- “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.”
- “Within 1 week of use, my tics disappeared and have stayed gone even with occasional use. This has never happened previously in my life, so it is very effective.”
- “At first it helped a lot but my seizures have returned.”
- “Spasms – only a little better.”

Symptom Improvement from Medical Cannabis Treatment

Table 6.6 summarizes the reported “most important benefits” which could be considered improvement of a symptom related to the patient’s qualifying condition from reports of patients, categorized by the benefit score reported by the patient. For patients with severe muscle spasms, reports of spasm reduction or pain reduction were considered symptom improvement. For patients with cancer (regardless of whether their condition was associated with severe/chronic pain, nausea or severe vomiting, cachexia or severe wasting, or a combination), pain reduction, nausea and/or vomiting reduction, and weight gain and/or appetite improvement were considered symptom improvement. For patients with seizures, reports of fewer seizures, less severe seizures, or both, were considered symptom improvement. For patients with Crohn’s disease, pain reduction, weight gain and/or appetite improvement, and reduction in related symptoms including stool frequency were considered symptom improvement. For patients with terminal illnesses (regardless of whether their condition was associated with severe/chronic pain, nausea or severe vomiting, cachexia or

severe wasting, or a combination), reduction in pain, nausea and/or vomiting and weight gain and/or appetite improvement were considered symptom improvement. For patients certified for HIV/AIDS, reduction in pain, nausea and/or vomiting, and weight gain and/or appetite improvement were considered symptom improvement. In patients with Tourette syndrome, reduced tics or specific mention of reduced Tourette symptoms were considered symptom improvement. In patients certified for glaucoma, reduction in intraocular pressure or reference to treatment of glaucoma "symptoms" was considered symptom improvement. Finally, for patients with ALS, reduction in pain or spasms were considered symptom improvement.

Among patients with severe and persistent muscle spasms, 26% reported pain reduction and another 25% reported spasm reduction as the most important benefit. Among seizure patients, 51% reported seizure reduction (either in frequency or severity). Among cancer patients, 26% reported pain reduction as the primary benefit; 25% reported weight gain, appetite improvement, or reduced nausea or vomiting. Among Crohn's disease respondents, 25% reported reduced pain, 16% reported reduced severity or frequency of gastrointestinal symptoms and 4% reported weight gain or appetite improvement as the primary benefit. Among patients with terminal illness, 21% reported reduced nausea or vomiting, 18% reported pain reduction and 8% reported weight gain or appetite improvement as the most important benefit. Thirty-one percent of glaucoma patient respondents reported reduction of glaucoma-related symptoms. Among ALS patients, 27% reported pain reduction and 9% reported spasm reduction as the most important benefit. Among HIV/AIDS patients, 25% reported reduced pain, 17% reported reduced nausea and/or vomiting and 12% reported weight gain or appetite improvement as the most important benefit. Finally, among patients with Tourette syndrome, 63% reported a reduction in tics or other symptoms of Tourette syndrome.

Table 6.6. Distribution of Symptom Improvement by Condition: Patient Surveys

	1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Muscle Spasms (n=373)								
Spasm Reduction	-	-	1 (0%)	11 (3%)	14 (4%)	24 (6%)	45 (12%)	95 (25%)
Pain Reduction	-	-	2 (1%)	6 (2%)	17 (5%)	24 (6%)	48 (13%)	97 (26%)
Cancer (n=157)								
Pain Reduction	-	-	-	3 (2%)	9 (6%)	12 (8%)	17 (11%)	41 (26%)

	1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Reduced Nausea/Vomiting	-	-	-	1 (1%)	2 (1%)	2 (1%)	14 (9%)	19 (12%)
Weight Gain/Appetite Improvement	-	1 (1%)	-	2 (1%)	1 (1%)	6	10 (6%)	20 (13%)
Seizures (n=182)								
Seizure Reduction	-	3 (2%)	4 (2%)	9 (5%)	15 (8%)	22 (11%)	39 (21%)	92 (51%)
Crohn's Disease (n=55)								
Pain Reduction	-	-	-	-	3 (5%)	4 (5%)	7 (13%)	14 (25%)
Reduced Crohn's Symptoms	-	-	-	-	-	2 (4%)	7 (13%)	9 (16%)
Weight Gain/Appetite Improvement	-	-	-	-	1 (2%)	1 (2%)	-	2 (4%)
Terminal Illness (n=38)								
Reduced Nausea/Vomiting	-	-	-	1 (3%)	-	1 (3%)	6 (16%)	8 (21%)
Pain Reduction	-	-	-	1 (3%)	1 (3%)	-	5 (13%)	7 (18%)
Weight Gain/Appetite Improvement	-	-	-	-	-	-	3 (8%)	3 (8%)
HIV/AIDS (n=24)								
Pain Reduction	-	-	1 (4%)	1 (4%)	-	3 (13%)	3 (13%)	6 (25%)
Reduced Nausea/Vomiting	-	-	-	-	-	-	4 (17%)	4 (17%)

	1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Weight Gain/Appetite Improvement	-	-	1 (4%)	-	-	-	2 (8%)	3 (12%)
Tourette Syndrome (n=16)								
Reduced Tics/Tourette Symptoms	-	-	-	-	1 (6%)	4 (25%)	5 (31%)	10 (63%)
Glaucoma (n=13)								
Reduced Glaucoma Symptoms	-	-	-	-	-	1 (8%)	3 (23%)	4 (31%)
ALS (n=11)								
Spasm Reduction	-	-	-	-	-	1 (9%)	-	1 (9%)
Pain Reduction	-	-	-	-	-	1 (9%)	2 (18%)	3 (27%)

Patient Perceptions of Global Health Benefits from Medical Cannabis

Many patients responded to the question regarding "most important benefit" by describing benefits not specifically related to the symptoms of their qualifying conditions. These responses were reviewed and classified into categories of "global health benefits"- broader benefits which impact the patient's overall health. Global health benefits reported by patients included improvement in quality of life, improvement in sleep (whether or not explicitly tied to reduction in symptoms related to qualifying condition), improved mobility and/or ability to function or perform regular tasks, reduced anxiety or increased calmness, improved alertness and/or cognitive functioning, and reduced usage of other medications (often reported as reduction in dosage and/or side effects related to use of other medications). Clearly, global health benefits may be due to improvements in symptoms specifically related to the qualifying condition, so the dividing line between these categories is a bit blurry.

Table 6.7 shows the number of responses by type of global health benefit, along with the associated benefit score reported by the patient. Overall, 6% of patient respondents reported

improved sleep as the most important benefit from medical cannabis; 4% reported improved quality of life, 4% reported reduced usage of other medication, 3% reported reduced anxiety, and 2% reported improved alertness or cognitive function.

Table 6.7. Distribution of Global Health Benefits Condition: Patient Surveys

	1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Muscle Spasms (n=373)								
Weight Gain/ Appetite Improvement	-	-	-	-	1 (0%)	3 (1%)	2 (1%)	6 (2%)
Improved Alertness/ Cognitive Functioning	-	-	-	-	-	-	1 (0%)	1 (0%)
Improved Quality of Life	-	-	2 (1%)	1 (0%)	1 (0%)	3 (1%)	10 (3%)	17 (5%)
Improved Sleep	-	1 (0%)	-	5 (1%)	7	4 (1%)	8 (2%)	25 (7%)
Improved Mobility/Ability to Function	-	1 (0%)	-	-	-	1 (0%)	10 (3%)	12 (3%)
Decreased Anxiety	-	1 (0%)	-	1 (0%)	-	5 (1%)	4 (1%)	11 (3%)
Reduced Dosage and/or Side Effects of Other Medications				-	-	2 (1%)	16 (4%)	18 (5%)
Cancer (n=157)								
Reduced Anxiety	-	1 (1%)	-	2 (1%)	-	1 (1%)	2 (1%)	6 (4%)
Improved Sleep	-	-	1 (1%)	2 (1%)	2 (1%)	1 (1%)	5 (3%)	11 (7%)
Improved Quality of Life	-	-	-	1 (1%)		2 (1%)	1 (1%)	4 (3%)
Improved Alertness/Cognitive Functioning	-	-	-	-	-	-	1 (1%)	1 (1%)

	1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Reduced Dosage and/or Side Effects of Other Medications	-	-	-	-	-	2 (1%)	3 (2%)	5 (3%)
Seizures (n=182)								
Decreased Anxiety	-	1 (1%)	-	-	1 (1%)	-	-	2 (1%)
Improved Sleep	-	-	-	-		1 (1%)	1 (1%)	2 (1%)
Reduced Dosage and/or Side effects of Other Medications	-	-	-	-	1 (1%)	1 (1%)	3 (2%)	5 (3%)
Improved Quality of Life	-	-	-	-	2 (1%)	1 (1%)	4 (2%)	7 (4%)
Improved Alertness/Cognitive Functioning	-	2 (1%)	1 (1%)	3 (2%)	2 (1%)	5 (3%)	4 (2%)	17 (9%)
Crohn's Disease (n=55)								
Improved Quality of Life	-	-	-	1 (2%)	-	-	5 (9%)	6 (11%)
Improved Sleep	-	-	1 (2%)	2 (4%)	2 (4%)	1 (2%)	-	6 (11%)
Decreased Anxiety	-	-	-	-	1 (2%)	2 (4%)	-	3 (5%)
Terminal Illness (n=38)								
Decreased Anxiety	-	-	-	-	-	1 (3%)	-	1 (3%)
Improved Alertness/ Cognitive Functioning	-	-	-	-	-	-	1 (3%)	1 (3%)
Improved Sleep	-	-	1 (3%)	1 (3%)	-	-	2 (5%)	4 (11%)

	1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Improved Quality of Life	-	-	-	-	-	2 (5%)	1 (3%)	3 (8%)
HIV/AIDS (n=24)								
Improved Sleep	-	-	-	-	-	-	1 (4%)	1 (4%)
Decreased Anxiety	-	-	-	-	-	-	2 (8%)	2 (8%)
Tourette Syndrome (n=16)								
Improved Quality of Life	-	-	-	-	-	-	1 (6%)	1 (6%)
Decreased Anxiety	-	-	-	1 (6%)	-	1 (6%)	-	2 (13%)
Glaucoma (n=13)								
Improved Quality of Life	-	-	-	-	-	-	1 (8%)	1 (8%)
ALS (n=11)								
Reduced Anxiety	-	-	-	1 (9%)	-	1 (9%)	1 (9%)	3 (27%)
Improved Sleep	-	-	-	-	1 (9%)	-	1 (9%)	2 (18%)

Health Care Practitioner Survey Results

HCP Survey Response Rate

As a result of changing the survey schedule during the first program year, the healthcare providers of 774 patients who were enrolled and made a first medical cannabis purchase in the first medical cannabis purchase in the first six months of the program (July 1 – December 31, 2015) received a survey three months after the patient's first purchase; the remaining 717 could therefore not be included in the reporting below. The subset of Patient Experience survey responses that corresponds to this group of HCP responses is included below for comparison. Of 774 patients in this group, 437 patients (57%) submitted a survey three months after making the first purchase. Of the 262 health care practitioners (HCP) who certified these patients, 114 (43.5%) completed surveys for 251 (32%) patients.

Table 6.8. Healthcare Practitioner and Patient Experience survey response rates by age group.

	Total	HCP Responses	Patient Responses
0-4	15	7 (47%)	9 (60%)
5-17	90	36 (40%)	49 (54%)
18-24	48	18 (38%)	28 (58%)
25-35	110	32 (29%)	59 (54%)
36-49	194	66 (34%)	114 (59%)
50-64	225	65 (29%)	131 (58%)
65+	92	27 (29%)	47 (51%)
Total	774	251 (32%)	437 (58%)

Table 6.9. Patient total counts and HCP/patient response rates by qualifying medical condition.

	Total	HCP Responses	Patient Responses
Muscle Spasms	305	98 (32%)	182 (60%)
Cancer	192	51 (27%)	84 (44%)
Seizures	189	64 (34%)	120 (63%)
Crohn's Disease	58	25 (43%)	34 (59%)
Terminal Illness	43	12 (28%)	21 (49%)
HIV/AIDS	26	12 (46%)	15 (58%)
Tourette Syndrome	11	4 (36%)	6 (55%)
Glaucoma	11	3 (27%)	5 (45%)
ALS	15	5 (33%)	7 (47%)

Table 6.10. Patient total counts and HCP/patient response rates by race and ethnicity.

	Total	HCP Responses	Patient Responses
American Indian	16	6 (38%)	7 (44%)
Asian	17	8 (47%)	7 (41%)
Black	41	14 (35%)	15 (37%)
Hawaiian	1	0 (0%)	0 (0%)
White	665	218 (33%)	395 (59%)
Other	14	5 (36%)	6 (43%)
Hispanic	18	4 (22%)	6 (33%)

Response rates for the Patient Experience and HCP surveys varied widely across age group, qualifying condition and race and ethnicity (Tables 6.8-6.10). Patient response rate was lowest among the oldest age group (65+; 51%) and HCP response rate was generally lower for older age groups. Among HCP responses, certifiers of patients with HIV/AIDS and Crohn's disease had the highest response rates (46% and 43%, respectively). Among patient responses, patients certified for severe and persistent muscle spasms, seizures and Crohn's disease had the highest response rates (60%, 63%, and 59%, respectively). Finally, racial and ethnic minorities were generally under-represented among patient responses.

Healthcare Practitioner Perceptions of Benefit

The Patient Experience and HCP surveys both ask respondents to report how much benefit they believe the patient received from using medical cannabis, on a scale from 1 (no benefit) to 7 (a great deal of benefit). Figures 6.11-6.20 show the distribution of benefit scores on this scale, as reported by HCPs, for all patients and by patients with each qualifying condition.

A note on how proportions were calculated: the total number of HCP responses is reflected in Figures 6.11-6.20; this includes 45 HCP responses with either no response or a "0" option selected for the benefit scale, which indicates that the HCP did not have enough information about the patient to answer the question of benefit.)

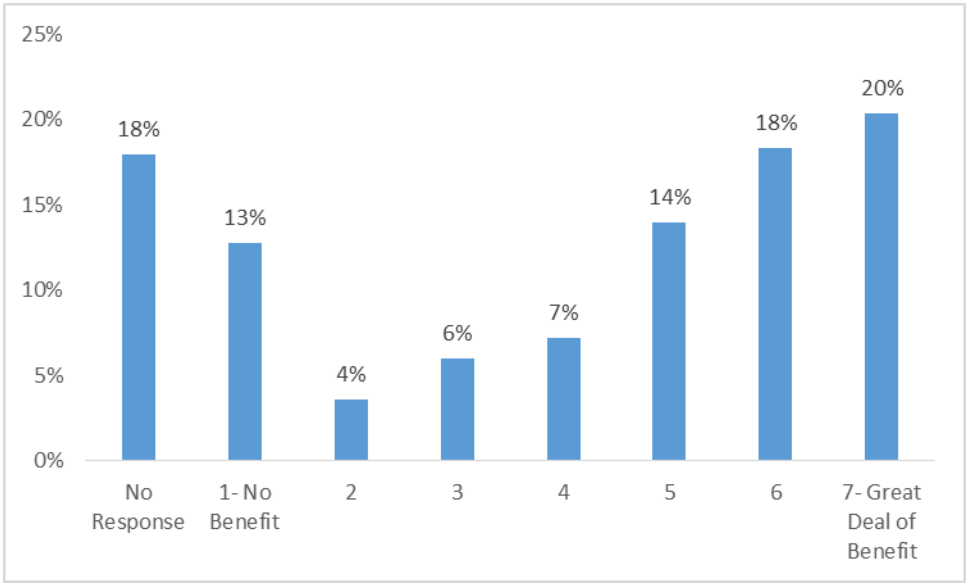
Note that results from patient surveys (Figures 6.1-6.10) and health care practitioner surveys (Figures 6.11-6.20) do not pertain to identical groups of patients. That is, some patients have

only a patient survey completed, some have only a HCP survey completed, some have neither completed, and some (n=126) have a completed survey from both the patient and their certifying HCP. For this reason, comparison of results from patient and HCP surveys must be approached with caution, except for the last group, where there is a completed survey from both the patient and the HCP. Further on in this section (Table 6.13 and Figures 6.21-6.28) comparisons for that last group are presented. In general, responses from HCPs report a lower degree of benefit than the patient responses.

ALL QUALIFYING CONDITIONS

Figure 6.11 shows all HCP responses about degree of benefit experienced. Benefit ratings were provided on 206 of the 251 submitted surveys. Among the 251 surveys, 32 (13%) reported no benefit and 51 (20%) reported the highest degree of benefit (score of 7); 150 (60%) reported a benefit score ≥ 4 on the seven-point scale.

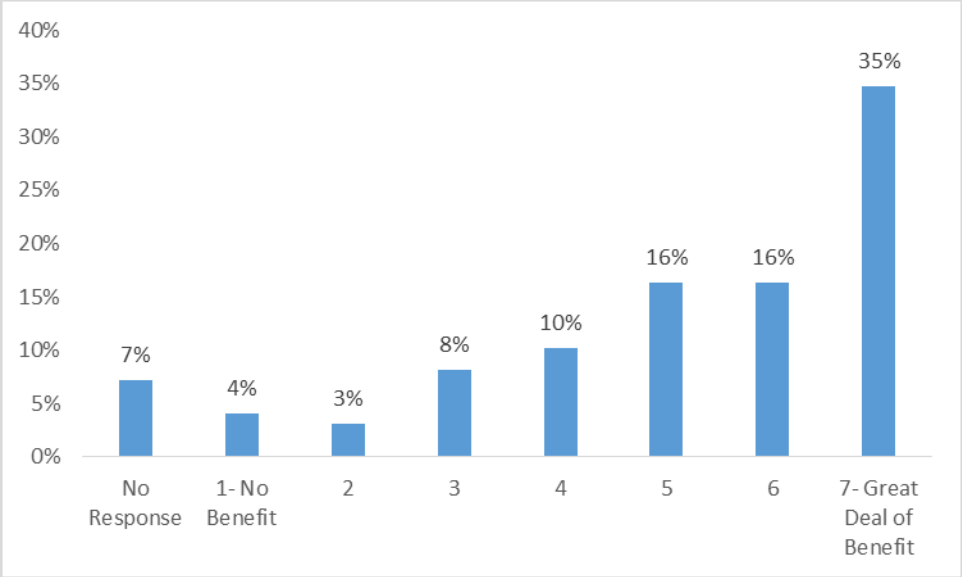
Figure 6.11. HCP-Perceived Benefit: All Conditions (N=251)



SEVERE AND PERSISTENT MUSCLE SPASMS

Figure 6.12 shows HCP benefit score responses for patients certified for severe and persistent muscle spasms. Benefit ratings were provided on 91 of the submitted surveys. Among the 91 responses, 4 reported no benefit and 34 reported the highest degree of benefit (score of 7); 76 (84%) reported a benefit score ≥ 4 on the seven-point scale.

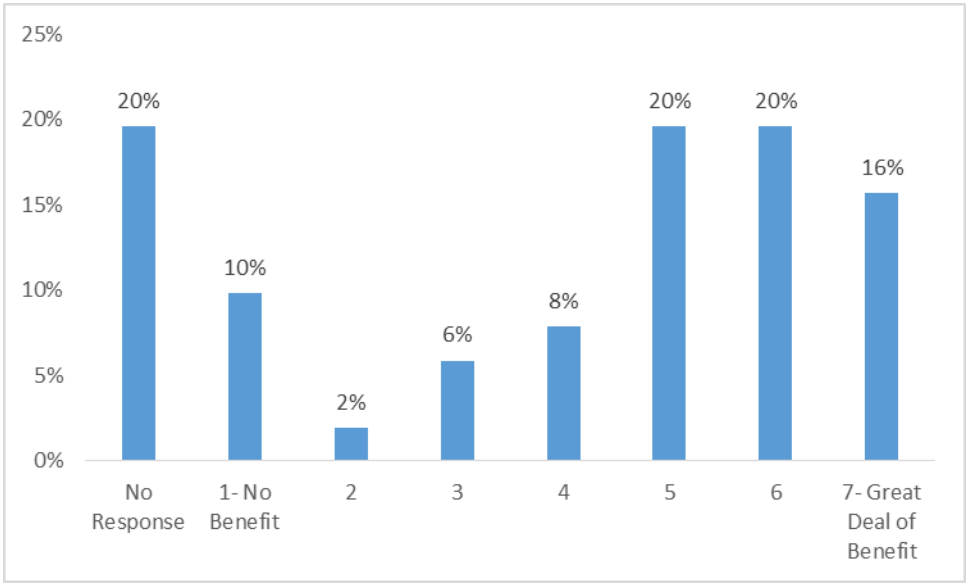
Figure 6.12. HCP-Perceived Benefit: Severe and Persistent Muscle Spasms (N=98)



CANCER

Figure 6.13 shows HCP benefit score responses for patients certified for cancer. Benefit ratings were provided on 41 of the submitted surveys. Among the 41 responses, 5 reported no benefit and 8 reported the highest degree of benefit (score of 7); 32 (78%) reported a benefit score ≥ 4 on the seven-point scale.

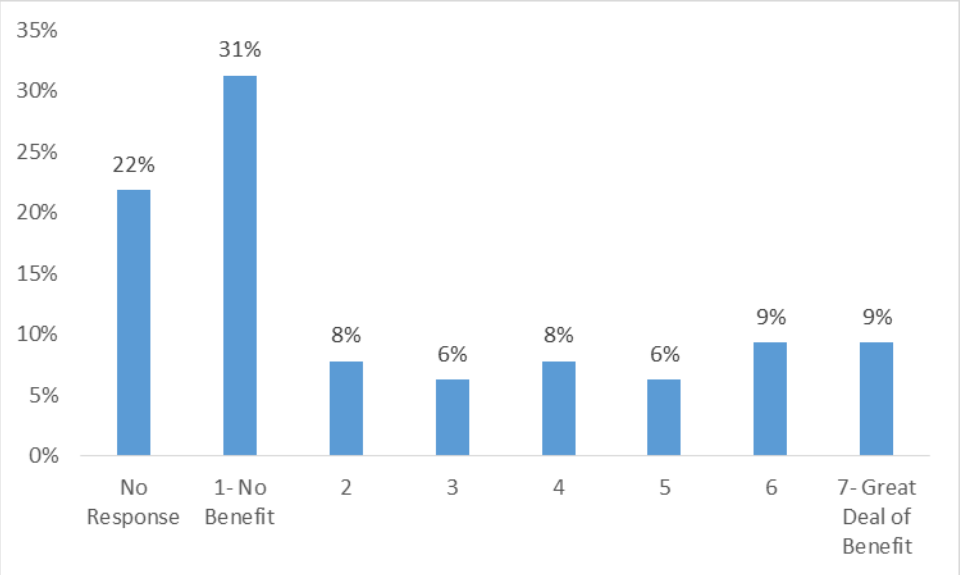
Figure 6.13. HCP-Perceived Benefit: Cancer (N=51)



SEIZURES

Figure 6.14 shows HCP benefit score responses for patients certified for seizures. Benefit ratings were provided on 50 of submitted surveys. Among the 50 responses, 20 reported no benefit and 6 reported the highest degree of benefit (score of 7); 21 (42%) reported a benefit score ≥ 4 on the seven-point scale.

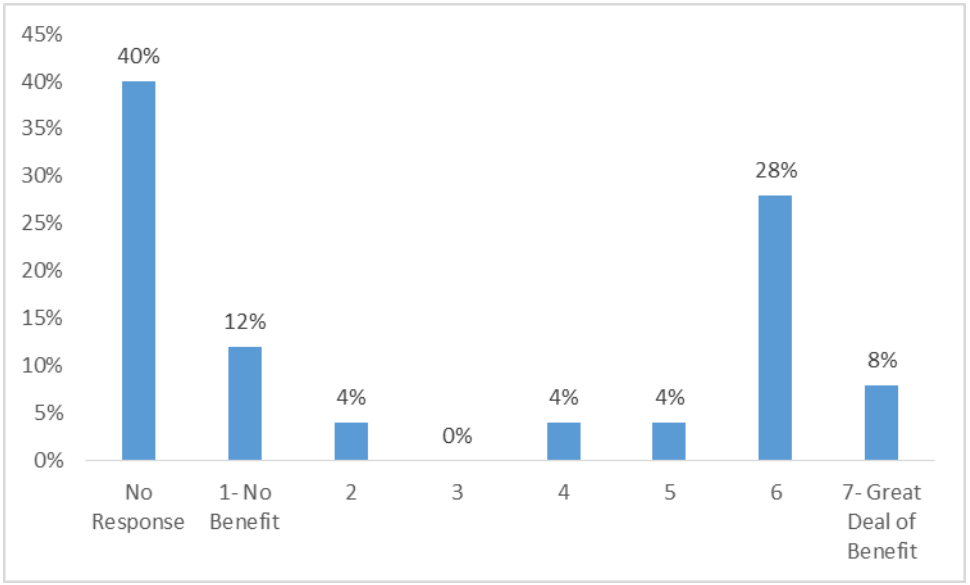
Figure 6.14. HCP-Perceived Benefit: Seizures (N=64)



CROHN'S DISEASE

Figure 6.15 shows HCP benefit score responses for patients certified for Crohn's disease. Benefit ratings were provided on 15 of the completed surveys. Among the 15 responses, 3 reported no benefit and 2 reported the highest degree of benefit (score of 7); 11 (73%) reported a benefit score ≥ 4 on the seven-point scale.

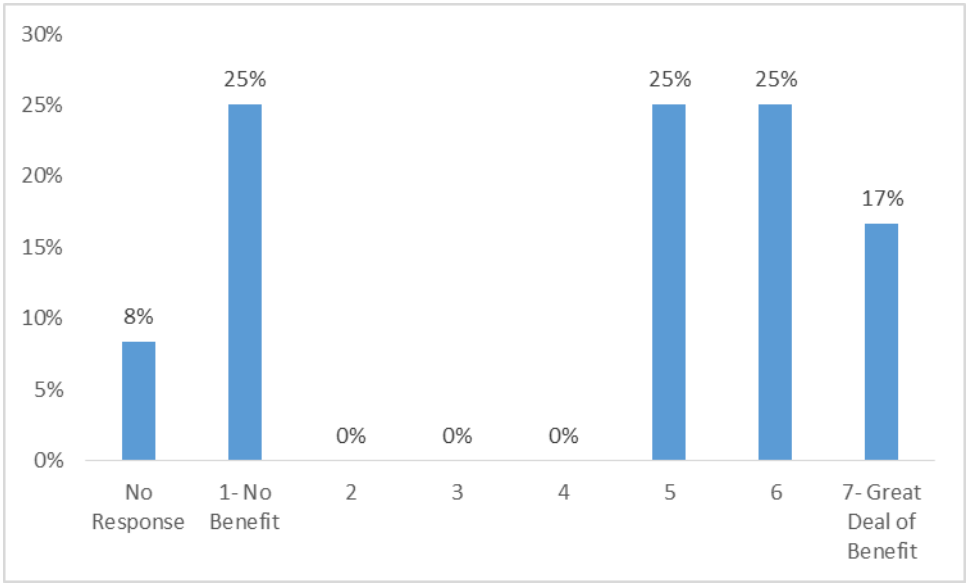
Figure 6.15. HCP-Perceived Benefit: Crohn's Disease (N=25)



TERMINAL ILLNESS

Figure 6.16 shows HCP benefit score responses for patients certified for terminal illness. Benefit ratings were provided on 11 of the completed surveys. Among the 11 responses, 3 reported no benefit and 2 reported the highest degree of benefit (score of 7); 8 (73%) reported a benefit score ≥ 4 on the seven-point scale.

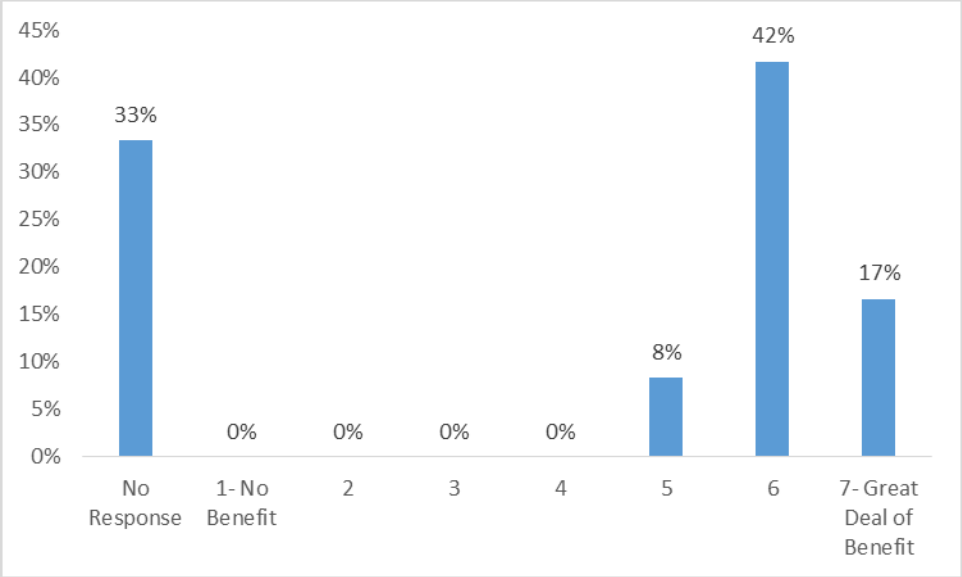
Figure 6.16. HCP-Perceived Benefit: Terminal Illness (N=12)



HIV/AIDS

Figure 6.17 shows HCP benefit score responses for patients certified for HIV/AIDS. Benefit ratings were provided on 8 of the 12 completed surveys. Among the 8 responses, none reported no benefit and two reported the highest degree of benefit (score of 7); all eight reported a benefit score ≥ 4 on the seven-point scale.

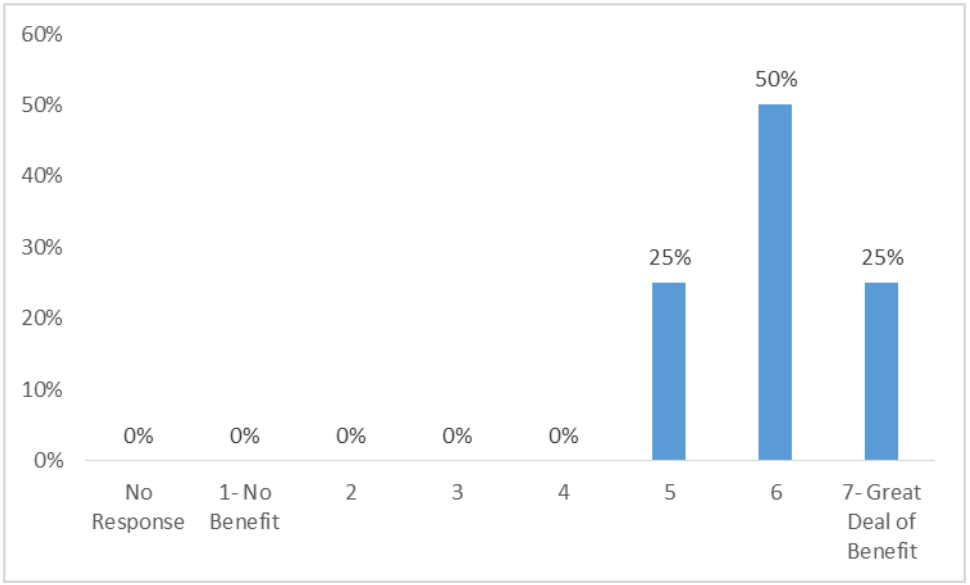
Figure 6.17. HCP-Perceived Benefit: HIV/AIDS (N=12)



TOURETTE SYNDROME

Figure 6.18 shows HCP benefit score responses for patients certified for Tourette syndrome. Benefit ratings were provided on all four of the completed surveys. Among the 4 responses, none reported no benefit and one reported the highest degree of benefit (score of 7); all four reported a benefit score ≥ 4 on the seven-point scale.

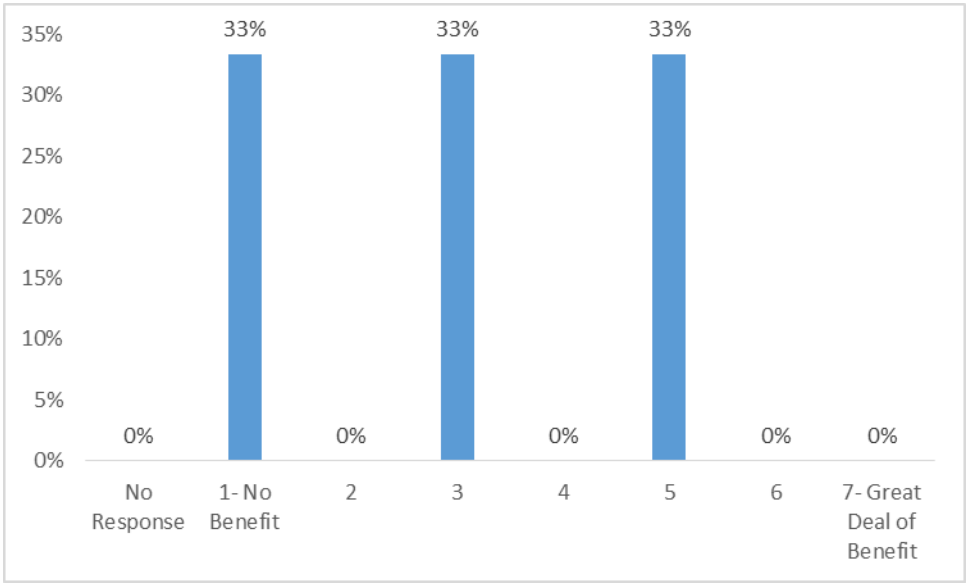
Figure 6.18. HCP-Perceived Benefit: Tourette Syndrome (N=4)



GLAUCOMA

Figure 6.19 shows HCP benefit score responses for patients certified for glaucoma. Benefit ratings were provided on all three of the completed surveys. Among the 3 responses, one reported no benefit and none reported the highest degree of benefit (score of 7); only one reported a benefit score ≥ 4 on the seven-point scale.

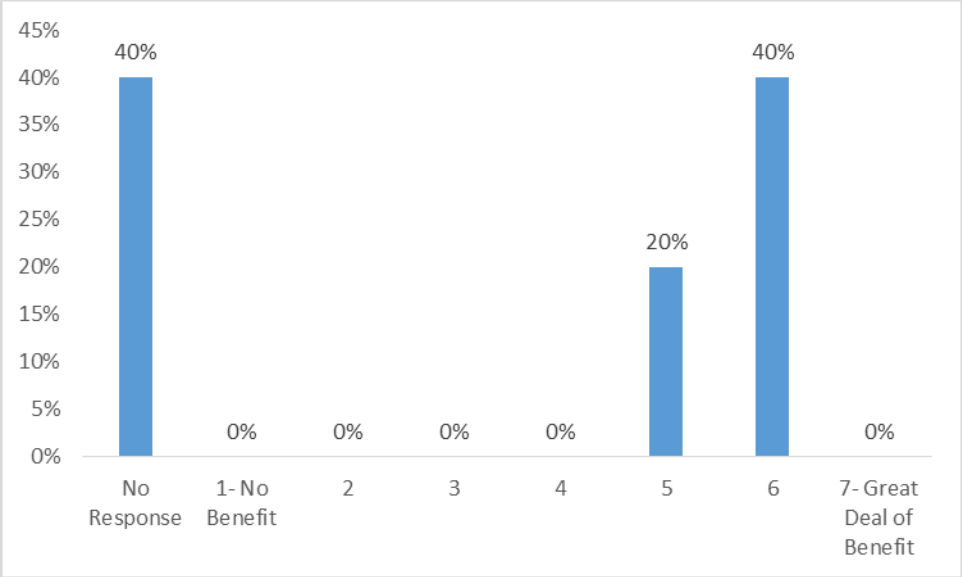
Figure 6.19. HCP-Perceived Benefit: Glaucoma (N=3)



ALS

Figure 6.20 shows HCP benefit score responses for patients certified for ALS. Benefit ratings were provided on 3 of the 5 completed surveys. Among the 3 responses, none reported no benefit and none reported the highest degree of benefit (score of 7); all three reported a benefit score ≥ 4 on the seven-point scale.

Figure 6.20. HCP-Perceived Benefit: ALS (N=5)



HCP Perceptions of Symptom Improvement from Medical Cannabis Treatment

Similar to the format in the Patient Experience survey, the HCP surveys asks certifying HCPs to describe the most significant benefit to the patient that is associated with medical cannabis treatment. Each response was reviewed and classified into broad categories of symptom improvement or global health benefits, as described in an earlier section. A full report of all benefit comments from HCPs can be found in *Appendix B: Healthcare Practitioner-Reported Benefits from Surveys*. Table 6 summarizes the reported "most important benefits" which could be considered improvement of a symptom related to the patient's qualifying condition from reports of both patients and HCPs, again using a subset of patient responses from the same time window as HCP responses (surveys for patients making a first purchase between July 2015 and December 2015).

Table 6.11 Distribution of Symptom Improvement by Condition

Symptom Improvement by Score		1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Muscle Spasms									
Spasm Reduction	Patient (n=182)	-	-	-	6 (3%)	5 (3%)	14 (8%)	25 (14%)	50 (28%)
	HCP (n= 98)	-	-	1 (1%)	2 (2%)	6 (6%)	9 (9%)	9 (9%)	28 (29%)
Pain Reduction	Patient (n=182)	-	-	2 (1%)	3 (2%)	10 (6%)	10 (6%)	22 (12%)	47 (26%)
	HCP (n= 98)	-	1 (1%)	-	3 (3%)	4 (4%)	3 (3%)	11 (11%)	22 (22%)
Cancer									
Pain Reduction	Patient (n=84)	-	-	-	3 (4%)	7 (8%)	6 (7%)	7 (8%)	23 (27%)
	HCP (n= 51)	1 (2%)	-	2 (4%)	1 (2%)	2 (4%)	2 (4%)	2 (4%)	10 (20%)
Reduced Nausea/Vomiting	Patient (n=84)	-	-	-	1 (1%)	2 (2%)	1 (1%)	10 (12%)	14 (17%)

Symptom Improvement by Score		1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Weight Gain/Appetite Improvement	HCP (n= 51)	-	-	-	1 (2%)	5 (10%)	3 (6%)	4 (8%)	13 (26%)
	Patient (n=84)	-	-	-	-	1 (1%)	3 (4%)	7 (8%)	11 (13%)
	HCP (n= 51)	-	-	-	-	-	1 (2%)	-	1 (2%)
Seizures									
Seizure Reduction	Patient (n=120)	-	3 (3%)	1 (1%)	4 (3%)	11 (9%)	17 (14%)	31 (26%)	67 (56%)
	HCP (n= 64)	1 (2%)	2 (3%)	2 (3%)	2 (3%)	2 (3%)	5 (8%)	4 (6%)	18 (28%)
Crohn's Disease									
Pain Reduction	Patient (n=34)	-	-	-	-	2 (6%)	2 (6%)	4 (12%)	8 (24%)
	HCP (n= 25)	-	-	1 (4%)	-	-	3 (12%)	-	4 (16%)
Reduced Gastrointestinal Symptoms	Patient (n=34)	-	-	-	-	-	1 (3%)	4 (12%)	5 (15%)
	HCP (n= 25)	-	-	-	-	1 (4%)	-	1 (4%)	2 (8%)
Weight Gain/Appetite Improvement	Patient (n=34)	-	-	-	-	1 (3%)	1 (3%)	-	2 (9%)
	HCP (n= 25)	-	-	-	-	-	-	-	-
Terminal Illness									
Reduced Nausea/Vomiting	Patient (n=21)	-	-	-	1 (5%)	-	1 (5%)	4 (19%)	6 (29%)

Symptom Improvement by Score		1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Pain Reduction	HCP (n= 12)	-	-	-	-	1 (8%)	1 (8%)	1 (8%)	3 (25%)
	Patient (n=21)	-	-	-	1 (5%)	-	-	4 (19%)	5 (24%)
Weight Gain/Appetite Improvement	HCP (n= 12)	-	-	-	-	1 (8%)	-	1 (8%)	2 (17%)
	Patient (n=21)	-	-	-	-	-	-	2 (10%)	2 (10%)
HIV/AIDS	HCP (n= 12)	-	-	-	-	1 (8%)	1 (8%)	-	2 (17%)
Pain Reduction	Patient (n=15)	-	-	1 (7%)	-	-	1 (7%)	3 (20%)	5 (33%)
	HCP (n= 12)	-	-	-	-	1 (8%)	1 (8%)	-	2 (17%)
Reduced Nausea/Vomiting	Patient (n=15)	-	-	-	-	-	-	3 (20%)	3 (20%)
	HCP (n= 12)	-	-	-	-	-	2 (17%)	-	2 (17%)
Weight Gain/Appetite Improvement	Patient (n=15)	-	-	-	-	-	-	2 (13%)	2 (13%)
	HCP (n= 12)	-	-	-	-	-	-	-	-
Tourette Syndrome									
Reduced Tics/Tourette Symptoms	Patient (n=6)	-	-	-	-	1 (17%)	-	3 (50%)	4 (67%)
	HCP (n= 5)	-	-	-	-	-	2 (40%)	1 (20%)	3 (60%)

Symptom Improvement by Score		1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Glaucoma									
Reduced Glaucoma Symptoms	Patient (n=5)	-	-	-	-	-	-	2 (40%)	2 (40%)
	HCP (n= 3)	-	-	1 (33%)	-	-	-	-	1 (33%)
ALS									
Spasm Reduction	Patient (n=7)	-	-	-	-	-	1 (14%)	-	1 (14%)
	HCP (n= 5)	-	-	-	-	1 (20%)	1 (20%)	-	2 (40%)
Pain Reduction	Patient (n=7)	-	-	-	-	-	1 (14%)	2 (29%)	3 (43%)
	HCP (n= 5)	-	-	-	-	-	1 (20%)	-	1 (20%)

Patients represented in Patient Experience survey responses and in HCP responses were different; thus a direct comparison cannot be made between the proportions of patients and HCPs reporting any given benefit. However, it is worth noting that relatively high levels of symptom improvement benefit (most scores are above 4) are seen in both patient and HCP survey results. Among patient respondents certified for muscle spasms, 22% report spasm reduction at a high degree of benefit (scores of 6 or 7) and 18% of HCP responses for patients with muscle spasms report spasm reduction at a high degree of benefit. Among responses of patients certified for seizures, 40% reported reduction in seizure number or severity at a high degree of benefit; among HCP responses for patients with seizures, 14% reported seizure reduction (severity or frequency) at a high degree of benefit. Among patient responders certified for cancer, 15% reported pain reduction at a high degree of benefit; 13% reported reduced nausea or vomiting at a high degree of benefit and 12% reported weight gain or appetite improvement at a high degree of benefit. Among HCP responses for patients certified for cancer, 8% reported pain reduction at a high degree of benefit, 14% reported reduced nausea or vomiting and 2% reported weight gain or appetite improvement at a high degree of benefit.

HCP Perceptions of Global Health Benefits from Medical Cannabis Treatment

Table 6.12 summarizes responses to the Patient Experience and HCP surveys about the most significant benefit to the patient that were not classified as improvement of symptoms related to the qualifying medical condition.

As with Table 6.11, the proportion of patients reporting a type of global health benefit cannot be directly compared to the proportion of HCPs reporting a type of global health benefit to the patient because each group of responders is different. However, in general a higher proportion of the patient responses report a global health benefit as the primary benefit from medical cannabis than HCP responses and generally global health benefits are reported at a relatively high degree of perceived benefit (scores of 4 or greater).

Overall, 1% of HCP respondents and 6% of patient respondents reported improved sleep as the most important benefit from medical cannabis; 3% of HCP respondents and 4% of patients reported improved quality of life; 2% of HCP reports and 3% of patient reports cited reduced usage of other medications or related side effects as the most important benefit.

A full report of all benefit comments from HCPs can be found in *Appendix B: Healthcare Practitioner-Reported Benefits from Surveys*.

Table 6.12 Distribution of Global Health Benefits by Condition

Global Health Benefits by Score		1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Muscle Spasms									
Improved Quality of Life	Patient (n=182)	-	-	-	-	-	2 (1%)	3 (2%)	5 (3%)
	HCP (n= 98)	-	-	-	1 (1%)	1 (1%)	1 (1%)	1 (1%)	4 (4%)
Improved Sleep	Patient (n=182)	-	-	-	2 (1%)	3 (2%)	3 (2%)	6 (3%)	14 (8%)
	HCP (n= 98)	-	-	-	1 (1%)	-	-	1 (1%)	2 (2%)
Improved Mobility/Ability to Function	Patient (n=182)	-	1 (1%)	-	-	-	-	6 (3%)	7 (4%)
	HCP (n= 98)	-	-	-	-	-	-	-	-
Decreased Anxiety	Patient (n=182)	-	-	-	-	-	1 (1%)	2 (1%)	3 (2%)
	HCP (n= 98)	-	-	1 (1%)	-	-	-	-	1 (1%)

Global Health Benefits by Score		1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Reduced Usage of Other Medications	Patient (n=182)	-	-	-	-	-	-	6 (3%)	6 (3%)
	HCP (n= 98)	-	-	-	-	-	1 (1%)	3 (3%)	4 (4%)
Cancer									
Reduced Anxiety	Patient (n=84)	-	-	-	1 (1%)	-	-	1 (1%)	2 (2%)
	HCP (n= 51)	-	-	-	-	-	-	-	-
Improved Sleep	Patient (n=84)	-	-	1 (1%)		1 (1%)		5 (6%)	7 (8%)
	HCP (n= 51)	-	-	-	-	-	-	-	-
Improved Quality of Life	Patient (n=84)	-	-	-	-	-	1 (1%)	1 (1%)	2 (2%)
	HCP (n= 51)	-	-	-	-	1 (2%)	-	-	1 (2%)
Improved Alertness/Cognitive Functioning	Patient (n=84)	-	-	-	-	-	-	1 (1%)	1 (1%)
	HCP (n= 51)	-	-	-	-	-	-	-	-
Reduced Usage of Other Medications	Patient (n=84)	-	-	-	-		1 (1%)	3 (4%)	4 (5%)
	HCP (n= 51)	-	-	-	-	-	-	-	-
Seizures									
Improved Sleep	Patient (n=120)	-	-	-	-	-	1 (1%)	-	1 (1%)
	HCP (n= 64)	-	-	-	-	-	-	-	
Reduced Usage of Other Medications	Patient (n=120)	-	-	-	-	-	-	1 (1%)	1 (1%)
	HCP (n= 64)	-	-	-	-	-	-	-	-
Improved Quality of Life	Patient (n=120)	-	-	-	-	2 (2%)	1 (1%)	1 (1%)	4 (3%)
	HCP (n= 64)	-	-	-	1 (2%)	-	-	-	1 (2%)

Global Health Benefits by Score		1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
Improved Alertness/Cognitive Functioning	Patient (n=120)	-	2 (2%)	1 (1%)	3	2 (2%)	4 (8%)	1 (1%)	13 (11%)
	HCP (n= 64)	-	-	-	-	-	-	-	-
Crohn's Disease									
Improved Quality of Life	Patient (n=34)	-	-	-	-	-	-	4 (12%)	4 (12%)
	HCP (n= 25)	-	-	-	-	-	-	-	-
Improved Sleep	Patient (n=34)	-	-	1 (3%)	1 (3%)	1 (3%)	1 (3%)	-	4 (12%)
	HCP (n= 25)	-	-		1 (4%)	-	-	-	1 (4%)
Decreased Anxiety	Patient (n=34)	-	-	-	-	-	1 (3%)	-	1 (3%)
	HCP (n= 25)	-	-	-	-	-	1 (4%)	-	1 (4%)
Terminal Illness									
Improved Alertness/ Cognitive Functioning	Patient (n=21)								
	HCP (n= 12)	-	-	-	-	-	-	1 (8%)	1 (8%)
Improved Sleep	Patient (n=21)	-	-	1 (5%)	-	-	-	2 (10%)	3 (14%)
	HCP (n= 12)	-	-	-	-	-	-	-	-
Reduced Usage of Other Medications	Patient (n=21)	-	-	-	-	-	-	-	-
	HCP (n= 12)	-	-	-	-	-	1 (8%)		1 (8%)
Improved Quality of Life	Patient (n=21)	-	-	-	-	-	1 (5%)	1 (5%)	2 (10%)
	HCP (n= 12)	-	-	-	-	-	-	-	-
HIV/AIDS									
Improved Quality of Life	Patient (n=15)	-	-	-	-	-	-	-	-

Global Health Benefits by Score		1 (No Benefit)	2	3	4	5	6	7 (Great Deal of Benefit)	Total
	HCP (n= 12)	-	-	-	-	-	-	1 (8%)	1 (8%)
Improved Sleep	Patient (n=15)	-	-	-	-	-	-	1 (7%)	1 (7%)
	HCP (n= 12)	-	-	-	-	-	-	-	-
	Patient (n=15)	-	-	-	-	-	-	-	-
Decreased Anxiety	HCP (n= 12)	-	-	-	-	-	1 (8%)	-	1 (8%)
Tourette Syndrome									
Improved Quality of Life	Patient (n=6)	-	-	-	-	-	-	1 (2%)	1 (2%)
	HCP (n= 5)	-	-	-	-	-	-	-	-
Glaucoma									
Improved Sleep	Patient (n=5)	-	-	-	-	-	-	-	-
	HCP (n= 3)	-	-	-	-	1 (33%)	-	-	1 (3%)
ALS									
Reduced Anxiety	Patient (n=7)	-	-	-	-	-	1 (14%)	1 (14%)	2 (29%)
	HCP (n= 5)	-	-	-	-	-	-	-	-

Additional Clinical Observations

Healthcare practitioners were asked to provide any additional clinical observations or insights on the impact of medical cannabis treatment on the patient's condition, and were specifically prompted to report any observations on drug interactions. A third of the 114 observations describe a decrease in the patients' other medications- mainly opioids and benzodiazepines. The survey healthcare practitioners will complete for patients certified for intractable pain will ask specifically about this issue. There were a few comments about drug interactions with anti-epileptic drugs, including in some cases the anticipated ability to decrease dose of Clobazam. A full report of these observations can be found in *Appendix C: Healthcare Practitioner-Reported Clinical Observations from Surveys*.

Patient Versus HCP Perceptions of Benefit from Medical Cannabis

Among survey respondents, there were 126 patients who submitted a survey for whom their certifying health care practitioner also completed a survey. Comparison of benefit scores reported by the patient to benefit scores reported by the healthcare practitioner are shown in Table 6.13, grouping scores of 1 or 2 in a category representing no or little benefit; scores of 3, 4, or 5 were grouped into a category representing mild or moderate benefit and scores of 6 or 7 were placed in a category representing strong benefit. Among these 126 patients and their HCPs, 81 (64%) of patient-HCP pairs were in general agreement regarding degree of benefits experienced: 46% reported strong benefit from medical cannabis; 15% reported mild or moderate benefit and 3% reported no or little benefit (Table 6.13). When interpreting the meaning of these comparisons, it must be kept in mind that the 126 patients for whom both Patient Experience and HCP survey results are available are not necessarily representative of all patients who enrolled in the program during its first year of operation.

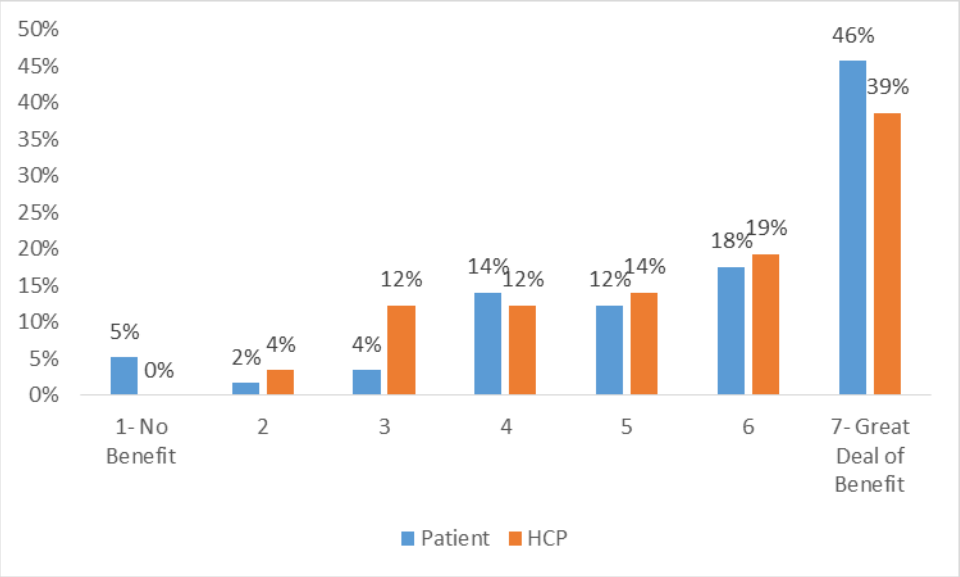
Table 6.13. Distribution of patient-reported benefits and HCP-reported benefits for patients with both patient and HCP surveys completed (n=126).

	HCP-Perceived Benefit		
Patient-Perceived Benefit	**No/Little Benefit (1-2)**	**Mild/Moderate Benefit (3-5)**	**Strong Benefit (6-7)**
No/Little Benefit (1-2)	**4 (3%)**	1 (1%)	2 (2%)
Mild/Moderate Benefit (3-5)	7 (6%)	**19 (15%)**	10 (8%)
Strong Benefit (6-7)	2 (2%)	23 (18%)	**58 (46%)**

Severe and Persistent Muscle Spasms

Figure 6.21 shows benefit scores reported by patients and their certifying HCPs for muscle spasms patients for whom both scores were available (n=57). Comparison of proportions of patients and HCPs reporting each benefit score shows fairly good agreement: 46% of patients and 39% of HCPs report scores of 6 or 7; 5% of patients and 0% HCPs report no benefit.

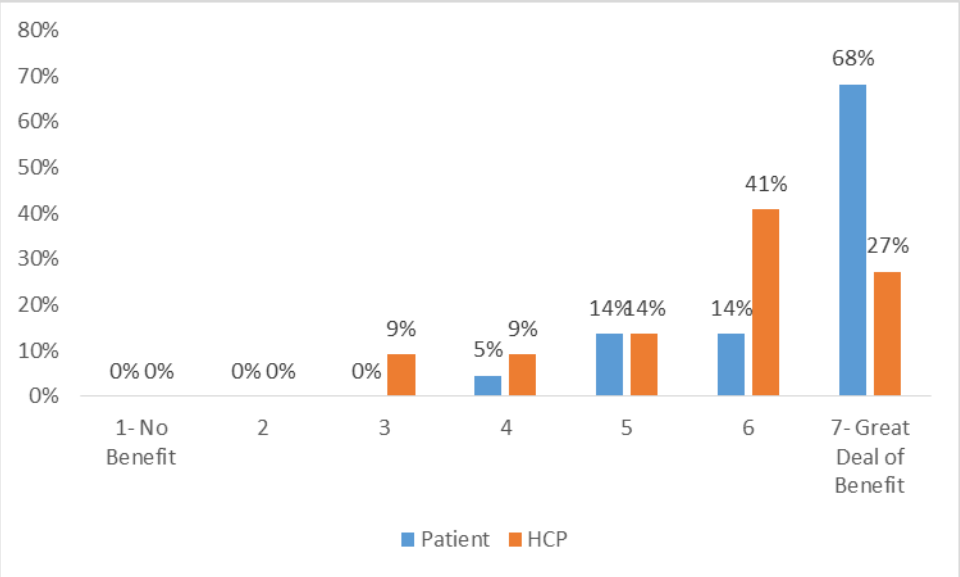
Figure 6.21. Muscle Spasms (N=57): Perceived Benefit



Cancer

Figure 6.22 shows benefit scores reported by patients and their certifying HCPs for cancer patients for whom both scores were available (n=22). Comparison of proportions of patients and HCPs reporting each benefit score shows differences in effect size but general agreement that patients experienced some benefit. Among this group, 68% of patients and 27% of HCPs report scores of 6 or 7; 0% patients and 0% HCPs report scores of 1 or 2.

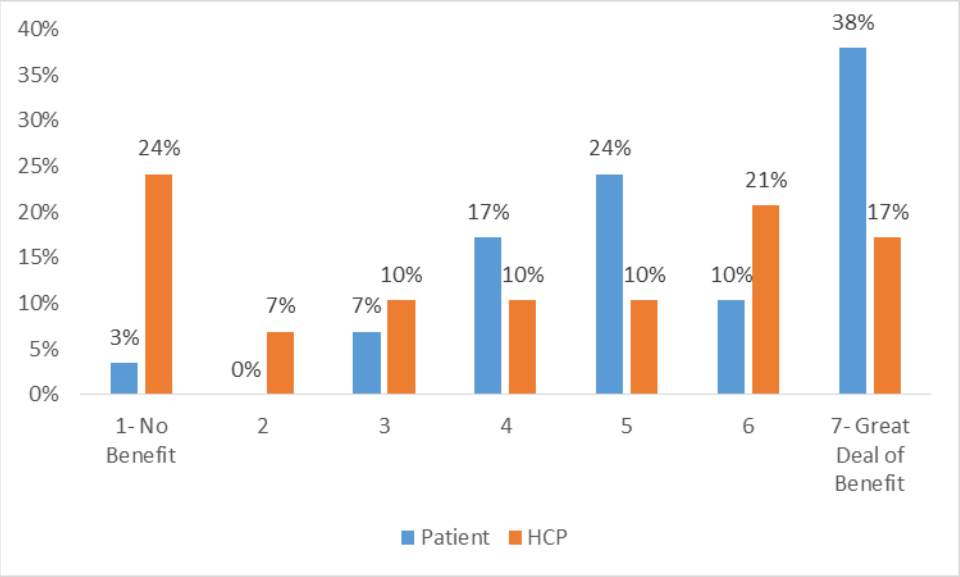
Figure 6.22. Cancer (N=22): Perceived Benefit



Seizures

Figure 6.23 shows benefit scores reported by patients and their certifying HCPs for seizure patients for whom both scores were available (n=29). Comparison of proportions of patients and HCPs reporting each benefit score shows that generally patients report higher degrees of benefit than HCPs: 38% of patients versus 17% of HCPs report scores of 6 or 7; 3% of patients versus 24% HCPs report no benefit.

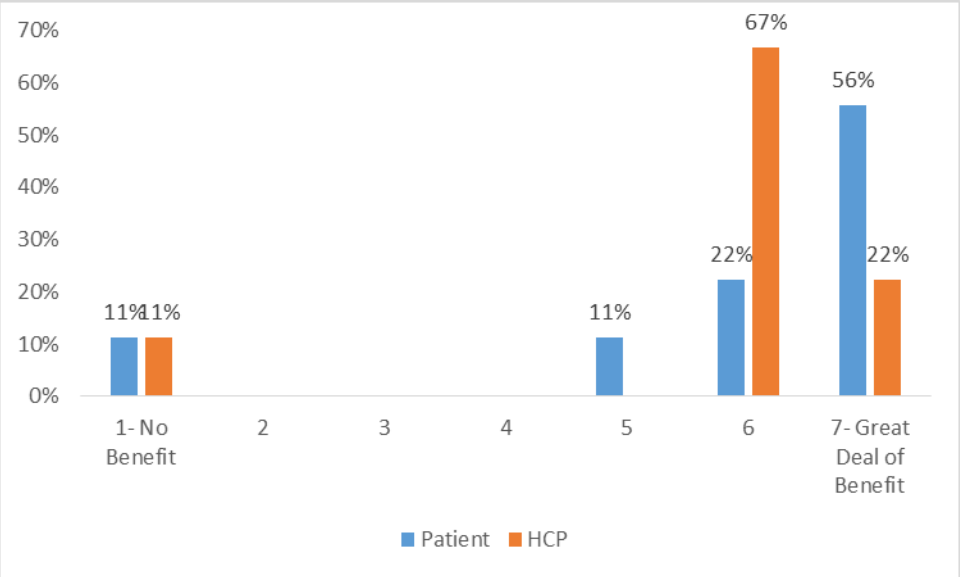
Figure 6.23. Seizures (N=29): Perceived Benefit



Crohn's Disease

Figure 6.24 shows benefit scores reported by patients and their certifying HCPs for Crohn's disease patients for whom both scores were available (n=9). Comparison of proportions of patients and HCPs reporting each benefit score shows general agreement about degree of benefit experienced: 89% of patients and 78% of HCPs report scores of 6 or 7; 11% of both patients and HCPs report scores of 1.

Figure 6.24. Crohn's Disease (N=9): Perceived Benefit



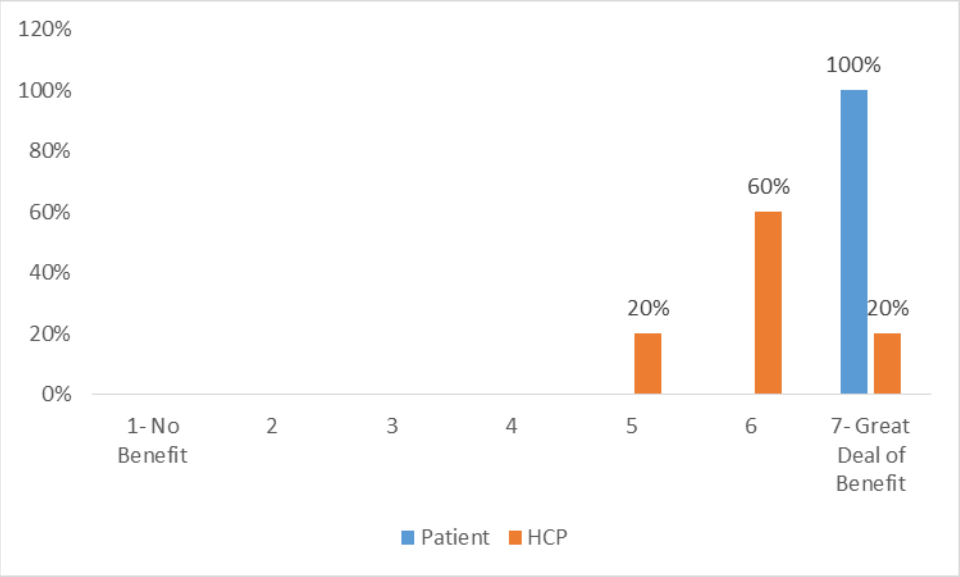
Terminal Illness

No patients with terminal illness had both an HCP-submitted survey and patient-submitted survey.

HIV/AIDS

Figure 6.25 shows benefit scores reported by patients and their certifying HCPs for HIV/AIDS patients for whom both scores were available (n=5). Comparison of proportions of patients and HCPs reporting each benefit score shows general agreement about degree of benefit experienced: 100% of patients and 80% of HCPs report scores of 6 or 7.

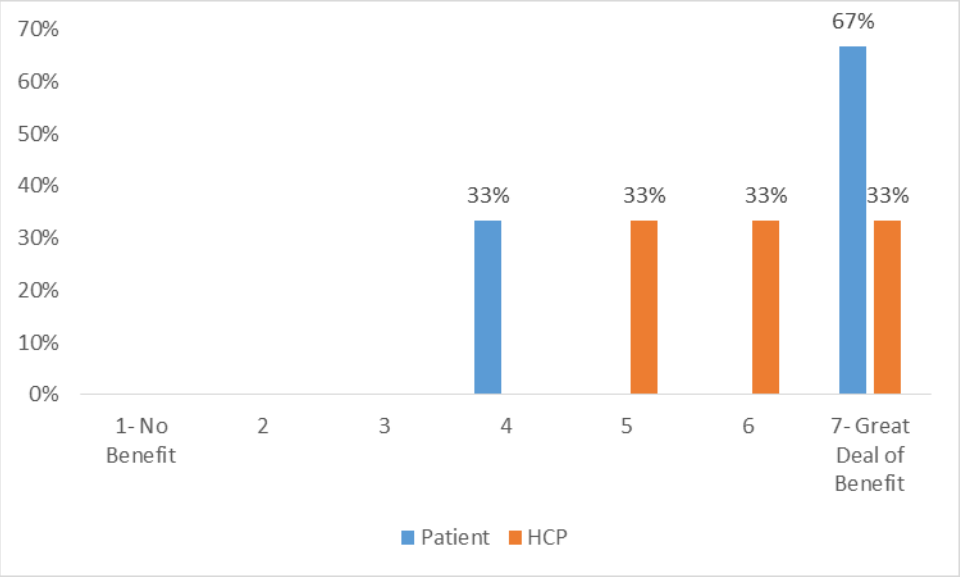
Figure 6.25. HIV/AIDS (N=5): Perceived Benefit



Tourette Syndrome

Figure 6.26 shows benefit scores reported by patients and their certifying HCPs for Tourette syndrome patients for whom both scores were available (n=3). Comparison of proportions of patients and HCPs reporting each benefit score shows general agreement about degree of benefit experienced: 67% of patients and 67% of HCPs report scores of 6 or 7.

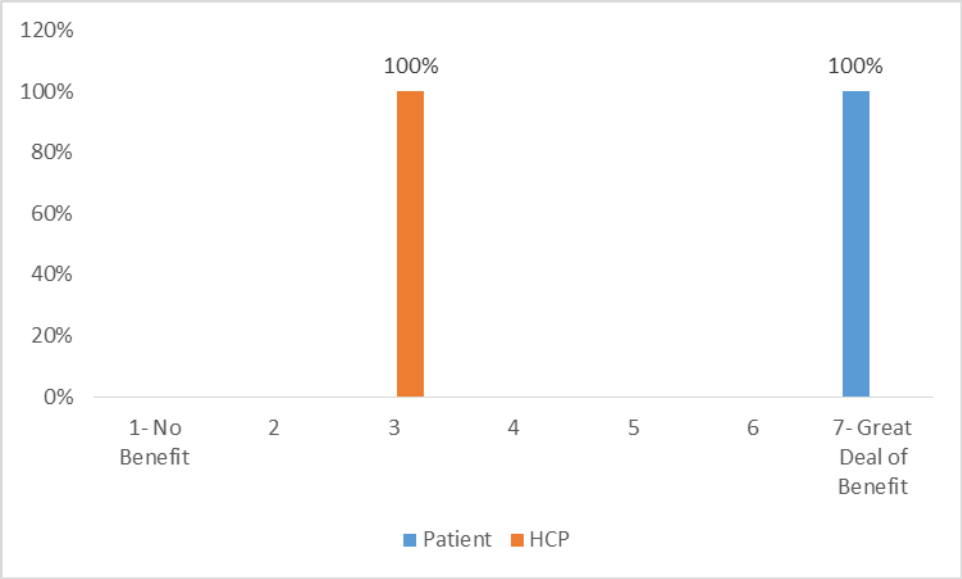
Figure 6.26. Tourette Syndrome (N=3): Perceived Benefit



Glaucoma

Figure 6.27 shows the benefit scores reported for one glaucoma patient who completed a survey (reported benefit score of 7) and whose HCP also completed a survey (reported benefit score of 3).

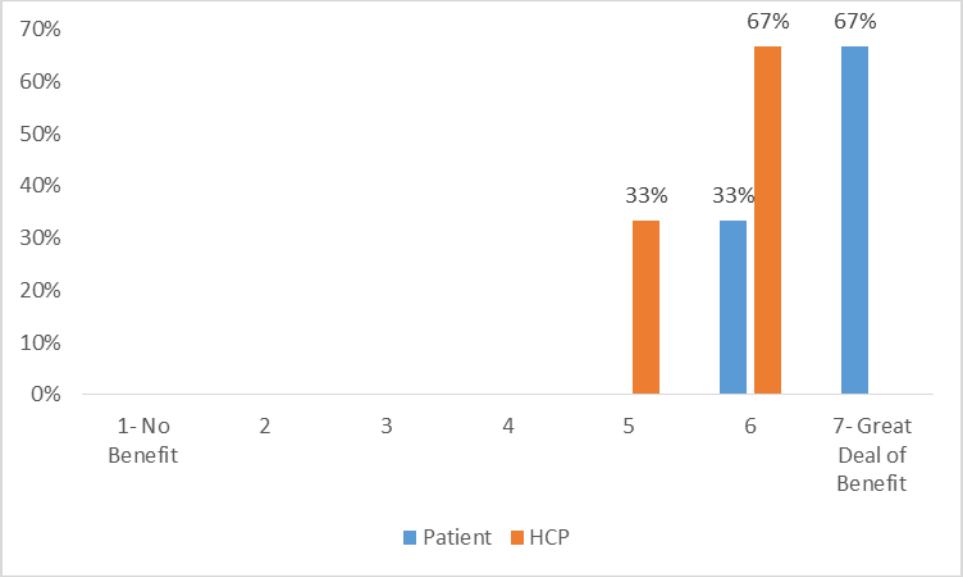
Figure 6.27. Glaucoma (N=1): Perceived Benefit



ALS

Figure 6.28 shows benefit scores reported by patients and their certifying HCPs for ALS patients for whom both scores were available (n=3). Comparison of proportions of patients and HCPs reporting each benefit score shows general agreement about degree of benefit experienced: 100% of patients and 67% of HCPs report scores of 6 or 7.

Figure 6.28. ALS (N=3): Perceived Benefit



Benefits Reported on Surveys: Conclusions

Of 1491 patients making a purchase in the first program year, 53% completed a survey three months after the first purchase. Among respondents, 43% reported experiencing the highest degree of benefit from medical cannabis and 87% reported at least a moderate degree of benefit (score of 4 or greater on a 1 to 7 scale). Patients reported the types of benefits experienced, which were predominantly (64%) various types of symptom improvement; many patients (25%) also reported global health benefits as the most important benefits from medical cannabis.

For patients making a purchase in the first six months of the program (n=774), 32% of HCP surveys were submitted. Overall, HCP reports of benefit were more conservative than those of patients, but 20% reported that the patient experienced the highest degree of benefit from medical cannabis and 60% reported at least a moderate degree of benefit. Among patients purchasing in the first six program months, 126 patients had both patient and HCP surveys completed and comparison of benefit scores indicated general agreement between the two scores for most patients.

Benefits Reported on the Patient Self-Evaluation

The Patient Self-Evaluation (PSE) contains questions that allow the Office of Medical Cannabis (OMC) to look for improvements in symptoms over time. Patients are required to complete a PSE prior to each medical cannabis purchase (including before their first medical cannabis purchase). This allows for capture of the patients' symptoms at baseline – prior to taking any medical cannabis, as well as prior to each subsequent medical cannabis purchase. Hence, symptom change over time can be analyzed during the patients' participation in the program.

All patients received a standard set of 8 symptom measures on the PSE. In addition, some patients received additional symptom questions depending on their qualifying medical condition(s). These two sets of symptom measures will be subsequently discussed below. Data from the PSE were extracted from patients who enrolled during the first program year (enrolled between July 1, 2015 and June 30, 2016; 1660 patients enrolled during this time period).

Standard 8 Symptom Measures

The standard 8 symptom measures that all patients received are answered on a 0-10 numerical rating scale (NRS), with 0 indicating absence of the symptom to 10 indicating that the symptom is as bad as the patient can imagine (see Box 6.1). Therefore, higher scores on these measures indicate poorer management of these symptoms. Patients are asked to rate symptom severity over the past 24 hours.

Box 6.1. Listing of the Standard 8 symptom measures that all patients answer, including the responses options available to patients.

Standard 8 Symptom Measures:

Anxiety	Fatigue
Lack of Appetite	Nausea
Depression	Pain
Disturbed Sleep	Vomiting

Response Options (0 – 10 NRS):

0 1 2 3 4 5 6 7 8 9 10

Symptom not present ... Symptom as bad as one can image

To understand whether patients derived any symptom benefits during their participation in the program, the following three questions were explored for each Standard 8 symptom measure:

QUESTION 1

Of those patients who experienced moderate to severe symptoms at baseline (score of 4 or higher at baseline), what percentage of them experienced at least a 30% improvement in symptoms within four months of their first medical cannabis purchase? The threshold of ≥30% reduction on a 0-10 point scale was chosen because this threshold has been documented in clinical trials to represent clinically meaningful change – especially for pain reduction and spasticity reduction. Examples of ≥30% change include moving from a score of 10 to a score of 7, from 9 to 6, from 8 to 5, from 7 to 4, etc.

QUESTION 2

If a patient achieved at least a 30% improvement on symptoms within 4 months of their first medical cannabis purchase (determined in Question 1), what percentage of them will, on average, still maintain that level of improvement in the four months following that initial 30% symptom improvement? [Four-month follow-up period]

QUESTION 3

What medical cannabis products were purchased just *prior* to the patient's initial report of symptom improvement (first time patient indicated ≥30% improvement on the PSE)? What was the average daily intake of delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) for these product types?

To address Question 1 the following procedure was adopted for each standard 8 measure: all patients who scored 4 or higher at baseline were identified as those experiencing moderate to severe symptoms, and all standard 8 responses that were submitted within 4 months of their first medical cannabis purchase were retained. From this dataset, each patient's standard 8 responses were compared to their baseline response over time. The first instance a patient achieved at least a 30% symptom improvement was recorded, effectively demonstrating when – during the first 4 months following their first medical cannabis purchase – the patient achieved symptom improvement, if at all.

Calculating the percentage of patients who achieved ≥30% symptom improvement within 4 months of their first medical cannabis purchase (Question 1) was done in two ways. In one method, the number of patients who achieved ≥30% symptom improvement within 4 months was divided by the total number of patients that ever made a first purchase (patients with baseline PSE data). In the other method, the number of patients achieving ≥30% symptom improvement within 4 months was divided by patients who had submitted additional PSE data (beyond their baseline response) within 4 months of their first purchase. The denominator in

the former method includes all patients who made a first purchase (all patients with a baseline PSE submission), while the latter method effectively restricts the dominator to those patients who submitted additional PSE symptom data following their baseline submission and within 4 months of their first purchase. Therefore, the former method allows for a more conservative estimation of symptom benefit. In the text of this report, we present results using the former, more conservative estimate of benefit. Those who made no additional purchases after their first purchase may have discontinued use because of lack of effectiveness, though they may have discontinued use for other reasons as well (i.e., medical cannabis cost, side effects, etc.).

Since Question 1 examines symptom improvement within 4 months of their first medical cannabis purchase, patients who had not been enrolled in the program for at least 4 months since their first medical cannabis purchase were not included in the analysis. When PSE data were extracted in late December 2016, 1512 patients from the first year cohort (91.1% of the 1st year cohort) had been enrolled for at least 4 months since their first medical cannabis purchase—results on the standard 8 symptom measures are reported on this cohort subset.

Question 2 was addressed by observing all symptom responses in the four months *following* the time point when the patient first achieved ≥30% symptom improvement. For each patient, all symptom responses identified during those follow-up four months were averaged together. Patients who, on average, still maintained at least a 30% symptom improvement from baseline were identified as those showing persistence in their symptom benefits.

For Question 3, products that were purchased just *prior* to each patient's initial ≥30% symptom improvement were identified and categorized by their THC/CBD ratio and intended route of administration (ROA). See Box 6.2 for definitions of these categories.

Box 6.2. Categories to describe medical cannabis products purchased by patients.

Medical Cannabis Products Categorized by THC:CBD Content Ratio:

- **Very High THC to CBD** = 100:1 or higher
- **High THC to CBD** = >4:1 up to 99:1
- **Balanced** = 1:1 up to 4:1
- **High CBD to THC** = ≥1:1 up to 99:1
- **Very High CBD to THC** = 100:1 or higher

Product Routes of Administration (ROA):

- **Enteral:** for absorption through the gastrointestinal tract (includes capsules and oral solutions to swallow).
- **Inhalation:** for absorption through the lungs (includes products for vaporization)
- **Oromucosal:** for absorption through the oral mucosa (includes sublingual sprays and tinctures to hold in the mouth)

Overall Results on Standard 8 Symptom Measures

Data on the Standard 8 symptom measures were first analyzed across all patients regardless of their qualifying condition(s) and are displayed in Table 6.14 (n = 1512). The third and fourth column respectively display the number and percentage of patients (out of 1512 patients) experiencing moderate to severe symptoms at baseline (baseline response ≥ 4) on a given Standard 8 measure. With the exception of vomiting, the responses from patients indicated a high degree of burden on all symptom measures at baseline (~60-90% patients indicated moderate to severe symptoms).

The fifth column in Table 6.14 shows the percentage and number of patients (out of those reporting at moderate to severe levels at baseline) who had achieved at least a 30% symptom improvement at any time within 4 months of their first medical cannabis purchase. Anywhere from 36% to 60% of patients reported achieving at least a 30% improvement in symptoms within 4 months of their first medical cannabis purchase. Improvements in pain and fatigue were the least likely to reach ≥30% improvement in patients (respectively at 36.3% and 40.2%), with the greatest proportion of patients reaching ≥30% improvement in nausea (55.6%), depression (56.8%), and vomiting (60.2%).

The number of patients who had symptom data in the 4-month period *following* their initial ≥30% symptom improvement are listed in the sixth column in Table 6.14. All symptom responses during this time period were averaged together within each patient. The seventh column shows the percentage and number of patients who had achieved ≥30% symptom improvement that had – on average – maintained at least that level of improvement in the 4-

month follow-up period. Roughly a half to two-thirds of the patients who achieved at least 30% symptom improvement had maintained it in the following 4 months. Lastly, the right-most column shows the percentage of all patients who both achieved and maintained at least a 30% symptom improvement in the 4-month follow-up period. For the majority of all symptoms, roughly a third of all patients experiencing moderate to severe symptoms will both achieve and maintain at least a 30% improvement in symptoms for at least 4 months.

For a more detailed look on overall results from the eight standard symptom measures, please refer to *Appendix D: Symptom Results from the Patient Self-Evaluation*. This Appendix shows the following for each Standard 8 measure: 1) a figure showing the distribution of patient responses at baseline, 2) a figure showing the cumulative percentage of patients achieving at least 30% symptom improvement at 2 weeks, 1 month, 2 months, 3 months, and 4 months (the denominator is different between the orange and blue bars; orange bars include all moderate to severe scoring patients at baseline while blue bars restrict analyses to only those patients who submitted data by the time point indicated on the x-axis), and 3) a figure showing the frequency distribution of patients by the average symptom change (%) each patient experienced in the 4-month follow-up period since they initially achieved ≥30% symptom reduction.

Table 6.14. Overall standard 8 symptom results.

Condition	Standard 8 Symptom Measure	# of Patients Reporting at Moderate to Severe Levels at Baseline	% of Patients Reporting at Moderate to Severe Levels at Baseline	% of Patients Achieving ≥30% Symptom Improvement within 4 months of First Purchase out of all Moderate to Severe Baseline Scorers (n)	# of Patients with Data in 4-mo Period Following Initial ≥30% Symptom Improvement	% of Patients Who Achieved ≥30% Symptom Improvement that Maintained it for at Least 4 months (n)	% of Patients that Both Achieved ≥30% Symptom Improvement and Retained that Degree of Improvement for at Least 4 months
All Patients - Collapsed Across Conditions (n = 1512)	Anxiety	1185	78.4	53.8 (638)	460	53.1 (339)	28.6
	Appetite Lack	963	63.7	53.7 (517)	383	57.1 (295)	30.6
	Depression	1000	66.1	56.8 (568)	419	56.7 (322)	32.2
	Disturbed Sleep	1323	87.5	50.3 (665)	519	52.0 (346)	26.2
	Fatigue	1381	91.3	40.2 (555)	415	48.6 (270)	19.6
	Nausea	864	57.1	55.6 (480)	362	59.2 (284)	32.9
	Pain	1312	86.8	36.3 (476)	329	45.0 (214)	16.3
	Vomiting	480	31.7	60.2 (289)	213	57.8 (167)	34.8

Results on Standard 8 Symptom Measures Stratified by Qualifying Condition

Data on the Standard 8 symptom measures were also analyzed separately by qualifying condition. Results are presented in Table 6.15 below. The first column indicates the qualifying condition and the total number of patients who had been enrolled in the program for at least 4 months since their first medical cannabis purchase. For some conditions, results are further broken down by condition subcategories (i.e., breakdown cancer patients based on whether their certifying condition was accompanied by pain, nausea/vomiting, etc.); condition subcategories are preceded by a star (*)). The third and fourth columns in Table 6.15 indicate the number and percentage of patients who experienced moderate to severe symptoms (score ≥4) at baseline for each symptom.

The fifth column in Table 6.15 indicates the percentage and number of patients (out of those reporting at moderate to severe levels at baseline) that had achieved at least a 30% symptom improvement at any time within 4 months of their first medical cannabis purchase. The number of patients who had symptom data in the 4-month period *following* their initial ≥30% symptom improvement are listed in the sixth column in Table 6.15. All symptom responses submitted during this time period were averaged together within each patient. The seventh column shows the percentage and number of patients that had achieved at least a 30% symptom improvement that had subsequently maintained it, on average, for at least 4 months. Lastly, the right-most column shows the percentage of all patients that had both achieved and maintained at least a 30% symptom improvement for at least 4 months.

Results generally show a high degree of burden for these eight symptoms at baseline. The instances where symptom severity is noticeably lower tend to be as expected; for example, nausea and vomiting in patients with Tourette syndrome and in patients with glaucoma. Among baseline responses to the eight symptom measures, those with the highest proportion rated as moderate to severe (score ≥4) include fatigue, disturbed sleep, pain, and anxiety. For each of the medical conditions, a substantial proportion of patients achieved ≥30% reduction in most of the eight symptoms. Improvement was generally a bit higher in patients with seizures and with Tourette Syndrome and a bit lower in patients with cancer. Overall, a smaller proportion of patients achieved ≥30% reduction of pain and fatigue and a higher proportion of patients achieved ≥30% improvement in appetite and reduction in vomiting. For each medical condition, roughly half to three-quarters of the patients who experienced a ≥30% reduction in a particular symptom within the first four months maintained that level of improvement over the following four months.

Table 6.15. Standard 8 symptom results stratified by qualifying condition.

Condition	Standard 8 Symptom Measure	# of Patients Reporting at Moderate to Severe Levels at Baseline	% of Patients Reporting at Moderate to Severe Levels at Baseline	% of Patients Achieving ≥30 Symptom Improvement within 4 months of First Purchase (n)	# of Patients with Data in 4-mo Period Following Initial ≥30% Symptom Improvement	% of Patients Who Achieved ≥30% Symptom Improvement that Maintained it for at Least 4 months (n)	% of Patients that Both Achieved ≥30% Symptom Improvement and Retained that Degree of Improvement for at Least 4 months
Muscle Spasms (n = 667)	Anxiety	553	82.9	54.8 (303)	250	60.7 (184)	33.3
	Appetite Lack	407	61.0	58.2 (237)	198	65.0 (154)	37.8
	Depression	471	70.6	58.0 (273)	227	63.0 (172)	36.5
	Disturbed Slee	604	90.6	49.7 (300)	265	61.7 (185)	30.6
	Fatigue	624	93.6	42.0 (262)	227	55.3 (145)	23.2
	Nausea	366	54.9	63.1 (231)	195	65.4 (151)	41.3
	Pain	640	96.0	33.8 (216)	188	51.4 (111)	17.3
	Vomiting	192	28.8	65.1 (125)	103	66.4 (83)	43.2
Cancer (n = 405)	Anxiety	309	76.3	45.0 (139)	112	56.1 (78)	25.2
	Appetite Lack	321	79.3	39.3 (126)	102	57.1 (72)	22.4
	Depression	274	67.7	48.5 (133)	101	55.6 (74)	27.0
	Disturbed Slee	355	87.7	42.0 (149)	122	47.0 (70)	19.7
	Fatigue	384	94.8	25.3 (97)	83	41.2 (40)	10.4
	Nausea	283	69.9	38.2 (108)	85	60.2 (65)	23.0
	Pain	356	87.9	28.9 (103)	80	40.8 (42)	11.8
	Vomiting	168	41.5	47.6 (80)	64	57.5 (46)	27.4
*Cancer: Pain (n = 285)	Pain	268	94.0	31.0 (83)	64	41.0 (34)	12.7
*Cancer: Nausea/Vomiting (n = 235)	Appetite Lack	200	85.1	41.0 (82)	66	57.3 (47)	23.5
	Nausea	184	78.3	34.8 (64)	49	54.7 (35)	19.0
	Vomiting	113	48.1	44.2 (50)	39	52.0 (26)	23.0
*Cancer: Cachexia/Wasting (n = 147)	Appetite Lack	124	84.4	38.7 (48)	39	58.3 (28)	22.6
Seizures (n = 299)	Anxiety	202	67.6	67.3 (136)	120	71.3 (97)	48.0
	Appetite Lack	145	48.5	76.6 (111)	97	73.9 (82)	56.6
	Depression	158	52.8	73.4 (116)	101	74.1 (86)	54.4
	Disturbed Slee	242	80.9	69.0 (167)	155	63.5 (106)	43.8
	Fatigue	246	82.3	61.8 (152)	143	64.5 (98)	39.8
	Nausea	138	46.2	72.5 (100)	93	79.0 (79)	57.2
	Pain	190	63.5	60.0 (114)	106	69.3 (79)	41.6
	Vomiting	90	30.1	80.0 (72)	66	79.2 (57)	63.3

Table 6.15 Continued. Standard 8 symptom measures.

Condition	Standard 8 Symptom Measure	# of Patients Reporting at Moderate to Severe Levels at Baseline	% of Patients Reporting at Moderate to Severe Levels at Baseline	% of Patients Achieving ≥30 Symptom Improvement within 4 months of First Purchase (n)	# of Patients with Data in 4-mo Period Following Initial ≥30% Symptom Improvement	% of Patients Who Achieved ≥30% Symptom Improvement that Maintained it for at Least 4 months (n)	% of Patients that Both Achieved ≥30% Symptom Improvement and Retained that Degree of Improvement for at Least 4 months
Crohn's Disease (n = 102)	Anxiety	87	85.3	57.5 (50)	43	54.0 (27)	31.0
	Appetite Lack	80	78.4	53.8 (43)	37	58.1 (25)	31.3
	Depression	68	66.7	51.5 (35)	31	65.7 (23)	33.8
	Disturbed Slee	89	87.3	42.7 (38)	37	65.8 (25)	28.1
	Fatigue	96	94.1	36.5 (35)	31	48.6 (17)	17.7
	Nausea	72	70.6	65.3 (47)	31	59.6 (28)	38.9
	Pain	97	95.1	41.2 (40)	32	47.5 (19)	19.6
	Vomiting	31	30.4	54.8 (17)	16	82.4 (14)	45.2
Terminal Illness (n = 81)	Anxiety	60	74.1	51.7 (31)	28	58.1 (18)	30.0
	Appetite Lack	64	79.0	37.5 (24)	19	45.8 (11)	17.2
	Depression	54	66.7	48.1 (26)	22	61.5 (16)	29.6
	Disturbed Slee	65	80.2	44.6 (29)	28	55.2 (16)	24.6
	Fatigue	76	93.8	21.1 (16)	14	37.5 (6)	7.9
	Nausea	56	69.1	44.6 (25)	23	64.0 (16)	28.6
	Pain	72	88.9	19.4 (14)	11	50.0 (7)	9.7
	Vomiting	35	43.2	57.1 (20)	18	50.0 (10)	28.6
*Terminal Illness: Pain (n = 57)	Pain	54	94.7	20.4 (11)	8	45.5 (5)	9.3
*Terminal Illness: Nausea/Vomiting (n = 36)	Appetite Lack	31	86.1	41.9 (13)	11	61.5 (8)	25.8
	Nausea	28	77.8	35.7 (10)	10	70.0 (7)	25.0
	Vomiting	18	50.0	50.0 (9)	8	44.4 (4)	22.2
*Terminal Illness: Cachexia/Wasting (n = 29)	Appetite Lack	23	79.3	43.5 (10)	9	60.0 (6)	26.1
HIV/AIDS (n = 48)	Anxiety	44	91.7	50.0 (22)	20	68.2 (15)	34.1
	Appetite Lack	39	81.3	48.7 (19)	17	63.2 (12)	30.8
	Depression	34	70.8	47.1 (16)	15	75.0 (12)	35.3
	Disturbed Slee	44	91.7	50.0 (22)	18	50.0 (11)	25.0
	Fatigue	41	85.4	46.3 (19)	15	47.4 (9)	22.0
	Nausea	33	68.8	60.6 (20)	17	65.0 (13)	39.4
	Pain	45	93.8	40.0 (18)	14	50.0 (9)	20.0
	Vomiting	20	41.7	50.0 (10)	9	80.0 (8)	40.0

Table 6.15 Continued. Standard 8 symptom measures.

Condition	Standard 8 Symptom Measure	# of Patients Reporting at Moderate to Severe Levels at Baseline	% of Patients Reporting at Moderate to Severe Levels at Baseline	% of Patients Achieving ≥30 Symptom Improvement within 4 months of First Purchase (n)	# of Patients with Data in 4-mo Period Following Initial ≥30% Symptom Improvement	% of Patients Who Achieved ≥30% Symptom Improvement that Maintained it for at Least 4 months (n)	% of Patients that Both Achieved ≥30% Symptom Improvement and Retained that Degree of Improvement for at Least 4 months
Tourette Syndrome (n = 28)	Anxiety	26	92.9	69.2 (18)	17	72.2 (13)	50.0
	Appetite Lack	8	28.6	50.0 (4)	3	75.0 (3)	37.5
	Depression	20	71.4	75.0 (15)	14	86.7 (13)	65.0
	Disturbed Slee	21	75.0	76.2 (16)	16	75.0 (12)	57.1
	Fatigue	21	75.0	66.7 (14)	13	50.0 (7)	33.3
	Nausea	5	17.9	100.0 (5)	5	80.0 (4)	80.0
	Pain	17	60.7	64.7 (11)	11	90.9 (10)	58.8
	Vomiting	1	3.6	100.0 (1)	1	100.0 (1)	100.0
Glaucoma (n = 21)	Anxiety	14	66.7	42.9 (6)	6	50.0 (3)	21.4
	Appetite Lack	7	33.3	85.7 (6)	5	66.7 (4)	57.1
	Depression	14	66.7	85.7 (12)	11	58.3 (7)	50.0
	Disturbed Slee	18	85.7	61.1 (11)	10	54.5 (6)	33.3
	Fatigue	19	90.5	42.1 (8)	7	37.5 (3)	15.8
	Nausea	6	28.6	16.7 (1)	1	100.0 (1)	16.7
	Pain	18	85.7	33.3 (6)	6	50.0 (3)	16.7
	Vomiting	1	4.8	0.0 (0)	0	-- (0)	0.0
ALS (n = 21)	Anxiety	17	81.0	52.9 (9)	7	55.6 (5)	29.4
	Appetite Lack	8	38.1	87.5 (7)	5	57.1 (4)	50.0
	Depression	15	71.4	40.0 (6)	5	50.0 (3)	20.0
	Disturbed Slee	18	85.7	33.3 (6)	6	83.3 (5)	27.8
	Fatigue	20	95.2	35.0 (7)	7	71.4 (5)	25.0
	Nausea	9	42.9	55.6 (5)	4	80.0 (4)	44.4
	Pain	17	81.0	47.1 (8)	7	25.0 (2)	11.8
	Vomiting	2	9.5	50.0 (1)	1	100.0 (1)	50.0

Appendix D: Symptom Results from the Patient Self-Evaluation shows the following for each Standard 8 measure stratified by qualifying medical condition: 1) a figure showing the distribution of patient responses at baseline, 2) a figure showing the cumulative percentage of patients achieving at least 30% symptom improvement at 2 weeks, 1 month, 2 months, 3 months, and 4 months (the denominator is different between the orange and blue bars; orange bars include all moderate to severe scoring patients at baseline while blue bars restrict analyses to only those patients who submitted data by the time point indicated on the x-axis), 3) a figure showing the frequency distribution of patients by the average symptom change (%) each patient experienced in the 4-month follow-up period since they initially achieved ≥30% symptom reduction, and 4) a table of medical cannabis products patients purchased just prior to achieving ≥30% symptom improvement for the first time, along with the average daily THC and CBD dose taken by patients.

Medical cannabis products that were purchased just prior to the initial 30% symptom improvement are discussed only briefly in this section (Question 3), and the reader is encouraged to see *Appendix D: Symptom Results from the Patient Self-Evaluation* for the full table of results. Here, only a few results regarding medical cannabis purchases are discussed as examples—some in relation to improvements on a particular Standard 8 measure, and others in relation to a particular condition-specific symptom measure.

Table 6.16 below shows the most common medical cannabis products that were purchased by cancer patients just prior to achieving the initial 30% reduction in nausea symptoms. The second column from the right indicates the number of patients who purchased specific products just prior to that initial symptom reduction (products purchased indicated by "X"s). The table also shows the average daily amount of THC and CBD (mg) patients consumed (right-most column), which was derived from manufacturer-supplied product information and pharmacist-entered calculations of how long the purchased supply would last. Very High THC:CBD vaporization products were purchased most frequently (n = 20), followed by a combination of Very High THC:CBD enteral products and Very High THC:CBD vaporization products (n = 12). See *Appendix D: Symptom Results from the Patient Self-Evaluation* for full results.

Table 6.16. Top 5 medical cannabis product(s) purchased by cancer patients just prior to achieving the initial 30% reduction in the Standard 8 nausea measure.

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 109 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
					X										18.3 (20)	55.9 mg/0.4 mg
X					X										11.0 (12)	71.6 mg/0.5 mg
										X					8.3 (9)	86.3 mg/0.4 mg
		X													6.4 (7)	135.5 mg/83.2 mg
X		X			X										4.6 (5)	61.4 mg/15.6 mg

Table 6.17 below shows the most common medical cannabis products that were purchased by terminal illness patients just prior to achieving the initial 30% reduction in nausea symptoms. The most frequently purchased products were a combination of both Very High THC:CBD products for oral administration and vaporization (n = 3), followed by Balanced THC:CBD products for inhalation only (n = 3). See *Appendix D: Symptom Results from the Patient Self-Evaluation* for full results.

Table 6.17. Top 7 medical cannabis product(s) purchased by terminal illness patients just prior to achieving the initial 30% reduction in the Standard 8 nausea measure.

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 26 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
X					X										11.5 (3)	67.1 mg/0.5 mg
					X										11.5 (3)	44.5 mg/0.4 mg
X		X			X										7.7 (2)	45.5 mg/37.5 mg
		X			X		X								7.7 (2)	110.1 mg/5.9 mg
		X								X					7.7 (2)	78.6 mg/61.1 mg
		X													7.7 (2)	49.0 mg/46.0 mg
			X												7.7 (2)	4.4 mg/206.7 mg

Table 6.18 below shows the most common medical cannabis products purchased by HIV/AIDS patients just prior to their initial 30% reduction in pain symptoms. Balanced THC:CBD products were purchased most frequently (n = 6), followed by Very High THC:CBD products for inhalation (n = 3). See *Appendix D: Symptom Results from the Patient Self-Evaluation* for full results.

Table 6.18. Top 4 medical cannabis product(s) purchased by HIV/AIDS patients just prior to achieving the initial 30% reduction in the Standard 8 pain measure.

Enteral			Inhalation			Oromucosal				
Very High THC to CBD	High THC to CBD	Balanced	Very High THC to CBD	High THC to CBD	Balanced	Very High THC to CBD	High THC to CBD	Balanced	% of Patients out of 18 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
		X							33.3 (6)	23.1 mg/22.1 mg
			X						16.7 (3)	65.2 mg/0.3 mg
X		X							11.1 (2)	5.0 mg/0.0 mg
			X		X				11.1 (2)	51.7 mg/18.2 mg

Condition-Specific Symptom Measures

In addition to the Standard 8 measures, some patients received additional symptom questions on the PSE to more adequately address condition-specific symptoms. These include, among others, questions on seizure frequency for seizure patients, questions on spasm frequency for muscle spasm and ALS patients, and Crohn's activity in Crohn's patients. While patients received the same response options on the Standard 8 measures (respond from 1-10 on a

numerical rating scale), response options for condition-specific measures varied and will be described in this section. All condition-specific measures were investigated within the same framework as the Standard 8 measures: 1) what percentage of patients achieved symptom improvement within the four months since their first medical cannabis purchase compared to their baseline responses, 2) what percentage of those achieving symptom improvement showed general persistence in the 4-month follow-up period, and 3) what medical cannabis products were purchased just prior to the patient reporting initial symptom improvements. A summary of results are similarly presented in a table like those presented for the Standard 8 measures (see Table 6.19 below).

The first column in Table 6.19 lists each condition that received additional symptom questions beyond the Standard 8. The second column briefly indicates the nature of these additional condition-specific symptom measures, with the number of patients included in the analysis at baseline indicated in the third column (baseline, meaning patients who provided data and met criteria on these measures at the beginning of the program – prior to purchasing any medical cannabis). The fourth column indicates the percentage and number of patients achieving a specified threshold of symptom improvement within four months of purchasing their first medical cannabis (denominator is patients included in the analysis at baseline). The threshold to determine symptom improvement for these analyses are subsequently described below, found in the descriptive section for each condition. The number of patients who had symptom data in the 4-month period following their initial symptom improvement are listed in the fifth column in Table 6.19. All symptom responses during this time period were averaged together within each patient. The sixth column indicates the percentage and number of patients who had achieved symptom improvement that subsequently still maintained that improvement for at least 4 months. Lastly, the right-most column shows the percentage of all patients who both achieved and maintained symptom improvements for at least 4 months. A more detailed discussion of these condition-specific results will follow Table 6.19.

Table 6.19. Condition-Specific Measures.

Condition	Condition-Specific Symptom Measure	# of Patients Included in Analysis	% of Patients Achieving Threshold Symptom Improvement within 4 months of First Purchase (n)	# of Patients with Data in 4-mo Period Following Initial Threshold Symptom Improvement	% of Patients Who Achieved Threshold Symptom Improvement that Maintained it for at Least 4 months (n)	% of Patients that Both Achieved Threshold Symptom Improvement and Retained that Degree of Improvement for at Least 4 months
Muscle Spasms	Weekly Spasms Frequency	629	48.0 (302)	225	57.6 (174)	27.6
	0-10 Spasticity Scale	618	36.4 (225)	197	47.1 (106)	17.2
Cancer: Nausea/Vomiting	Chemo-Induced Nausea	147	37.4 (55)	29	34.5 (19)	12.9
	Chemo-Induced Vomiting	77	41.6 (32)	20	56.3 (18)	23.4
Cancer: Cachexia/Wasting	Weight	147	13.6 (20)	15	45.0 (9)	6.1
Seizures	Weekly Seizure Frequency	262	68.3 (179)	150	70.9 (127)	48.5
Crohn's Disease	# Liquid Stools	41	51.2 (21)	17	57.1 (12)	29.3
	Abdominal Pain	73	53.4 (39)	29	35.9 (14)	19.2
	General Well-Being	15	46.7 (7)	5	28.6 (2)	13.3
	Measures Combined	102	51.0 (52)	41	42.3 (22)	21.6
	Weight	102	20.6 (21)	18	57.1 (12)	11.8
Terminal Illness: Cachexia/Wasting	Weight	29	20.7 (6)	5	50.0 (3)	10.3
HIV/AIDS	Weight	48	14.6 (7)	3	42.9 (3)	6.3
Tourette Syndrome	Weekly Tic Frequency	28	60.7 (17)	15	76.5 (13)	46.4
ALS	Weekly Spasms Frequency	18	33.3 (6)	4	66.7 (4)	22.2
	0-10 Spasticity Scale	15	20.0 (3)	3	100.0 (3)	20.0

Severe and Persistent Muscle Spasms

Patients with muscle spasms were given two questions to assess the severity of their muscle spasms. First, patients were given the option to respond to the number of muscle spasms they experienced the day before or the number of muscle spasms they experienced within the last week. These allowed for the calculation of weekly spasm frequency. Secondly, patients were asked to rate the severity of their muscle spasms on a 0-10 numerical rating scale (NRS), with 0 indicating absence of spasms to 10 indicating spasticity being as bad as the patient could imagine. For the analysis in Table 6.19 above, responses to the 0-10 spasticity measure were restricted to patients experiencing moderate to severe spasticity at baseline (score of 4 or higher), while all patients responding to the weekly spasms frequency question were included in the analysis. In the analysis of both measures, symptom improvement was defined as achieving at least a 30% reduction in symptoms (30% decrease in weekly spasm frequency; 30% decrease on the 0-10 NRS spasticity measure) compared to baseline.

Weekly spasm frequency was reduced by ≥30% in nearly half (48.0%) of the muscle spasm patients. Among patients who achieved ≥30% reduction, 58% (27.6% of patients included in analysis at baseline) retained that level of improvement over the next four months.

Severity of muscle spasticity was reduced by ≥30% for 36.4% of the patients with moderate to severe muscle spasticity at baseline. Among patients who achieved ≥30% reduction, 47% (17.2% of patients included in analysis at baseline) retained that level of improvement over the next four months.

Table 6.20 below shows the top 5 medical cannabis product types that were purchased by muscle spasm patients just prior to achieving ≥30% weekly spasm reduction for the first time, including the number of patients who purchased those specific product types (second column from right). It also shows the average daily amount of THC and CBD (mg) patients consumed (right-most column), which was derived from manufacturer-derived product information and pharmacist-entered calculations of how long the purchased supply would last. Full purchasing details are in *Appendix D: Symptom Results from the Patient Self-Evaluation*. The most frequently purchased product types preceding the initial symptom improvement were a combination of Balanced THC:CBD products for oral administration and Balanced THC:CBD products for vaporization (n = 34), followed by Very High THC:CBD products for vaporization (n = 30).

Table 6.20. Top 5 medical cannabis product types purchased by muscle spasm patients just prior to achieving ≥30% reduction in weekly spasms. Last column shows the average daily THC/CBD dose that was used by patients purchasing those product types (second column from right).

Enteral					Inhalation					Oromucosal						
Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 301 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
		X					X								11.3 (34)	55.3 mg/35.1 mg
					X										10.0 (30)	77.8 mg/0.5 mg
		X			X										9.6 (29)	79.6 mg/30.0 mg
		X													8.3 (25)	23.6 mg/22.4 mg
					X		X								7.0 (21)	99.8 mg/17.5 mg

Cancer: Nausea and Vomiting

Patients certified for cancer accompanied by severe and persistent nausea or vomiting were asked to assess the severity of chemotherapy-induced nausea and vomiting on a 0-10 numerical rating scale. Patients who experienced chemotherapy-induced nausea and vomiting at moderate to severe levels at baseline (score of 4 or higher) were included in the analysis in Table 6.19, with symptom improvement being defined as achieving at least a 30% improvement in symptoms (30% decrease on the 0-10 nausea/vomiting NRS) compared to baseline.

Severity of chemotherapy-induced nausea was reduced by ≥30% for 37.4% of the patients with moderate to severe chemotherapy-induced nausea at baseline. Among the patients who achieved ≥30% reduction, 35% (12.9% of patients included in analysis at baseline) retained that level of improvement over the next four months.

Severity of chemotherapy-induced vomiting was reduced by ≥30% for 41.6% of the patients with moderate to severe chemotherapy-induced vomiting at baseline. Among the patients who achieved ≥30% reduction, 56% (23.4% of patients included in analysis at baseline) retained that level of improvement over the next four months.

Cancer: Cachexia and Severe Wasting

Body weights were analyzed for patients certified for cancer accompanied by cachexia and/or severe wasting. Symptom improvement was defined as achieving at least a 3% increase in body weight compared to baseline weight.

An increase of at least 3% in body weight was reported by 13.6% of patients. Among the patients who achieved ≥3% increase in body weight, 45% (6.1% of patients included in analysis at baseline) retained that increase over the next four months.

Seizures

Patients with seizures were given two questions to assess the severity of their seizures. First, patients were given the option to respond to the number of seizures they experienced the day before or the number of seizures they experienced within the last week. These allowed for the calculation of weekly spasm frequency. Table 6.19 shows results from the weekly seizure frequency measure, with symptom improvement defined as achieving at least a 30% improvement in symptoms (30% decrease in weekly seizure frequency) compared to baseline.

Weekly seizure frequency was reduced by ≥30% in 68.3% of the seizure patients. Among patients who achieved ≥30% reduction, 71% (48.5% of patients included in analysis at baseline) retained that level of improvement over the next four months.

Table 6.21 below shows the top 5 medical cannabis product types that were purchased by seizure patients just prior to achieving ≥30% symptom improvement for the first time, including the number of patients who purchased those specific product types (second column from right). It also shows the average daily amount of THC and CBD (mg) patients consumed (right-most column), which was derived from manufacturer-derived product information and pharmacist-entered calculations of how long the purchased supply would last. Full purchasing details are in *Appendix D: Symptom Results from the Patient Self-Evaluation*. The most frequently purchased product types preceding the initial symptom improvement were skewed towards relatively high CBD:THC products, with preference for oral administration of these products.

Table 6.21. Top 5 medical cannabis product types purchased by seizure patients just prior to achieving ≥30% reduction in weekly seizures. Last column shows the average daily THC/CBD dose that was used by patients purchasing those product types (second column from right).

Enteral				Inhalation				Oromucosal					
Very High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	Very High THC to CBD	Balanced	High CBD to THC	Very High CBD to THC	% of Patients out of 178 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
		X										48.3 (86)	7.6 mg/159.5 mg
										X		16.9 (30)	13.2 mg/407.4 mg
	X				X							4.5 (8)	56.0 mg/37.4 mg
		X	X									3.4 (6)	4.9 mg/282.5 mg
	X											2.8 (5)	19.3 mg/15.9 mg

Crohn's Disease

Three questions from the Harvey-Bradshaw Index (HBI), which measures Crohn's disease activity, were included on the PSE for Crohn's disease patients. These three questions addressed the following: 1) the number of liquid or soft stools experienced yesterday, 2) general well-being yesterday (response options: "Very well", "Slightly below par", "Poor", "Very poor", "Terrible"), and 3) abdominal pain yesterday (response options: "None", "Mild", "Moderate", "Severe"). Responses to these three questions were summed into a combined score for each patient (combined according to HBI scoring guidelines) as well as analyzed separately in Table 6.19. The three questions were selected from the HBI because they were patient-reported measures (versus clinician assessments). The HBI has been validated, but since only three questions from the HBI were used, the clinical significance of these aggregate and individual scores is unclear. Lastly, body weight data submitted through the PSE were analyzed and included in Table 6.19.

Patients who indicated they experienced five or more liquid/soft stools at baseline were included in the analysis, with symptom improvement defined as achieving at least a 30% reduction in liquid/soft stools. Patients who indicated their general well-being was "Very Poor" or "Terrible" at baseline were included in the well-being analysis, with symptom improvement defined as feeling "Slightly Below Par" or "Very Well". Patients who indicated they experienced "Moderate" or "Severe" abdominal pains were included in the abdominal pain analysis, with symptom improvement defined as experiencing "Mild" to "No" abdominal pain. For the combined Crohn's activity measure (combined score on the three HBI measures), symptom improvement was defined as those achieving at least a 30% symptom improvement (30% decrease in the combined score compared to baseline). Lastly, body weight improvement was defined as a 3% increase in body weight.

Number of liquid/soft stools per day decreased by ≥30% for 51.2% of patients with at least five liquid/soft stools per day at baseline. Among patients who achieved ≥30% reduction, 57% (29.3% of patients included in analysis at baseline) retained that level of improvement over the next four months.

Severity of abdominal pain improved for 53.4% of patients with moderate or severe abdominal pain at baseline. Among patients who reported an improvement in abdominal pain, 36% (19.2% of patients included in analysis at baseline) retained that improvement over the next four months.

General well-being improved for 46.7% of patients who described their baseline well-being as "Very Poor" or "Terrible" at baseline. Among patients who reported an improvement in general well-being, 29% (13.3% of patients included in analysis at baseline) retained that improvement over the next four months.

On the combined Crohn's activity measure (number of liquid/soft stools, abdominal pain, general well-being), 51.0% of Crohn's Disease patients achieved ≥30% improvement. Among

patients who achieved ≥30% reduction, 42% (21.6% of patients included in analysis at baseline) retained that level of improvement over the next four months.

An increase of at least 3% in body weight was reported by 20.6% of patients. Among the patients who achieved ≥3% increase in body weight, 57% (11.8% of patients included in analysis at baseline) retained that increase over the next four months.

Terminal Illness

Body weight measures on the PSE were analyzed in patients certified for terminal illness: accompanied by cachexia or severe wasting. Symptom improvement was defined as a 3% increase in body weight from their baseline body weight.

An increase of at least 3% in body weight was reported by 20.7% of patients. Among the patients who achieved ≥3% increase in body weight, 50% (10.3% of patients included in analysis at baseline) retained that increase over the next four months.

HIV/AIDS

Body weight measures on the PSE were analyzed in HIV/AIDS patients. Similar to all body weight measures of improvement discussed previously, symptom improvement was defined as a 3% increase in body weight compared to their baseline body weight.

An increase of at least 3% in body weight was reported by 14.6% of patients. Among the patients who achieved ≥3% increase in body weight, 43% (6.3% of patients included in analysis at baseline) retained that increase over the next four months.

Tourette Syndrome

Patients with Tourette Syndrome were given two questions to assess the severity of their tics. First, patients were given the option to respond to the number of tics they experienced the day before or the number of tics they experienced within the last week. These allowed for the calculation of weekly tic frequency. For Table 6.19, weekly tic frequency was analyzed in all patients, with symptom improvement defined as a 30% improvement in symptoms (30% decrease in weekly tics compared to baseline).

Weekly tic frequency was reduced by ≥30% in 60.7% of the Tourette Syndrome patients. Among patients who achieved ≥30% reduction, 76% (46.4% of patients included in analysis at baseline) retained that level of improvement over the next four months.

Table 6.22 below shows the top 4 medical cannabis product types that were purchased by Tourette patients just prior to achieving ≥30% symptom improvement for the first time, including the number of patients who purchased those specific product types (second column from right). It also shows the average daily amount of THC and CBD (mg) patients consumed (right-most column), which was derived from manufacturer-derived product information and pharmacist-entered calculations of how long the purchased supply would last. Full purchasing details are in *Appendix D: Symptom Results from the Patient Self-Evaluation*. The most frequently purchased product types preceding the initial symptom improvement were Very High THC:CBD oromucosal products (4 patients) and a combination of Balanced THC:CBD oral products and Very High THC:CBD oral products (2 patients)

Table 6.22. Top 4 medical cannabis product types purchased by Tourette patients just prior to achieving ≥30% reduction in weekly tics. Last column shows the average daily THC/CBD dose that was used by patients purchasing those product types (second column from right).

Enteral			Inhalation			Oromucosal				
Very High THC to CBD	Balanced	High CBD to THC	Very High THC to CBD	Balanced	High CBD to THC	Very High THC to CBD	Balanced	High CBD to THC	% of Patients out of 17 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
						X			23.5 (4)	147.3 mg/0.7 mg
X	X								11.8 (2)	24.0 mg/15.0 mg
	X								11.8 (2)	11.5 mg/8.5 mg
			X						11.8 (2)	64.6 mg/0.2 mg

Glaucoma

Intraocular pressure results were collected on the PSE from Glaucoma patients and are presented in Table 6.23 for each of the 21 patients included in this analysis. At the first PSE (prior to first medical cannabis purchase) patients were asked to provide the date and results of the most recent intraocular pressure test. On subsequent PSEs patients were asked to provide the date and results of any intraocular pressure test done since submission of the last PSE.

Results for seven of the 21 patients (33%) suggest a decrease in intraocular pressure after initiation of medical cannabis: patients #4, 8, 9, 14, 16, 17, and 19. One of those seven did not show a decrease at 5 months, but did show a decrease at 9 months. Four of them had measurement results after the date of the result that indicated a decrease: patients #4, 16, 17, and 19. Of those four, three have results indicating persistence of reduction over several months. The fourth (#19) had a reduction in month 2 but returned toward pre-medical cannabis levels at month 4. More detailed study, including accessing medical record data, would be needed to confirm measurement results and to assess whether observed improvements could have been due to changes in glaucoma therapy other than medical cannabis use.

Table 6.23. Intraocular pressure test results (left eye/right eye) from glaucoma patients (n = 21). Test results are noted by the month they occurred prior to or after the patients' first medical cannabis purchase ("First Visit").

Before 1st Medical Cannabis Purchase								First	After 1st Medical Cannabis Purchase										
Patient	12-mo	11-mo	5-mo	4-mo	3-mo	2-mo	1-mo	Visit	1-mo	2-mo	3-mo	4-mo	5-mo	6-mo	7-mo	9-mo	10-mo	11-mo	13-mo
1		15 / 11										11 / 10		7 / 12					
2							20 / 17			17 / 14							18 / 16		
3							18 / 20		19 / 18			18 / 18		19 / 22	19 / 18				
4						26 / 28	26 / 28			18 / 18				18 / 16					
5							21 / 26												
6			20 / 20						20 / 20										
7							17 / 15												
8					34 / 30								33 / 33			26 / 24			
9							26 / 23		17 / 18										
10						30 / 30													
11			22 / 24	27 / 21	21 / 24														
12							12 / 10				12 / 12								
13							22 / 14		22 / 14										
14							9 / 26			8 / 12									
15						17 / 18			19 / 24										
16		22 / 20							16 / 16		17 / 17	16 / 16						18 / 19	
17							23 / 23		16 / 16	19 / 25		16 / 19	16 / 19			16 / 18			
18					10 / 12					12 / 15									
19							30 / 22			19 / 16		26 / 16							
20						17 / 19	19 / 17		19 / 17										
21							17 / 26		17 / 28		20 / 25				19 / 20				24 / 28

ALS

Patients with ALS were given two questions to assess the severity of their muscle spasms. First, patients were given the option to respond to the number of spasms they experienced the day before or the number of spasms they experienced within the last week. These allowed for the calculation of weekly spasm frequency. Table 6.19 presents results on weekly spasm frequency and spasm severity (0-10 NRS). For the spasticity scale measure, patients who experienced moderate to severe spasms at baseline (scored 4 or higher) were included in the analysis, with symptom improvement defined as achieving at least a 30% symptom improvement (30% decrease on the 0-10 NRS compared to baseline).

Weekly spasm frequency was reduced by ≥30% in 33.3% of the ALS patients. Among patients who achieved ≥30% reduction, 67% (22.2% of patients included in analysis at baseline) retained that level of improvement over the next four months.

Severity of muscle spasticity was reduced by ≥30% for 20.0% of the ALS patients with moderate to severe muscle spasticity at baseline. Among the three patients who achieved ≥30% reduction, all three retained that level of improvement over the next four months (20.0% of patients included in analysis at baseline).

Table 6.24 below shows the top 5 medical cannabis product types that were purchased by ALS patients just prior to achieving ≥30% weekly spasm reduction for the first time, including the number of patients who purchased those specific product types (second column from right). It also shows the average daily amount of THC and CBD (mg) patients consumed (right-most column), which was derived from manufacturer-derived product information and pharmacist-entered calculations of how long the purchased supply would last. Full purchasing details are in *Appendix D: Symptom Results from the Patient Self-Evaluation*. The most frequently purchased product types preceding the initial symptom improvement were skewed towards balanced THC:CBD products and relatively high THC:CBD products.

Table 6.24. Top 5 medical cannabis product types purchased by ALS patients just prior to achieving ≥30% reduction in weekly spasms. Last column shows the average daily THC/CBD dose that was used by patients purchasing those product types (second column from right).

Enteral			Inhalation				
Very High THC to CBD	High THC to CBD	Balanced	Very High THC to CBD	High THC to CBD	Balanced	% of Patients out of 6 (n)	Avg Daily THC Use (mg) / Avg Daily CBD Use (mg)
		X				33.3 (2)	12.8 mg/5.1 mg
X			X			16.7 (1)	59.8 mg/0.3 mg
	X	X	X		X	16.7 (1)	67.0 mg/6.0 mg
	X	X				16.7 (1)	37.5 mg/8.1 mg
			X			16.7 (1)	42.2 mg/0.3 mg

Benefits Reported on the Patient Self-Evaluation: Conclusions

Similar to survey results, the PSE also demonstrated improvements on symptoms in medical cannabis patients. Patients enrolling in the program initially report a high degree of symptom burden with anywhere from roughly 40-60% of patients reporting symptom improvements within the 4 month period following their first medical cannabis purchase. If patients experienced improvements in symptoms, roughly half to three-quarters of them maintained those levels of improvement in the 4-month period following their initial report of improvement.

There are some limitations on the PSE to consider when interpreting results. Firstly, there is no symptom data on patients who decide over time not to purchase medical cannabis any longer (or for extended periods of time). As discussed earlier, patients must complete a PSE prior to each medical cannabis purchase. If a patient stops purchasing medical cannabis, there will be a parallel pause in symptom data to understand whether there may have been a lack of symptom improvements to halt purchases. This is the reason for presenting many analyses on symptom improvements in the context of the initial baseline patient pool – regardless of whether they provided any subsequent symptom data or not. This allows for more of a conservative estimate of symptom benefit over time. A second limitation on the PSE has to do with the patient's approach and conscientiousness in completing the PSE—all symptom measures are self-reported which involves cognitive resources and motivation for the patient to complete the surveys as accurately as possible.

7. Adverse Side Effects

Summary

This chapter provides insight into the frequency and severity of adverse (negative) side effects through three sources of information: the Patient Self-Evaluation completed by the patient prior to each medical cannabis purchase, patient and health care practitioner surveys, and adverse event reports to the two medical cannabis manufacturers.

The three information sources tell a similar story. Around 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 3 or fewer unique side effects. 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 in patient age, medical condition, or type of medical cannabis product used. Results reported in this chapter are generally similar to those reported in published clinical trials of cannabis and cannabinoids, though with a somewhat lower frequency of occurrence reported in the program. Fortunately, up to the present no serious adverse events (life threatening or requiring hospitalization) have been reported.

Some limitations of the data should be mentioned. For example, when the patient completes a Patient Self-Evaluation and has it reviewed in consultation with pharmacist staff, the completeness and accuracy of reported side effects (on the Patient Self-Evaluation) ultimately depend on the attention and good communication of the patient. Perhaps a more significant risk for under-reporting through Patient Self-Evaluation data is the situation when a patient has an intolerable side effect and decides to make no more purchases of medical cannabis. If the patient doesn't go to a cannabis patient center for another purchase, the patient doesn't fill out another Patient Self-Evaluation, so the side effect is not documented through this mechanism. From anecdotal report and survey responses, we know this does occur. However, inquiries made of patients who have discontinued medical cannabis purchasing suggests this does not happen often. Finally, a weakness of the survey data is that many responders did not complete the question on most significant negative effect and a substantial proportion who did indicated cost or access issues, rather than physical or mental side effects. Though physical or mental side effects were probably minor or not present if the respondent indicated cost or access issues as the most significant negative effect, we don't know that for sure. We are unable to characterize most significant negative effect for those who did not submit a response a response.

Though the limitations mentioned in the paragraph above no doubt undercount the frequency of physical and mental side effects to some degree, their impact does not seem likely to

significantly change the main conclusions of the analyses reported in this section: at this point, the safety profile of the medical cannabis products available through the Minnesota program seems quite favorable.

Adverse Side Effects Reported on the Patient Self-Evaluation

Patients have the opportunity to report adverse side effects they attribute to medical cannabis on the Patient Self-Evaluation (PSE). Patients must complete a PSE prior to each medical cannabis purchasing transaction. Therefore, the administration of the PSE is timed so that patients can reflect on their experience with the medication they purchased previously and report those experiences on the following patient self-evaluation. A pharmacist at one of the eight medical cannabis dispensaries can then review PSE-reported information, which includes an opportunity to discuss side effects with the patient prior to approving that patient for another medical cannabis purchase. When reporting side effects on the PSE, patients are able to choose side effects from a pre-made list of options or write in side effects that do not fit one of the listed options. In addition, patients also indicate the severity with which each side effect is experienced (see Box 7.1).

Box 7.1. Definitions on severity provided to patients for adverse side effect reporting.

Adverse Side Effect Severity: Definitions

Mild: Symptoms do not interfere with daily activities
Moderate: Symptoms may interfere with daily activities
Severe: Symptoms interrupt usual daily activities

Adverse side effects were examined within the 1st program year cohort (n = 1660). Patients who had made at least their first medical cannabis purchase were identified, and from these patients, all PSEs that were submitted within the four months following their first medical cannabis purchase were included in a dataset. This led to a total of 1502 patients (90.5% of the cohort) being represented. For the following analyses, each side effect was counted once for a given patient if it was reported multiple times. If a side effect was reported multiple times, the observation that was categorized at the highest severity level was included in the analyses for this report. In cases where a patient opted to write in their side effects (rather than choosing from the pre-made list of options), their responses were assessed carefully for adjudication for coding purposes. Therefore – while not affecting a substantial number of side effect responses – it should be noted that one limitation for accurate coding is the patient's ability to adequately articulate their experiences.

Of the 1502 patients, 18.1% (n = 272) reported any adverse side effects within the four month period following their first medical cannabis purchase. Of those 272 patients reporting any adverse side effects, the majority reported only one (n = 164, 60.3%), with approximately 90% of them reporting three or fewer different, adverse side effects (Figure 7.1).

Figure 7.1. Distribution of patient counts by number of different, adverse side effects reported (out of 272 patients).

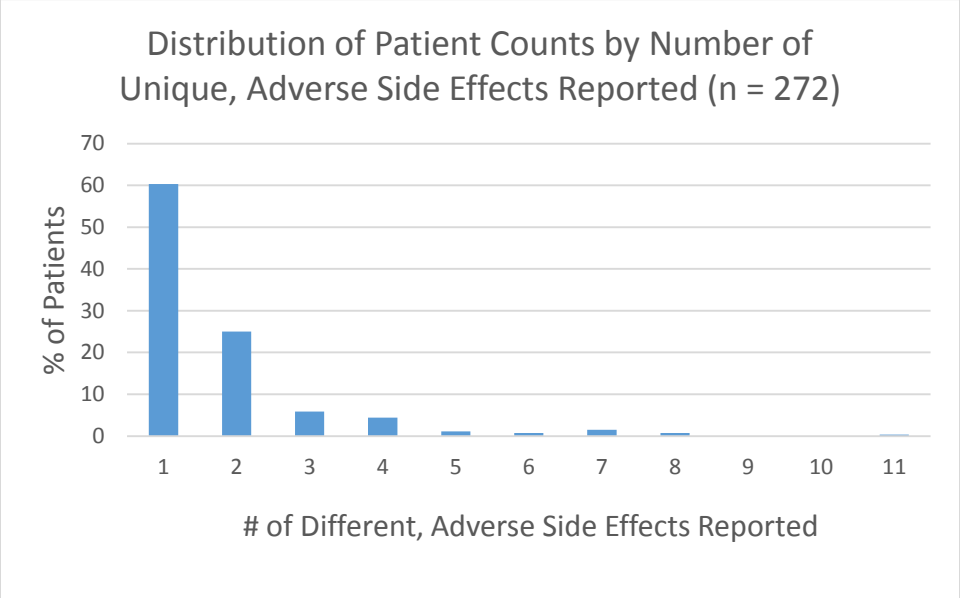


Figure 7.2 shows the percentage of patients reporting specific adverse side effects (Table 7.1 below lists adverse side effects that were reported by less than 2% of all patients). Of all side effects reported, dry mouth and drowsiness/somnolence/sedation were the most commonly reported side effects among patients. Overall, the frequency distribution of unique side effects mirrors typical clinical trial data on side effects from cannabis/cannabinoid use (see "A Review of Medical Cannabis Studies relating to Chemical Compositions and Dosages for Qualifying Medical Conditions" on the Office of Medical Cannabis website).

Figure 7.2. The most commonly reported adverse side effects represented by the percentage of patients reporting them (out of 272 patients).

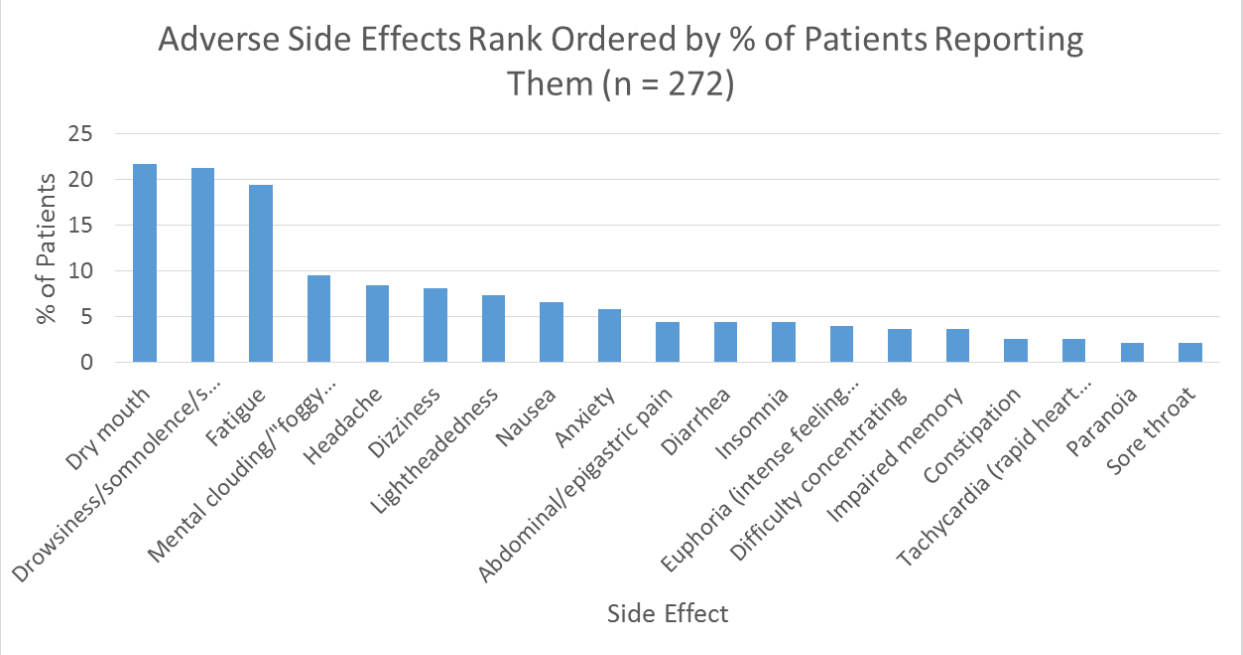


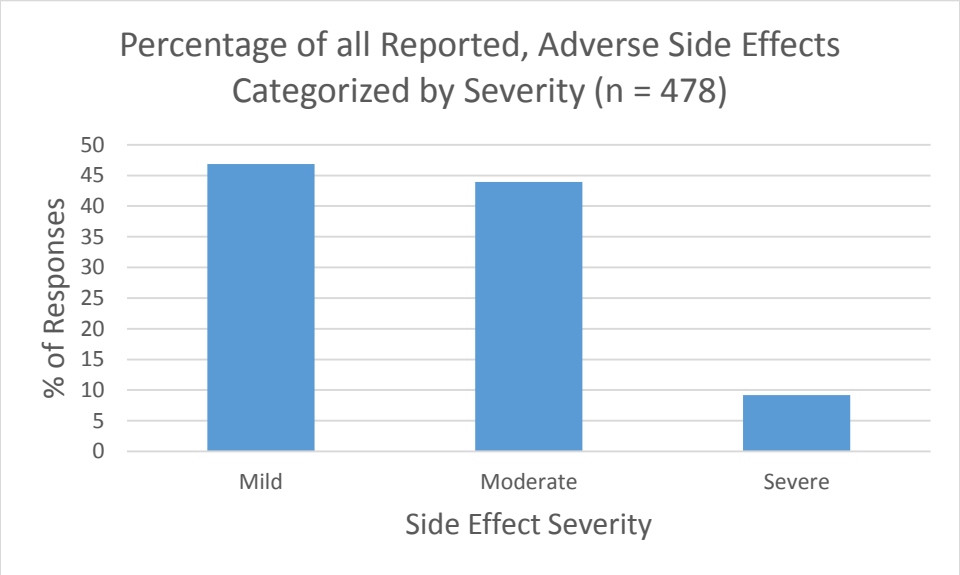
Table 7.1. Adverse side effects that were reported by less than 2% of patients (out of 272 patients).

Side Effect	% of Patients (n)
Asthenia (muscle weakness)	1.8% (5)
Chest pain	1.8% (5)
Confusion	1.8% (5)
Disorientation	1.5% (4)
Eye redness	1.5% (4)
Lethargy	1.5% (4)
Blurred Vision	1.1% (3)
Decreased muscle coordination/balance	1.1% (3)
Increased agitation	1.1% (3)
Numbness	1.1% (3)
Panic attack	1.1% (3)
Personality/mood change	1.1% (3)
Tinnitus (ringing perception in the ears)	1.1% (3)
"Stoned" feeling	0.7% (2)
Body stiffness	0.7% (2)
Coughing/lung irritation	0.7% (2)
Decreased appetite	0.7% (2)
Dry eyes	0.7% (2)
Feeling cold	0.7% (2)
Increased seizures	0.7% (2)
Tremors	0.7% (2)
"Wired" feeling	0.4% (1)
Bloating	0.4% (1)
Burping	0.4% (1)

Side Effect	% of Patients (n)
Change in quality of seizures	0.4% (1)
Chest colds	0.4% (1)
Cognitive change	0.4% (1)
Cramping with bowel movement	0.4% (1)
Dysphoria (intense feeling of unease or unpleasantness)	0.4% (1)
Exacerbation of lymphedema	0.4% (1)
Eye muscle twitching	0.4% (1)
Hives	0.4% (1)
Hyperactive bowel sounds	0.4% (1)
Hypomania	0.4% (1)
Increase in mucus secretions	0.4% (1)
Increased aggression	0.4% (1)
Increased urine output	0.4% (1)
Increased yelling	0.4% (1)
Mouth irritation/burning	0.4% (1)
Rash on face	0.4% (1)
Repressed immune system	0.4% (1)
Sleep disturbance	0.4% (1)
Sneezing	0.4% (1)
Thrush	0.4% (1)
Urinary retention	0.4% (1)
Vomiting	0.4% (1)
Worsening acne	0.4% (1)

The 272 patients reporting any adverse side effects submitted a combined total of 478 side effect responses within 4 months of their first medical cannabis purchase. When aggregating all side effect responses across patients, only 9.2% (44) of all responses were reported as severe (see Figure 7.3).

Figure 7.3. Percentage of all reported, adverse side effect responses categorized by severity.



Severe Adverse Side Effects

All adverse side effect responses that were categorized as severe are further broken down by the percent of patients categorizing them as such—please see Table 7.2 below.

Table 7.2. Table shows the number of patients reporting the listed side effects along with the percentage of those respondents who indicated that the side effect was severe.

Side Effect	# of Patients Reporting	% of Patients Reporting as Severe (n)
Dry mouth	59	6.8% (4)
Drowsiness/somnolence/sedation	58	5.2% (3)
Fatigue	53	3.8% (2)
Mental clouding/"foggy brain"	26	7.7% (2)
Headache	23	4.3% (1)
Dizziness	22	9.1% (2)
Lightheadedness	20	0% (0)
Nausea	18	11.1% (2)
Anxiety	16	12.5% (2)
Abdominal/epigastric pain	12	8.3% (1)
Diarrhea	12	16.7% (2)
Insomnia	12	8.3% (1)
Euphoria (intense feeling of well-being or pleasure)	11	9.1% (1)
Difficulty concentrating	10	20% (2)
Impaired memory	10	10% (1)
Constipation	7	14.3% (1)
Tachycardia (rapid heart rate)	7	28.6% (2)
Paranoia	6	16.7% (1)
Sore throat	6	0% (0)
Asthenia (muscle weakness)	5	60% (3)
Chest pain	5	20% (1)
Confusion	5	0% (0)
Disorientation	4	0% (0)
Eye redness	4	0% (0)
Lethargy	4	50% (2)
Blurred Vision	3	0% (0)
Decreased muscle coordination/balance	3	33.3% (1)
Increased agitation	3	0% (0)
Numbness	3	33.3% (1)
Panic attack	3	33.3% (1)
Personality/mood change	3	0% (0)
Tinnitus (ringing perception in the ears)	3	0% (0)
"Stoned" feeling	2	50% (1)
Body stiffness	2	0% (0)

Table 7.2 Continued. Table shows the number of patients reporting the listed side effects along with the percentage of those respondents who indicated that the side effect was severe.

Side Effect	# of Patients Reporting	% of Patients Reporting as Severe (n)
Coughing/lung irritation	2	0% (0)
Decreased appetite	2	0% (0)
Dry eyes	2	0% (0)
Feeling cold	2	0% (0)
Increased seizures	2	50% (1)
Tremors	2	0% (0)
"Wired" feeling	1	0% (0)
Bloating	1	0% (0)
Burping	1	0% (0)
Change in quality of seizures	1	0% (0)
Chest colds	1	0% (0)
Cognitive change	1	0% (0)
Cramping with bowel movement	1	0% (0)
Dysphoria (intense feeling of unease or unpleasantness)	1	0% (0)
Exacerbation of lymphedema	1	10% (1)
Eye muscle twitching	1	0% (0)
Hives	1	0% (0)
Hyperactive bowel sounds	1	0% (0)
Hypomania	1	0% (0)
Increase in mucus secretions	1	100% (1)
Increased aggression	1	100% (1)
Increased urine output	1	0% (0)
Increased yelling	1	0% (0)
Mouth irritation/burning	1	0% (0)
Rash on face	1	0% (0)
Repressed immune system	1	0% (0)
Sleep disturbance	1	0% (0)
Sneezing	1	0% (0)
Thrush	1	0% (0)
Urinary retention	1	0% (0)
Vomiting	1	0% (0)
Worsening acne	1	0% (0)

The 44 severe side effect responses (9.2% of total side effect responses) were attributed to 30 patients (11.0% of patients reporting any side effects). Patients experiencing severe side effects represent a wide range of ages, including children and elderly patients; 14 patients were male and 16 patients were female. Their age, gender, and certifying conditions generally matched the whole first year cohort. Half of patients reporting severe side effects were taking a form of balanced THC:CBD product (n=15); 10 patients were using a high CBD product, 9 patients were using a very high THC product and 4 patients were using a high THC product. Seven of 30 patients (23%) were using a combination of products with varying THC:CBD ratios (the most common combination was very high THC products and 1:1 THC:CBD products); 9 patients used a combination of products with different routes of administration (the most common combination was enteral and inhaled). Refer to Table 7.3 for details on the patients reporting severe side effects, along with the product types that were purchased just prior to experiencing the severe side effect.

PSE-Reported Adverse Side Effects: Conclusions

Less than a quarter of patients from the cohort (~18%) reported adverse side effects within the first 4 months since purchasing their first medical cannabis products. Roughly 90% of those that do report any side effects report 3 or fewer unique side effects during that time period. Results also suggest that relatively few patients experience severe, adverse side effects, with less than 10% of all responses (attributed to 30 patients) being categorized as severe.

Table 7.3. Patients reporting "severe" side effects: patient age, gender, and condition, product types purchased at most recent visit, and type of side effect reported.

Age	Gender	Condition(s)	Very High THC Product(s)	High THC Product(s)	High CBD Product(s)	1:1 THC:CBD Product(s)	Severe Side Effect Reported
55	M	HIV/AIDS	-	-	-	Enteral	Chest pain
67	F	Severe Muscle Spasms	Inhaled	-	Enteral	Enteral, Inhaled	Dry mouth
28	F	Severe Muscle Spasms	-	-	-	Enteral, Inhaled	Lethargy
58	F	Severe Muscle Spasms	-	-	-	Enteral, Inhaled	Panic attack
32	M	Severe Muscle Spasms	Inhaled	-	-	Inhaled	Asthenia (muscle weakness) Lethargy Tachycardia (rapid heart rate)
32	M	Severe Muscle Spasms	Inhaled	-	-	Inhaled	"Stoned" feeling
38	M	Severe Muscle Spasms	Inhaled	-	-	Inhaled	Insomnia
52	F	Severe Muscle Spasms	-	-	-	Enteral, Inhaled	Asthenia (muscle weakness) Drowsiness/somnolence/sedation
61	F	Cancer	-	-	Enteral	Enteral	Dry mouth
36	M	Seizures	-	-	Enteral	-	Diarrhea
41	M	Cancer, Terminal Illness	-	Enteral, Inhaled	-	-	Drowsiness/somnolence/sedation
87	F	Severe Muscle Spasms	-	Enteral, Oromucosal	-	-	Diarrhea
31	M	Cancer	Enteral, Inhaled	-	-	-	Nausea
71	F	Cancer	Inhaled	-	-	Enteral	

							Asthenia (muscle weakness) Exacerbation of lymphedema
26	F	Terminal Illness	Inhaled	-	-	Enteral, Inhaled, Oromucosal	Constipation Difficulty concentrating Drowsiness/somnolence/sedation Dry mouth Mental clouding/"foggy brain"
36	F	Cancer	-	-	-	Enteral	Headache
33	M	Crohn's Disease	-	-	-	Enteral	Fatigue
63	F	Crohn's Disease	-	-	-	Enteral	Dizziness
82	M	Cancer	-	-	-	Enteral	Dizziness
60	F	Seizures	-	-	Enteral	-	Anxiety
32	M	Seizures	-	-	Enteral	-	Nausea
48	M	Seizures	-	-	Enteral	-	Fatigue
18	F	Seizures	-	-	Enteral	-	Increased seizures
28	M	Seizures	-	-	Enteral	-	Anxiety Paranoia
5	M	Severe Muscle Spasms, Seizures	-	-	Enteral	-	Decreased muscle coordination/balance Increased aggression
10	F	Seizures	-	-	Oromucosal	-	Abdominal/epigastric pain Increase in mucus secretions
56	F	Cancer, HIV/AIDS	-	Enteral	-	-	Dry mouth Euphoria (intense feeling of well-being/pleasure)
21	M	Cancer	-	Inhaled	-	-	Tachycardia (rapid heart rate)
42	F	Severe Muscle Spasms	Inhaled	-	-	-	

							Impaired memory Difficulty concentration Mental clouding/"foggy brain"
45	F	Severe Muscle Spasms	Inhaled	-	-	-	Numbness

Adverse Side Effects Reported on Surveys

Patient-Reported Negative Effects of Medical Cannabis

For overall patient response rate to the survey three months after first purchase and comparison of responders and non-responders see the section with survey results in the Benefits chapter above.

The Patient Experience survey asks respondents to report the degree, or severity, of any negative effects they believe the patient received from using medical cannabis, on a scale from 1 (no negative effects) to 7 (a great deal of negative effects). The survey then asked the respondent to describe, in their own words, the most significant negative effect. Table 7.4 shows the distribution of negative effects by severity score within three broad categories: physical side effects (including dry mouth, fatigue, headache, dizziness, blurred vision); mental side effects (including mental clouding, paranoia, sedation or symptoms related to "high"); and issues related to accessing the medications (distance to distribution center, inconvenient operating hours for distribution centers, etc.). Based on anticipated reports on the high cost of medication, patients were asked to report on the affordability of the medication separately. However, 53 (7%) patients included cost in their estimation of the most significant negative effects related to medical cannabis; these reports are excluded from Table 7.4 but included in *Appendix E: Patient-Reported Negative Effects from Surveys*. Finally, please see the chapter titled, "Affordability and Suggestions for Improvement" for patient perceptions of medication affordability.

Of 792 completed patient surveys, 744 responses (94%) included a negative effects score and 441 (56%) included a response regarding most important negative effect, including comments stating "no negative effect." Of 744 negative effect scale responses, 452 (61%) reported a score of 1, or "no negative effect." This includes 13 patients who, though they entered a score of 1, entered a narrative description of physical or mental side effects. A total of 195 responses (25% of all patient responses) reported physical or mental negative effects. These reports generally mirrored side effects reported in clinical trials of medical cannabis (see "A Review of Medical Cannabis Studies relating to Chemical Compositions and Dosages for Qualifying Medical Conditions" on the Office of Medical Cannabis website). Reports of the most severe negative effects were as follows: scores of 7 (great deal of negative effects) were associated with reports of allergic reaction (n=1), pain (n=1), severe diarrhea (n=1), change in mood/behavior (n=1) and decreased awareness of surroundings (n=1). Scores of 6 were associated with reported physical side effects of dizziness or related symptoms (n=3), severe diarrhea (n=1), stomach pain (n=1), burning sensation with sublingual product (n=1), sleeping problems (n=1) and worsening seizures (n=2), and mental side effects of crying and irritability (n=1). Scores of 5 which reported physical negative effects included drug interactions, increased seizure activity, allergic reaction, lightheadedness, fatigue, headaches, visual impairment, dry mouth, a report that the

product "made me sick" and pain related to vaping (n=1 each). Scores of 5 which reported mental negative effects included reports of paranoia (n=2), inability to concentrate (n=1), and increased anxiety (n=1).

Apart from physical or mental negative effects, some patients reported issues related to program access, including distance to the nearest cannabis patient center (n=13). Other negative effects (not included in Table 7.4) were reported including issues related to the program design (n=9), negative attitudes of others toward the patient's use of medical cannabis (n=17) and fear of legal or employment-related consequences related to program participation (n=5). Finally, 16 reports of negative effects were related to lack of efficacy of the medicine in treating the patient's condition. A full listing of patient-reported negative effect comments is available in *Appendix E: Patient-Reported Negative Effects from Surveys.*

Table 7.4. Summary of most significant negative effects experienced by the patient, per patient reports.

	1: No Negative Effects	2	3	4	5	6	7: Great Deal of Negative Effects	Total
Physical Side Effects	10 (1%)	57 (7%)	15 (2%)	26 (3%)	10 (1%)	9 (1%)	3 (0%)	130 (16%)
Mental Side Effects	3 (0%)	18 (2%)	14 (2%)	19 (2%)	4 (1%)	1 (0%)	2 (0%)	61 (8%)
Access-Related Issues	4 (1%)	3 (1%)	1 (0%)	2 (0%)	1 (0%)	1 (0%)	1 (0%)	13 (2%)

Note: Results are broken down by negative effect scale scores. Percentages are calculated based on the total number of patient survey responses received (n=792).

HCP-Reported Negative Effects from Medical Cannabis

Like the Patient Experience survey, the HCP survey asks respondents to report the degree, or severity, of any negative effects they believe the patient received from using medical cannabis, on a scale from 1 (no negative effects) to 7 (a great deal of negative effects). Table 7.5 shows the distribution of negative effects by severity score within three broad categories: physical side effects (including dry mouth, fatigue, headache, dizziness, blurred vision); mental side effects (including mental clouding, paranoia, sedation or symptoms related to "high"); and issues related to accessing the medications (long distance to distribution center, inconvenient operating hours for distribution centers, etc.).

Of 251 total HCP survey responses, 200 responses (80%) included a negative effects score and 107 responses (43%) included a description of any negative effect(s). Of 200 negative effect scale responses, 128 (64%) reported a score of 1, or "no negative effect." This includes 6 HCP

reports which entered a narrative description of physical or mental side effects. There were 33 HCP reports (13% of all HCP survey responses) of physical or mental negative effects resulting from medical cannabis treatment. As seen in the patient survey results, these generally mirrored side effects described in clinical trials (see "A Review of Medical Cannabis Studies relating to Chemical Compositions and Dosages for Qualifying Medical Conditions" on the Office of Medical Cannabis website). Healthcare providers describing negative effects with high scores reported the following: a score of 7 was associated with a report of "abdominal discomfort"; dizziness (n=1) and sedation (n=1) were reported with scores of 6; finally, constipation, lethargy and worsened seizure activity (n=1) and a report of "too strong per patient" (n=1) were associated with a score of 5. Four HCP responses reported access-related issues as a negative effect. Additionally, 25 HCP reports (10% of all HCP survey responses) described cost as a negative effect related to medical cannabis (these reports are not included in Table 7.5).

A full listing of all negative effect comments from HCPs can be found in *Appendix F: Healthcare Practitioner-Reported Negative Effects from Surveys.*

Table 7.5. Summary of most significant negative effects experienced by the patient, per HCP reports.

Negative Effects By Score (1-7 Scale)	1 (No Negative Effects)	2	3	4	5	6	7 (Great Deal of Negative Effects)	Total
Physical Side Effects	4 (2%)	5 (2%)	6 (2%)	2 (1%)	1 (0%)	1 (0%)	1 (0%)	20 (8%)
Mental Side Effects	2 (1%)	6 (2%)	3 (1%)	1 (0%)	-	1 (0%)	-	13 (5%)
Access Issues	1 (0%)	2 (1%)	1 (0%)	-	-	-	-	4 (2%)

Note: Results are broken down by negative effect scale scores. Percentages in each cell are based on the total number of HCP survey responses (n=251).

Adverse Side Effects Reported on Surveys: Conclusions

Based on data from surveys completed by patients and their certifying healthcare practitioners three months after the patient's first medical cannabis purchase, 25% of patient respondents report physical or mental side effects related to medical cannabis use. A minority of healthcare provider responders (13%) report physical or mental side effects. Both groups describe negative effects related to medical cannabis use including the cost of products and issues related to

accessing medicine. Most patients and HCPs reporting physical or mental side effects report low degrees of severity (negative effect scale scores of 1-3).

Adverse Event Reporting to Manufacturers

There is potential for enrolled patients, their family and caregivers, and health care practitioners to be concerned about an adverse event potentially caused by medical cannabis and to want to register their concern quickly. Both manufacturers have processes in place to receive these messages by telephone and by email. They collect and document information related to the incident and report it to the Office of Medical Cannabis. In nature and severity these reports have been similar to the adverse events reported in Patient Self-Evaluations and surveys.

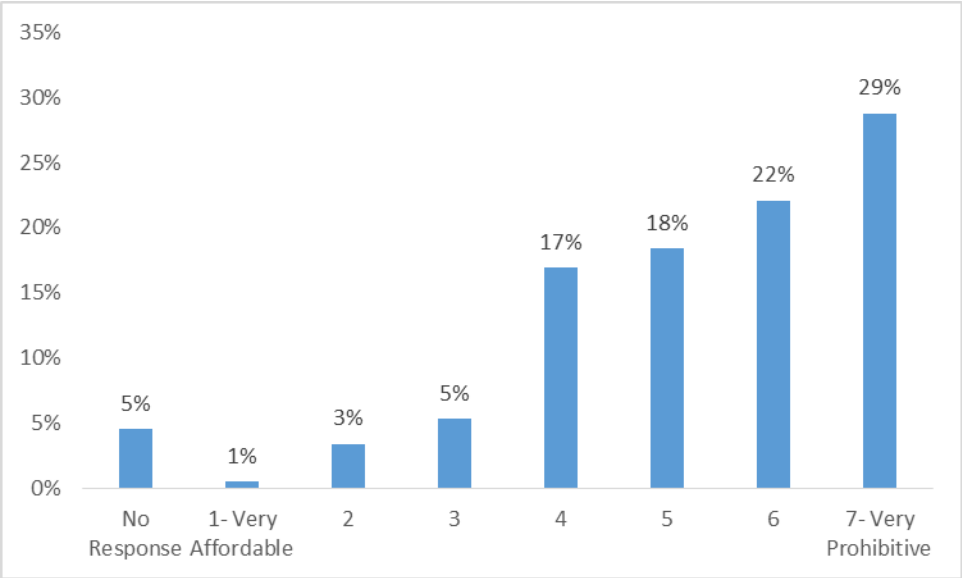
Patients, their registered caregivers, and certifying health care practitioners have a duty as program participants to report serious adverse events. Called “serious adverse incidents” in the program’s rules (4770.4002), these are essentially occurrences that lead to hospitalization or are life-threatening events. As of the date of this report, no reported adverse events have met the definition of “serious adverse incident.”

8. Affordability and Suggestions for Improving the Program

Patient Perceptions of Affordability

Unlike traditional pharmaceuticals whose costs are often covered through insurance reimbursement, medical cannabis must be purchased solely out of pocket. The Patient Experience survey asked patients to rate the cost of the medication on a scale from 1, or very affordable, to 7, or very prohibitive. Responses to this question are displayed in Figure 8.1. Of 792 respondents, 683 (86%) reported that they found medical cannabis to be at least somewhat unaffordable (score of 4 or greater).

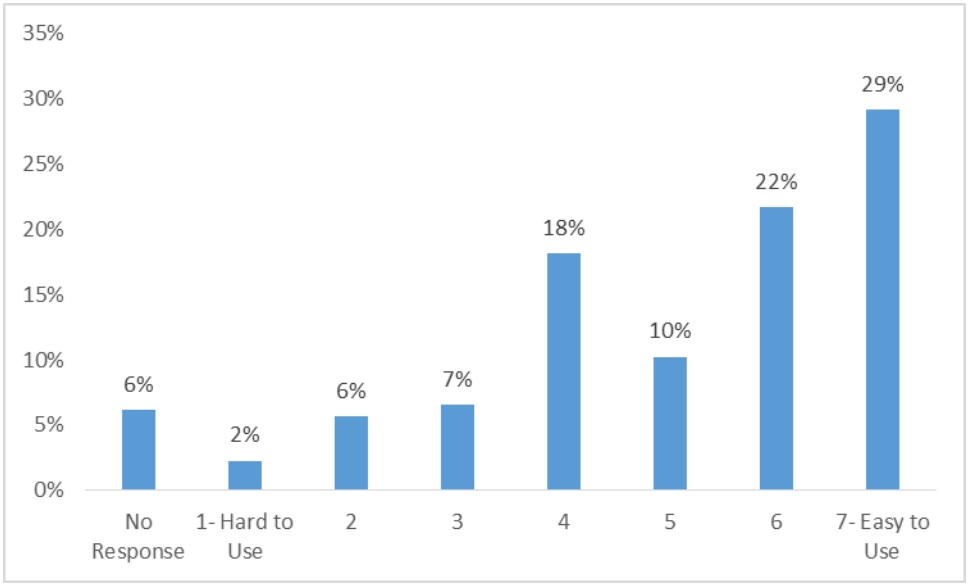
Figure 8.1. Patient Perceptions of Product Affordability



Patient Perceptions of Online Registry

Patients were asked how easy or difficult the online registry system, through which the Minnesota Medical Cannabis program is administered, is to use. Patients were asked to rate usability on a scale from 1, or very difficult to use, to 7, or very easy or intuitive to use. Responses were generally positive (Figure 2), with 51% of patients reporting high scores of usability (6 or 7).

Figure 8.2. Online Registry Ease of Use

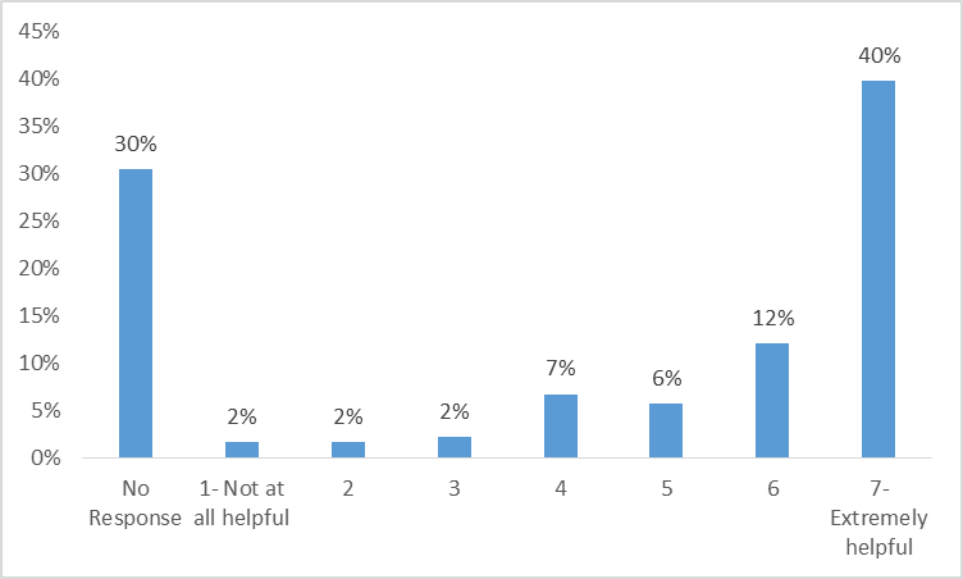


Patient reports on the ease of use of the Medical Cannabis Registry online system (1=very difficult to use; 4=neither difficult nor easy to use; 7=very easy/intuitive to use). Note: percentages are based on total number of patient responses; 49 patients did not complete this question and are not represented in the figure.

Patient Perceptions of Office of Medical Cannabis Call Center

Patients were asked to rate the helpfulness of the Office of Medical Cannabis Call Center (also known at the Support Center), which provides support for patients, caregivers and providers in navigating the registration and enrollment process as well as assisting with other program-related inquiries. The Patient Experience survey asked patients to rate the helpfulness of the call center on a scale from 1, or not very helpful, to 7, or very helpful. Over half of all patient responses reported high scores of helpfulness (6 or 7).

Figure 8.3. Call Center Helpfulness

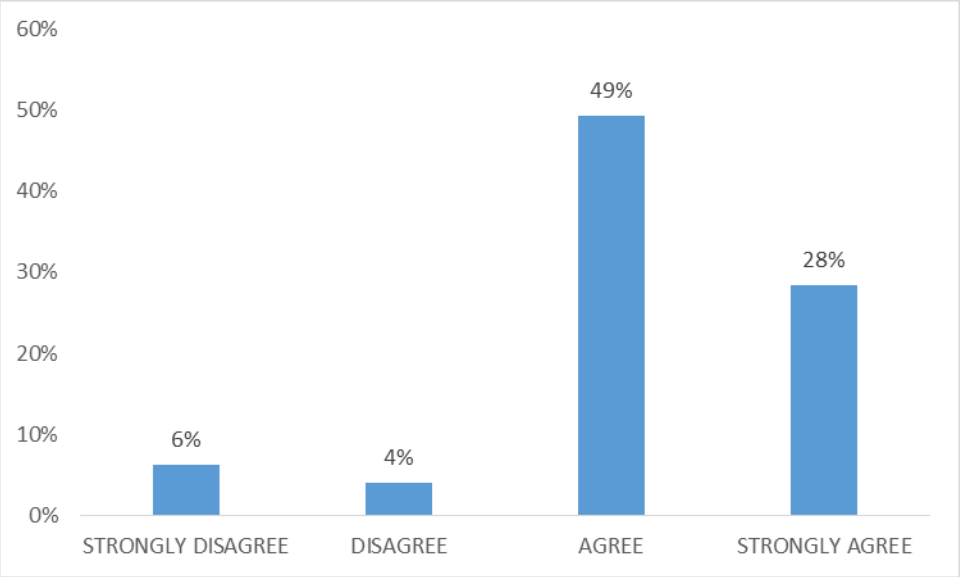


Patient reports on the helpfulness of the Office of Medical Cannabis Patient Support Center (1=not very helpful; 4=somewhat helpful; 7=very helpful). Note: percentages are based on total number of patient responses; 241 patients did not complete this question (several indicated no experience with the call center) and are not represented in the figure.

Patient Perceptions of Office of Medical Cannabis Website

Patients were asked to state their level of agreement with the statement: "The Office of Medical Cannabis website provides me with the information I need to understand and participate in the program." Among all patient respondents, 49% agreed and 28% strongly agreed that the website met their needs for information; however 10% expressed that they did not feel the website met their needs for program participation (Figure 8.4) and 12% did not respond to the survey question.

Figure 8.4. "The website provides the information I need to understand and participate in the program"



Patient Suggestions

Patients were asked to provide feedback on the program; all responses submitted from the first year cohort are tabulated in *Appendix G: Patient Suggestions for Improving the Program from Surveys*. Many patients used this space to elaborate on the program's impact on their lives; others suggested changes to the program's administration or reported concerns related to product cost or access to cannabis patient centers.

Suggestions and Information Requests from Healthcare Practitioners

Healthcare practitioners were asked to provide suggestions for improving the program, and were also asked if any additional information from the program would be useful to them. The full tabulation of comments is available in *Appendix H: Healthcare Practitioner Suggestions for Improving the Program and Requests for Additional Information from Surveys*. Many comments reported in these sections of the survey mirrored those reported as clinical observations; there were 39 additional comments relating to affordability of the products. Other common responses included requests for information on medical cannabis dosing and specific information on what products their patient was purchasing. Other responses included requests for more patient education regarding products, information on drug interactions, and data on efficacy in specific patient populations.