Medical Cannabis Therapeutic Use Program Impact Assessment Report

FEBRUARY 1, 2017

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Section 1. Introduction

The Minnesota Legislature passed a law in 2014 with bipartisan support legalizing the manufacture, sale and use of medical cannabis in Minnesota.[1] This law was designed to enable seriously ill patients to use cannabis for therapeutic purposes while preventing it from being misused or diverted from its medical purpose. The law was also designed to capture patient experiences with the program and to learn from them. MDH was directed to implement the program within aggressive timelines and to launch the program by July 1, 2015. The program has been operational for more than a year.

Minnesota is one of 28 states with a medical cannabis program.[2] Our medical cannabis law is one of the most restrictive in the country. The law permits consumption of cannabis or its chemical compounds in the form of (1) liquid, including oils, (2) pills, or (3) vaporized delivery methods using liquid or oils, but which does not require the use of dried leaves or plant form. Minnesota is one of only two states with legal medical cannabis to prohibit consumption of medical cannabis in raw plant form (that is, leaf) and the smoking of medical cannabis.[3]

Qualifying Medical Conditions

State law requires Minnesota residents with one or more of the qualifying medical conditions to have their medical condition certified by an enrolled health care practitioner before they enroll in the state's patient registry and access medical cannabis for therapeutic or palliative purposes.

Section 152.22, subdivision 14 defines the term "qualifying medical condition" as:

[1] The law is codified at Minn.Stat. 2016, §§ 152.22 – 152.37.

[2] Currently, 28 states plus the District of Columbia have full medical cannabis programs. An additional 17 states have limited programs that permit only cannabidiol (CBD), a non-intoxicating cannabinoid extracted from the cannabis plant and used to treat seizure disorders.

[3] Minn.Stat. 2016, § 152.22, subd. 6.

1. Cancer, if the underlying condition or treatment produces one of more of the following:
   (a) Severe or chronic pain; or
   (b) Nausea or severe vomiting; or
   (c) Cachexia or severe wasting;
2. Glaucoma;
3. Human immunodeficiency virus or acquired immune deficiency syndrome;
4. Tourette's syndrome;
5. Amyotrophic lateral sclerosis;
6. Seizures, including those characteristic of epilepsy;
7. Severe and persistent muscle spasms, including those characteristic of multiple sclerosis;
8. Inflammatory Bowel Disease, including Crohn's disease;[4]
9. Terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:
   (a) Severe or chronic pain; or
   (b) Nausea or severe vomiting; or
   (c) Cachexia or severe wasting;
10. Any other medical condition or its treatment approved by the commissioner.

Commissioner Additions. The Commissioner of the Department of Health was given the authority to add qualifying medical conditions to the list, but the legislature may block or modify any such addition.[5] The law required MDH to consider adding intractable pain as a qualifying medical condition before any other medical condition.[6] The Commissioner announced on December 2, 2015 his decision to add intractable pain to the list. This decision followed a community engagement process that included 13 public meetings around the state, an on-line public comment submission process. MDH also established an advisory panel comprised of clinicians and medical providers to look at the available medical evidence. The Department heard from nearly 500 Minnesotans – more than 90 percent supporting the addition of intractable pain as a qualifying condition—as part of this process. The addition of intractable pain as a qualifying medical condition became effective on August 1, 2016.

[4] The original legislation, Laws 2014, Chapter 314, referred only to "Crohn's disease," An amendment in 2016 extended this condition to Inflammatory Bowel Disease, including Crohn's disease." See Laws 2016, Chapter 179, section 27.

[5] Minn. Stat. 2016 §152.22, subd. 14 (10); *see also* §152.27, subd. 2(b).

[6] *See* Minn. Laws 2014, ch. 311, sec. 20.

MDH has also established a process through which members of the public may petition the commissioner of health to consider adding new qualifying medical conditions.[7] Petitions may be submitted from June 1 through July 31 each year, and a seven-member review panels assists the commissioner in this process. If the commissioner approves adding the petitioned condition, the chairs and ranking minority members of the legislative policy committees having jurisdiction over health and public safety must also receive proper notice.[8] If the legislature does not provide otherwise by law, MDH will publish the addition in the State Register and on the department's medical cannabis website, with an effective date of August 1st.

In 2016, MDH received 14 petitions seeking the addition of qualifying medical conditions. Of these petitions, eleven were accepted for the review of nine medical conditions.[9] Three were rejected for containing multiple medical conditions. The Review Panel appointed by MDH met four times and had access to more than 50 written comments filed with MDH about the petitions. The Panel delivered its report to the Commissioner of Health on November 1, 2016 and on December 1, 2016, the Commissioner announced his decision to add Post-Traumatic Stress Disorder as a qualifying condition, to become effective on August 1, 2017.

Qualifying Medical Conditions and Delivery Methods Added by the Commissioner of Health

Qualifying Medical Conditions:	*date approved*	*effective date*
Intractable Pain	December 1, 2015	August 1, 2016
Post-Traumatic Stress Syndrome (PTSD)	December 1, 2016	August 1, 2017
Delivery Methods:	*date approved*	*effective date*
Topical Applications	December 1, 2016	August 1, 2017

The department also received six petitions to add delivery methods. Four were accepted for review and two were rejected as being inconsistent with current statutory requirements.[10] These petitions were not reviewed by the Panel but public comments were received by MDH. On December 1, 2016, the Commissioner announced his decision to add topical applications, effective August 1, 2017.

[7] Minnesota Rules, part 4770.4003.

[8] Minn. Stat. 2016 § 152.27, subdivision 2.

[9] The nine petitioned conditions were: acquired absence of limb, arthritis, autism, diabetes, Ehlers-Danlos syndrome (EDS), insomnia, post-traumatic stress syndrome (PTSD), schizophrenia, and treatment-resistant depression.

[10] The delivery method petitions accepted for review were: edibles, topical applications, and vaporizable whole plant. The delivery method petitions rejected were: home delivery and smokeable.

A current list of qualifying medical conditions is available on the Office of Medical Cannabis' website: http://www.health.state.mn.us/topics/cannabis/patients/conditions.html.

Section 2. Program Design and Implementation

Key Elements of Minnesota's Medical Cannabis Program Implementation

Design Features.

Office of Medical Cannabis. After passage of the Act, the Department established the Office of Medical Cannabis ("OMC"). Michelle Larson was named director of the new office on August 13, 2014. The office currently has 11 full-time employees. The office website is: http://www.health.state.mn.us/topics/cannabis/index.html. MDH and the Office of Medical Cannabis provides the Task Force with regular updates on program implementation and operations.

Structure of the Program. There are two key structural design features of the Minnesota medical cannabis program. First, there are two manufacturers responsible for the cultivation, production, and distribution of medical cannabis within the state. Second, there is a medical cannabis patient registry. In order to achieve implementation and avoid delays, the legislature established strict deadlines in the enabling legislation to force the speedy implementation of the program. For example, the time from passage of legislation to registration of medical cannabis manufacturers afforded to MDH was less than half the time other states had required.

The legislation legalized the regulated production, possession, delivery and use of cannabis for medical purposes. It creates a system governing the production and distribution of medical cannabis and the certification and registration of patients and their caregivers. Manufacturers that are registered by the Department to cultivate and dispense medical cannabis must undergo a stringent vetting process. The Department's 2014 Request for Application (RFA) established the criteria used to select registered manufacturers, including those listed in Minnesota Statutes sections 152.25, subdivision 1(c): technical expertise, employee qualifications, financial stability ability to provide appropriate security, and projected patient

fees. Manufacturer registrations are to be renewed bi-annually and continual reporting to the Department is required.[11]

The Act also defines the population which may be granted permission for medical use and the circumstances governing such permission. Certified patients and their designated caregivers are registered with the Department and are only allowed to purchase a limited amount of cannabis for use at a given time. Patients certified to use medical cannabis must be under the care of a specified licensed practitioner. It also provides an opportunity for the accumulation of relevant data for further evaluation of the program's efficacy. All aspects of the system are to be substantially regulated by the Department.

Medical and Scientific Support. OMC's research staff, led by Dr. Tom Arneson, M.D., intend to learn from the experience of registry participants. Supporting evidence relating to the efficacy of medical cannabis is incomplete and one of the priorities of the program is data gathering. On December 1, 2014, the Department issued *"A Review of Medical Cannabis Studies relating to Chemical Compositions and Dosages for Qualifying Medical Conditions"* to satisfy a requirement set out in Minnesota Statutes section 152.25, subdivision 2. This report is updated annually. The current report can be viewed at http://www.health.state.mn.us/topics/cannabis/practitioners/dosage.pdf. The report summarizes clinical trials and prospective observational studies in humans, published in peer-reviewed journals. The studies reviewed are not limited to studies conducted in the United States but they do focus on medical cannabis formulations consistent with Minnesota's medical cannabis program. Relevant new study publications and newly discovered existing study publications will be included as they come to the attention of the Office of Medical Cannabis in periodic updates of the report.

The report focused on medical cannabis formulations consistent with Minnesota's medical cannabis program requirements and found relatively few relevant clinical trials, especially large clinical trials that can produce definitive results. However, the report points out that the number of clinical trials appears to be increasing in recent years.

During the late 1980's and early 1990's, a series of scientific breakthroughs revealed an internal system of cannabinoid receptors and cannabinoid signaling molecules in the human brain. Cannabinoid receptors are located throughout the central nervous system and peripheral tissues and are implicated in nervous system excitability, movement, analgesia, and neuroprotection. Following this period of scientific discovery and expanded understanding of

[11] Original legislation called for annual renewals of the manufacturer registrations. This was changed to bi-annual renewals by Minnesota Laws 2015, chapter 74, section 3.

the physiological basis of cannabinoid action, there was renewed interest in potential therapeutic applications of cannabinoid chemicals. Additional research is still needed to ascertain cannabis's general medical safety, therapeutic properties and to determine standard and optimal doses and routes of delivery.

Activities of Minnesota's Medical Cannabis Program

Manufacturer evaluation and selection

Minnesota Statutes, section 152.25, subdivision 1(a) required the Department to register two vertically integrated medical cannabis manufacturers by December 1, 2014 to produce medical cannabis to distribute to patients who qualify for the program.[12] The Department pursued a comprehensive and impartial evaluation and selection process for deciding on the two medical cannabis manufacturers that have been registered.

The Department registered two medical cannabis manufacturers within six months of the enabling legislation's effective date. The process used to select these manufacturers was fair, thorough and intense.

On August 8, 2014, the Department held an "Interested Parties" meeting for anyone who was interested in learning more about becoming a medical cannabis manufacturer in Minnesota. Over 230 parties attended the public meeting which was held at the Minnesota History Center.

On September 5, 2014, the Department issued a Request for Applications (RFA), inviting parties interested to prepare applications. As part of the RFA process, potentially interested parties were required to file an "intent to apply" letter by Sept. 19, 2014. The Department received 29 letters of intent, more than anticipated.

On October 3, 2014, MDH received 12 applications accompanied by a non-refundable $20,000 application fee. MDH then began the evaluation and review process, creating

MANUFACTURER SELECTION TIMELINE

The medical cannabis manufacturer evaluation process occurred over the following timeline:

- Manufacturer Interested Parties Conference – August 8, 2014
- Request for Applications (RFA) Published – September 5, 2014
- Intent to Apply Due Date – September 19, 2014
- Application Due Date – October 3, 2014
- Application Evaluation
  - Completeness review and pass/fail criteria evaluation
  - pass/fail criteria evaluation
  - Scoring applications
- Manufacturer Applicant Presentations – October 27 – 30, 2014
- Identification of Semi-finalists – November 3, 2014
- Semi-finalist Site Visits – November 10 – 18, 2014
- 2 Manufacturers Registered – December 1, 2014

[12] *See* Minnesota Statutes section 152.25, subdivision 1(a). Vertical integration means the supply chain of a company is owned by that company. In the context of medical cannabis, it means that each registered manufacturer is responsible for the cultivation, harvest, production, packaging and distribution of its medical cannabis.

an applicant selection panel to assist in the scoring of the applications received. This panel worked in sub-teams to focus their expertise on defined areas of the application and then the panel convened as a whole to receive reports from the sub-teams. The Review Panel then scored the applications.

Eleven of the manufacturer applicants were given the opportunity to further inform the applicant selection panel about the applicant's organization and operations as well as provide the opportunity for the panel the opportunity to ask questions of the applicants during the week of October 27, 2014. These presentations were not open to the public.

MDH leadership then conducted site visits to prototype operations affiliated or operated by four finalists. Following this, MDH selected and registered the two highest rated manufacturer applicants on December 1, 2014. These manufacturers are Leafline Labs, LLC and Minnesota Medical Solutions ("MinnMed"). Leafline Labs was registered to serve even-numbered congressional districts and located its manufacturing site in Cottage Grove. MinnMed serves odd-numbered congressional districts within the state and located its manufacturing center in Otsego, Minnesota.

Figure 1 is a graphical depiction of the process and the points in the process when some applicants were eliminated from consideration.

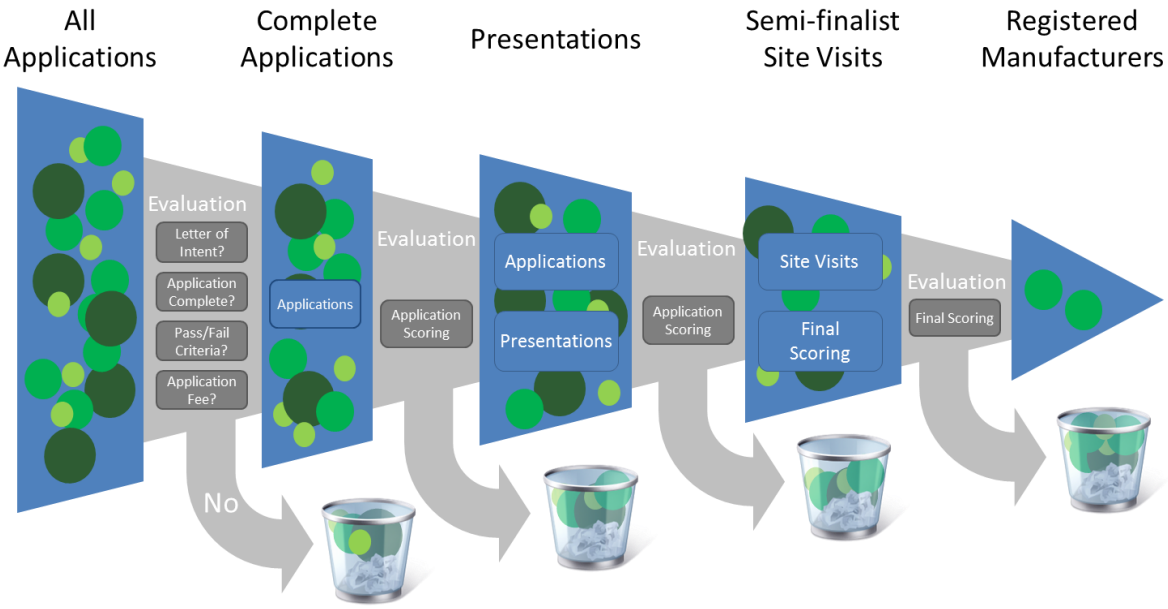
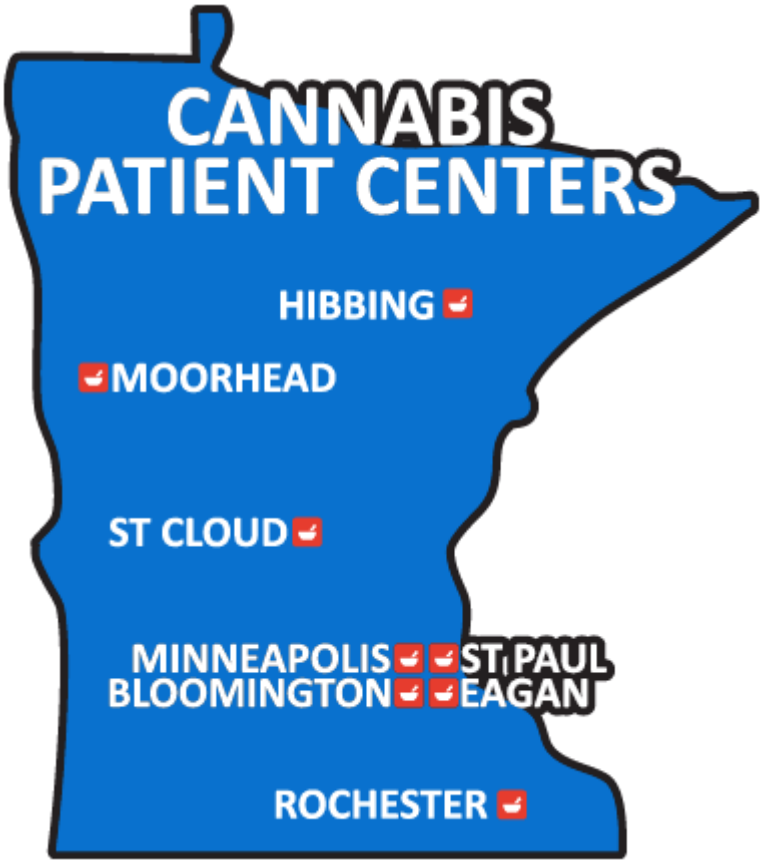


Figure 1. Medical Cannabis Application Process

The law requires each manufacturer to operate four distribution facilities, for a total of eight statewide. These distribution facilities, or cannabis patient centers, must be located

based on geographical need.[13] In registering the two manufacturers, MDH assigned service areas based on Minnesota's eight U.S. congressional districts, so that each congressional district with the state will have one distribution facility. As a result, there is one cannabis patient center in each of Minnesota's eight congressional districts. The congressional district siting method was selected to ensure geographical spread based on population. One consequence of this approach is that some qualified patients, especially those in the geographically larger districts, may live a long distance from the nearest distribution facility. The originally proposed locations for the distribution facilities as identified by the registered medical cannabis manufacturers leave areas of Greater Minnesota potentially underserved.

All eight patient center locations are operational as of July 1, 2016 but some locations have limited hours of operation due to lower patient demand.[14]



[13] Minnesota Statutes, section 152.29, subdivision 1.

[14] Days and hours of patient center operations presented below reflect November 2016 operations for illustrative purposes only and are subject to change.

Location	Address	Phone	Hours (as of December 1, 2016)
Bloomington	Bloomington 5232 W. 84th Street Bloomington, MN 55431	800-514-3707	Monday: 12:00PM – 7:00PM Tuesday: Closed Wednesday: 12:00PM – 7:00PM Thursday: Closed Friday: 11:00AM -6:00PM Saturday: Closed Sunday: 11:00AM – 4:00PM
Eagan	2795 Pilot Knob Road, Eagan, MN 55121	1-844-532-3546	Monday 10am–6pm Tuesday 10am–6pm Wednesday 10am–6pm Thursday 10am–6pm Friday 10am–4pm Saturday (1st and 3rd Saturday) 10am–2pm Sunday Closed
Hibbing	302 East Howard Street Hibbing, MN 55746	1-844-LEAFLINE (1-844-532-3546)	Monday 9am-5pm Tuesday 9am-5pm Wednesday 9am-5pm (by appointment only) Thursday 9am-5pm (by appointment only) Friday 9am-3pm Saturday (1st and 3rd Saturday) 9am-1pm Sunday Closed
Minneapolis	207 South 9th Street, Minneapolis, MN 55402	1-800-514-3707	Monday: Closed Tuesday: 10:00AM – 5:00PM Wednesday: 10:00AM – 5:00PM Thursday: 10:00AM – 5:00PM Friday: 10:00AM – 5:00PM Saturday: 11:00AM – 4:00PM Sunday: Closed
Moorhead	104 7th Street S. Moorhead, MN 56560	218-206-6600	Monday to Friday: Closed Saturday: 11:00AM – 4:00PM Sunday: Closed
Rochester	3456 E. Circle Drive NE Rochester, MN 55906	1-800-514-3707	Monday: Closed Tuesday: 11:00AM – 4:00PM Wednesday: Closed Thursday: 11:00AM – 4:00PM Friday: Closed Saturday: Every other Saturday Sunday: Closed
St. Cloud	141 33rd Avenue South, St. Cloud MN 56301	1-844-532-3546	Monday 10am-6pm Tuesday 10am-6pm Wednesday 10am-6pm Thursday 10am-6pm Friday 10am-4pm Saturday (Every 2nd and 4th Saturday) 10am-2pm Sunday Closed
St. Paul	550 Vandalia Street Saint Paul, MN 55114	1-844-LEAFLINE (1-844-532-3546)	Monday 8am-6pm Tuesday 8am-6pm Wednesday 8am-6pm Thursday 8am-6pm Friday 8am-2pm Saturday (Every 2nd and 4th Saturday) 10am-2pm Sunday Closed

Patient Registry

Minnesota Statutes section 152.27, subdivision 1 provides that the Department will establish a medical cannabis therapeutic use patient registry. Any Minnesota resident with a qualifying medical condition may be entered into the patient registry after paying the applicable patient registration fee.[15]

In order to qualify as a patient under the program, a person must have written certification from a health care practitioner affirming that the person has been diagnosed with a qualifying medical condition. A health care practitioner is defined as a medical doctor, physician's assistant, or advanced practice registered nurse licensed in Minnesota. Minnesota Statutes section 152.28, subdivision 1, requires a certifying health care practitioner to:

(1) determine whether the patient suffers from one of the qualifying medical conditions;

(2) determine whether the patient requires a designated caregiver due to developmental or physical disability;

(3) advise patients, caregivers, and guardians of the existence of nonprofit patient support groups or organizations;

(4) provide patients with explanatory information produced by MDH, program application information, and a Tennessen warning required by section 13.04, subdivision 2; and

(5) agree to continue treating the patient's medical condition and report medical findings to MDH.

If a health care practitioner's patient is enrolled in the medical cannabis registry, the practitioner will:

(1) Participate in the patient registry reporting system
(2) Report health records of the patient; and
(3) Annually determine whether the patient has a qualifying medical condition.

Health care practitioner participation in the registry program is voluntary.[16]

[15] Minnesota Statutes, section 152.35(a).

[16] *See* Minnesota Statutes, section 152.28, subdivision 1(c).

Medical Cannabis Patient Registry. The Department entered an agreement with MN.IT for the development of an electronic patient and caregiver registration and payment process. The registration and payment process is managed through an encrypted web application that provides security of personal, medical, and financial information of the applicant. The platform was designed to allow MDH the ability to gather and evaluate data on patient demographics, effective treatment options, clinical outcomes, and quality of life outcomes. Although this work could be done manually, it would require a significant increase in staffing and cost. In addition, absent a functioning IT platform, there would be greater difficulty obtaining and analyzing patient data. A manual work-around process has been established to serve patients without the technical expertise or capacity to participate in the program via computer.

Patient Counts

Figure 2 displays the weekly number of patients enrolled and in active status in the registry since June 1, 2015 when patients were first eligible to register through September 30, 2016. As of September 30, 2016, there are 2,806 patients actively enrolled in the patient registry, an increase of 1,218 from the 1,588 enrolled on June 30, 2016. This increase is due primarily to the addition of Intractable Pain as a qualifying medical condition.

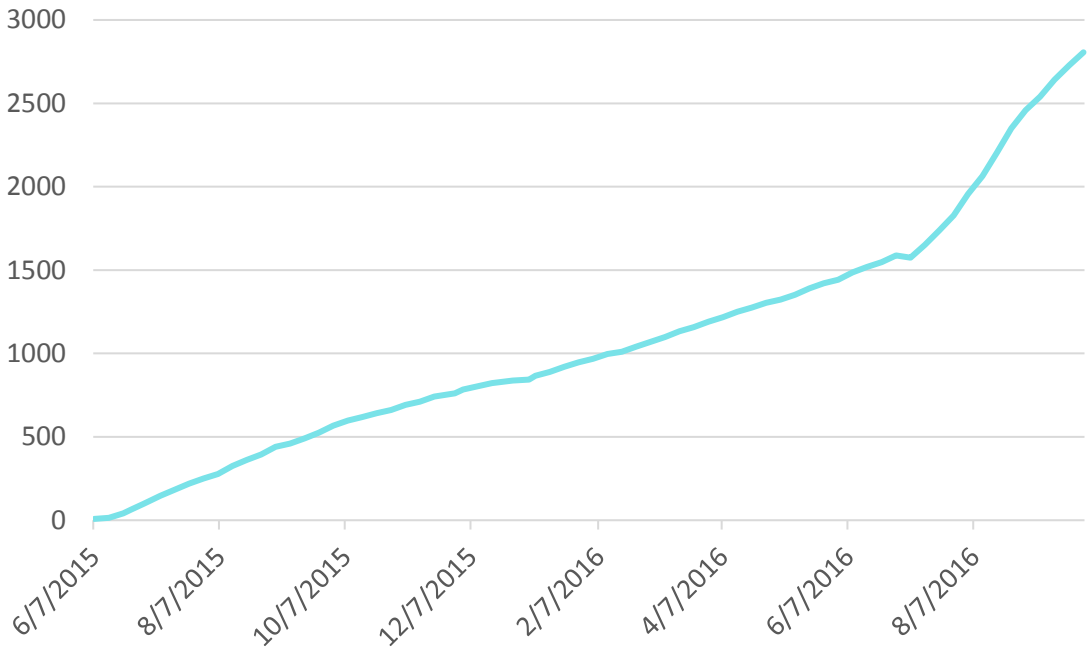


Figure 2. Weekly number of patients enrolled and in active status in registry.

Patients must pay a $200 enrollment fee before they are eligible to legally purchase and possess medical cannabis.[17] Patients who receive government assistance (MN Care, Social Security Disability, Supplemental Security Income, Medicaid/MA and CHAMPVA) qualify for a reduced fee of $50. Figure 3 shows that approximately 52 percent of registered patients have qualified for the reduced enrollment fee, a decrease of 5 percent from the 57 percent qualifying for the lower fee as of June 30, 2016.

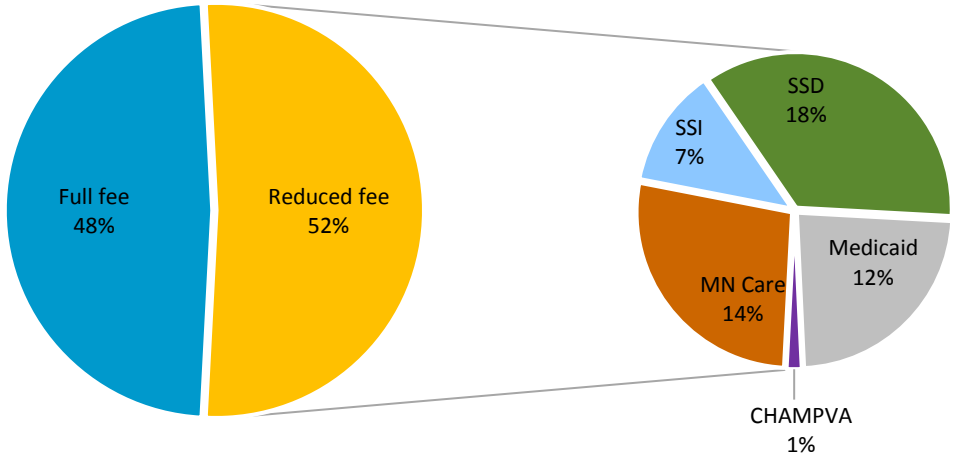


Figure 3. Breakdown of active patients by fee type (reduced vs. full fee) and types of government assistance for reduced fees.

Costs of Implementation

Minnesota Statutes, section 152.35, subdivision 3, requires the commissioners affected by the medical cannabis therapeutic research act to report on costs incurred to implement the law compared to estimated costs to implement the law. The Department of Health has filed a cost report in each of 2015, 2016, and 2017. These reports are public documents and are available for inspection. No other agency has submitted a cost report to the Task Force.

[17] Minnesota Statutes, section 152.35(a).

Administrative Rulemaking

The Department received authority to adopt and implement administrative rules for the program using the expedited rulemaking process. Minnesota Statutes, section 152.25, subdivision 3(a) provides:

> The commissioner shall adopt rules necessary for the manufacturer to begin distribution of medical cannabis to patients under the registry program by July 1, 2015, and have notice of proposed rules published in the State Register before January 1, 2015.

And section 152.26 provides:

> The commissioner may adopt rules to implement sections 152.22 to 152.37. Rules for which notice is published in the State Register before January 1, 2015, may be adopted using the process in section 14.389.

Therefore, the Department was given authority to adopt and implement rules necessary for medical cannabis manufacturers to begin distributing medical cannabis to patients.
Three medical cannabis rulemakings have been completed:

- Minn. Rules, part 4770.0400 et seq., effective January 20, 2015 – Manufacturer Rules
- Minn. Rules, part 4770.4000 et seq., effective June 29, 2015 – Patient Registry Rules
- Minn. Rules, part 4770.0200 et seq., effective June 11, 2016 – General rulemaking

A fourth rulemaking relating to laboratory testing requirements for medical cannabis is open for public comment (Revisor's #04427; Request for Comments published September 19, 2016).[18]

Manufacturer Rules. MDH published in the State Register proposed rules applicable to medical cannabis manufacturers on October 6, 2014, which became effective on January 20, 2015.

These expedited rules spell out restrictions for producing medical cannabis starting with planting, growing, and harvesting cannabis plants through processing them into medical cannabis. These rules also specify how the manufacturers must handle the medical cannabis until it is dispensed. This rulemaking addressed:

- Packaging and labeling the medical cannabis for patients;
- Site security;
- Transportation of medical cannabis and its corresponding security;
- Advertising and marketing the manufactured medical cannabis;
- Disposing cannabis plant material and waste medical cannabis;
- Quality assurance of the medical cannabis produced; and
- Record keeping.

[18] MN State Register, *available at*: http://mn.gov/admin/assets/SR41_12%20-%20Accessible_tcm36-263472.pdf.

In addition to the manufacturers' operation requirements, the rules describe MDH's administration of the following oversight functions:

- Manufacturer registration;
- Facility inspection;
- Testing labs approval;
- Registration revocation; and
- Voluntary facility closure.

Patient and Health Care Practitioner Rules. MDH adopted rules applicable to medical cannabis patients and health care practitioners which were effective on June 29, 2015. These rules were also promulgated using the expedited process and established requirements for patients, caregivers, and healthcare practitioners taking part in the registry. The patient registry requirements explain:

- Application qualifications and procedures for patients, designated caregivers, and health care practitioners;
- Procedure for health care practitioners providing a written certification of a patient's qualifying medical condition;
- Prohibitions for health care practitioners;
- Revocation or suspension of a qualifying patient or designated caregiver registration; and
- Record keeping and reporting requirements for health care practitioners.

In addition, these rules established the following processes and functions:

- Procedure for requesting a medical condition or delivery method be added to the list of qualifying medical conditions;
- Procedure for requesting a delivery method be added to the list of approved delivery methods;
- Medical cannabis point-of-distribution requirements, including dosage calculation and purchasing limits;
- Reporting requirements for serious health effects and unauthorized possession incidents
- Disposal of unused medical cannabis by persons authorized to possess it.

Additional rulemakings. A third rulemaking process, following the regular, or formal, rulemaking process, utilized a stakeholder advisory committee comprised of members representing the following stakeholder groups: patients and patient advocates, health care practitioners, public safety and law enforcement, medical cannabis manufacturers, and pharmacists. This rulemaking allowed the department to fill in gaps left after the expedited rulemakings and to address new concerns that arose. These rules became effective following a public hearing and became effective on June 11, 2016.

A fourth rulemaking has been announced. The Minnesota Department of Health published a request for comments in the State Register on September 19, 2016.[19] The Department is considering new rules to modify, clarify, and formalize existing laboratory testing requirements for medical cannabis. These rules will protect patient health and safety by establishing laboratory testing requirements for potency, consistency, the presence of contaminants, and to support label accuracy.

Assessment of rulemakings. The Department took advantage of its expedited rulemaking authority given in Minnesota Statutes section 152.26 to propose administrative rules in order to implement the program by July 1, 2015. It met all statutory deadlines. Running two expedited rulemaking processes in parallel with strict deadlines, while still in program start-up mode put at risk a certain amount of public involvement and deliberation. Formal rulemaking process allowed for a more deliberative review of the rules adopted in the expedited processes and also provided an opportunity to modify the rules in response to legislative changes.

Section 3. Impact on Health Care Practitioners

Health care practitioners are defined by the statute to include physicians, physician assistants and advanced practice registered nurses licensed in Minnesota.[20] The law does not require health care practitioners participate in the program and it does not allow them to prescribe or distribute medical cannabis. However, those who choose to participate will "certify" patients have been diagnosed with at least one of the qualifying medical conditions required for registration in the program.[21] Health care practitioners should use their professional judgment when deciding whether to certify a particular patient. Tobe eligible for the program, the patient must apply to and register with the Minnesota Department of Health after receiving this

[19] MN State Register, *available at*: http://mn.gov/admin/assets/SR41_12%20-%20Accessible_tcm36-263472.pdf.

[20] Minn.Stat. § 152.22, subd. 4.

[21] Minn.Stat. § 152.28.

certification.[22] Practitioners in a group medical practice may register with MDH as a "designated certifier" and may certify patients on behalf of the medical group.[23]

The program's administrative rules require the health care practitioner to have a medical relationship with each patient they certify. The health care practitioner is required to conduct a full assessment of the patient's history and current medical condition, including an in-person physical examination of the patient appropriate to confirm the diagnosis of the qualifying medical condition. And the health care practitioner is required to develop a treatment plan for the condition.[24]

The law requires that patients "continue to receive regularly scheduled treatment" for their condition from their health care provider.[25] The law also requires that health care practitioners "determine, on a yearly basis, if the patient continues to suffer from a qualifying medical condition and, if so, issue the patient a new certification of that diagnosis."[26] Each patient must renew their enrollment in the program every year.

Finally, once a patient is participating in the program, the Department of Health has the authority to request from the certifying medical provider the patient's health records relating to the qualifying medical condition.[27]

The Department of Health works with physicians and other health care practitioners to prevent the unauthorized release of patient data.

Non-federal health care practitioners are given protection from any civil or disciplinary penalties by the Minnesota Board of Medical Practice, the Board of Nursing, or by any State of Minnesota business, occupational or professional licensing board or entity solely for the participation in the program.[28]

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[22] Minn. Stat. § 152.27 .

[23] *See* Office of Medical Cannabis, Information Bulletin #1: http://www.health.state.mn.us/topics/cannabis/rulemaking/infobulletin1.pdf

[24] Minn.Rules, part 4770.4014, subp. 2.

[25] Minn.Stat. § 152.30(b)(1).

[26] Minn.Stat. § 152.28, subd. 1(b)(3).

[27] Minn.Stat. § 152.28, subd. 1(b)(2).

[28] Minn. Stat. §152.32. subd. 2(c).

The law creates several new criminal penalties for patients and health care providers.[29] A patient or caregiver who diverts medical cannabis is guilty of a felony. Further, a health care practitioner who "knowingly refers" a patient to a caregiver, advertises as a manufacturer, or issues certifications of qualifying condition while holding a financial interest in a manufacturer is guilty of a misdemeanor.

Health Care Facilities

Under the original medical cannabis statute and an amendment passed in 2015, health care facilities may impose reasonable restrictions on use of medical cannabis on their premises. The 2015 amendment extended protections and immunities to employees of non-federal health care facilities *carrying out their employment duties* for possessing medical cannabis legally acquired by an enrolled patient. This includes providing care to or distributing medical cannabis to a patient who is registered in the MN medical cannabis program and is actively receiving treatment at the facility.[30]

- Covered health care facilities are:
    - health care facilities licensed under chapter 144A,
    - boarding care homes licensed under section 144.50,
    - assisted living facilities, and
    - facilities owned, controlled, managed, or under common control with hospitals licensed under chapter 144.
    - Home care is also now included as a covered health care facility[31]

Section 4. Patient Experiences

The program is open only to residents of the state of Minnesota and has no reciprocity with other state medical marijuana programs. That is, enrollment in another state's medical marijuana program does not authorize purchase of medical cannabis or make possession of any medical cannabis product legal under Minnesota law.

[29] Minn.Stat. § 152.33.

[30] 2015 Laws, Chapter 74, Section 6, amending Minn. Stat. 152.34.

[31] *See* Laws 2016, Chapter 179, sec. 11, amending Minn. Stat. 2014, section 144A.4791.

A distinctive attribute of Minnesota's medical cannabis program is its intent to learn from the experience of the participants and to understand the impact of the program on this state. Patients who enroll in the program consent to having the information collected from them through participation in the program to be used for aggregate reporting and observational research and health care practitioners who certify patients in the program agree to provide medical record information for that patient, upon request of the commissioner.

During the application process patients agree to enroll in the web-based registry that is used to operate the program and that data in the registry can be used for aggregate reports and research. There is an annual enrollment fee of $200, discounted to $50 for patients enrolled in specified medical assistance programs.[32] No government or private insurance covers the cost of medical cannabis at this time, so patients need to pay that full cost out-of-pocket.

The law includes several legal protections for registered patients.[33] The law creates a presumption that a registered patient, registered designated caregiver, or a parent or legal guardian of the patient who is registered to act as caregiver, are legally possessing medical cannabis for the patient's medical use. That presumption can be rebutted by evidence that the patient used the cannabis recreationally. A patient's possession of a registry verification or application does not constitute probable cause or reasonable suspicion and cannot be used to support a search of the person or property. Note that the statutory definition of medical cannabis currently excludes any form of cannabis other than pills or liquids.[34] If a patient is found in possession of any other form of cannabis, the patient may be subject to criminal penalties.

Patients enrolled in the registry receive other protections. Antidiscrimination provisions provide some protection for program participants in employment, parental rights, housing, education, and medical care.[35]

Medical cannabis cannot be used in a manner that puts others at risk.[36] Use of medical cannabis is prohibited in school buses and vans, on school grounds, in correctional facilities, and on the grounds of child care facilities and home day cares. In addition, vaporizing medical cannabis is prohibited in public places, on public transportation, and anywhere the vapor could be inhaled by a child who is not a patient. Operating a motor vehicle while under the influence of medical cannabis is not permitted.

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[32] Minnesota Statutes, section 152.35(a).

[33] Minnesota Statutes, section 152.32.

[34] Minnesota Statutes, section 152.22, subdivision 6.

[35] Minnesota Statutes, section 152.32, subdivision 3.

[36] Minnesota Statutes, section 152.23(a).

The program's online registry which integrates information from the patient, certifying health care provider and manufacturer, provides centralized data capture. Medical cannabis treatment falls outside the traditional model of healthcare as certifying health care practitioners do not actively participate in the assessments and dispensing at the cannabis treatment centers. However, the research component of the program relies on the ongoing relationship between the patient and the health care practitioner who certified their qualifying medical condition and seeks to integrate clinical observations into the understanding of patient experience through a brief periodic survey.

One element of information-gathering which contributes to this learning is survey administration to patients and their certifying health care practitioners in the program. These surveys are sent three months after the patient's first medical cannabis purchase and capture information on the types and degree of perceived benefit and negative effects the patient experiences as a result of medical cannabis treatment. The patient survey is repeated at 6 months and every six months after that. The patient's certifying health care practitioner receives a parallel survey at the same time as the patient. An additional survey asks patients who have not purchased medical cannabis for two months whether they have discontinued treatment, and what their reasons for doing so may be. Survey response is not a condition of participation in the program, but response is encouraged through written communications.

Results of early surveys for patients who initiated participation in the program during its first three months: July – September, 2015. Though the number of patients is relatively small (n=435), the response rate was quite good for both patients (55%) and health care practitioners (39%). Results shared here should be considered an early look; reports later in 2016 and early in 2017 will include both larger numbers of patients and broader sources of data, including patient reported changes in specific symptom severity scores over time.

Patients and their certifying health care practitioners were asked to rate the benefit they received from medical cannabis on a scale from 1 (no benefit) to 7 (a great deal of benefit). Overall, Figure 4 shows both patient and practitioner perceptions of benefit were quite high: 88% of the 238 complete patient reports and 69% of the 142 complete practitioner reports chose a score of 4 or greater. Among the top three qualifying conditions (muscle spasms, cancer, and seizures), cancer patients appeared to gain the greatest benefit from medical cannabis.

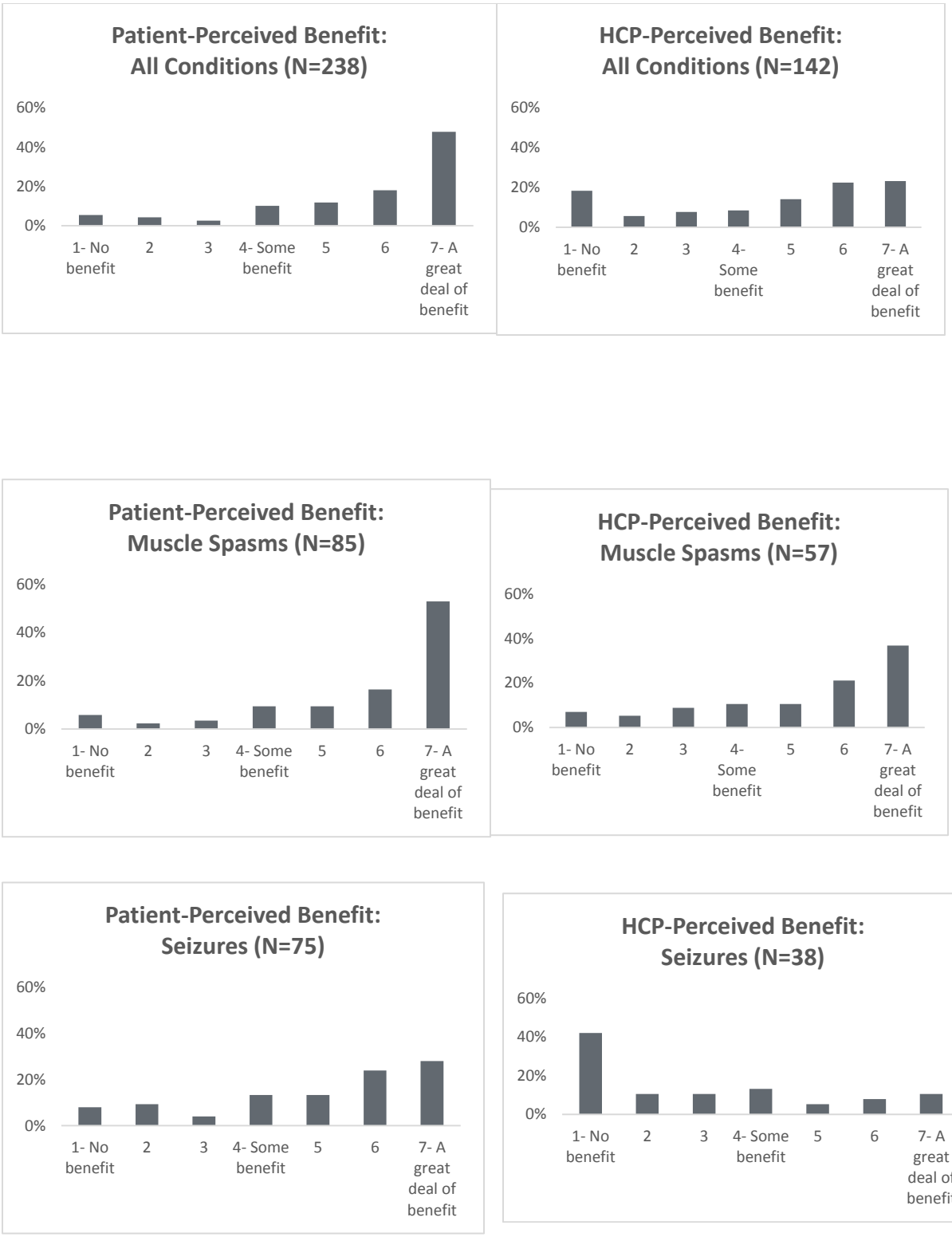

Figure 4. Distribution of reported benefit score from patients and Health Care Practitioners (HCP): patients with all qualifying medical conditions, patients with severe muscle spasms and patients with seizures.

Notably, both patient and practitioner scores varied by condition. Health care practitioners reported that patients certified for muscle spasms (n=85) seemed to have experienced a greater degree of benefit (79.0% of practitioners reported some benefit) than the overall group of respondents. Patients certified for seizures reported lower rates of benefit from medical cannabis than the overall patient population. Of the 38 practitioners, only 36.8% reported some benefit for patients with seizures. Health care practitioner reports of benefit were generally more conservative than patient reports.

Patient-perceived benefit scores were compared with the practitioner-perceived benefit scores in the group of 78 patients with completed data for both scores. A high level of agreement was found between patient and practitioner perceptions of benefit: 4% of patient-practitioner pairs agreed the patient received no or little benefit (score of 1-2); 14% agreed the patient received mild or moderate benefit (score of 3-5) and 45% agreed the patient received significant benefit (score of 6-7) from medical cannabis.

Patient and health care practitioners also had opportunities to report the most important benefit to the patient. Most of these reports cited direct benefits (reduction of symptoms related to the qualifying medical condition). Notably, comparison of benefit scores and most important benefits showed that symptom improvement was seen at relatively high degrees of benefit (most scores were above 4). Many patients and some practitioners, however, indicated that the most important benefit to the patient was a more general benefit, such as improved quality of life, sleep, mobility, cognitive functioning, or reduced anxiety.

As with benefit, patients and practitioners were asked to report on type and severity of negative effects related to medical cannabis use. Reported negative effects were not frequent: 20% of patients and 16% of practitioners reported some type of physical or mental harm including dry mouth, fatigue, mental clouding, and sedation. Most negative effects were reported at low levels (scores of below 4 on a scale from 1 (no negative effects) to 7 (great deal of negative effects).

Review of the 84 responses to surveys sent to 204 patients who made their first purchase in the first three months of the program and had a 2-month pause in purchasing showed that 51% of respondents intended to continue medical cannabis treatment. Reasons for pausing treatment included a variety of responses, though cost was the most common reason. Of the 16 (20%) patients who planned to discontinue treatment, most reported low levels of benefit from the treatment.

Early survey results from the Minnesota Medical Cannabis Program suggest that many patients have experienced substantial benefit from medical cannabis through the program. These data also suggest correlation between patient perception of benefit and health care practitioner perception of benefit. Furthermore, reported negative effects from medical cannabis use were generally minor, suggesting that medical cannabis treatment has been a safe option for most patients in the program so far. For full detail on survey results for patients who enrolled during

the first 3 months of the program see the report on the Office of Medical Cannabis web site: http://www.health.state.mn.us/topics/cannabis/about/surveyresults0516.pdf

Registered Caregivers

Registered caregivers are allowed under the law to assist registered patients incapable of obtaining or self-administering medical cannabis (for example, a child or severely disabled individual). These caregivers must apply to and register with the Department of Health separately from the patient under their care.[37]

There are restrictions on who can be a caregiver. The Department of Health will only register a designated caregiver if a health care practitioner has certified the patient needs a caregiver, the caregiver is at least 21 years of age, and the caregiver has not been convicted of a state or federal felony violation of a controlled substances law. In a typical situation, a designated caregiver may provide support to only one patient under the law, thus foreclosing any problems with "caregivers for hire." Parents can serve as a patient's caregiver through registration, without going through all the steps of becoming a registered caregiver. As of September 30, 2016, 323 patients (12% of total) had a registered caregiver.

Table 1. The number of active designated caregivers by condition.

Table 1. ***Active Caregivers by Condition***

Qualifying Condition	Total Patients	Patient with Caregivers: N (%)	Patients with PLGs: N (%)
Glaucoma	31	6 (19%)	0 (0%)
HIV/AIDS	48	2 (4%)	1 (2%)
Tourette Syndrome	34	1 (3%)	20 (59%)
ALS	14	9 (64%)	1 (7%)
Seizures	292	47 (16%)	174 (60%)
Muscle Spasms	869	96 (11%)	25 (3%)
Inflammatory Bowel Disease, Including Crohn's Disease	129	11 (9%)	5 (4%)

[37] Minn.Stat. § 152.27, subd. 4.

Table 1. *Active Caregivers by Condition*			
Cancer	492	114 (23%)	20 (4%)
Terminal Illness	89	29 (33%)	10 (11%)
Intractable Pain	1212	74 (6%)	14 (1%)
All Conditions	2807	323 (12%)	253 (9%)

Section 5. Substance Abuse Incidence Impacts

There have been no substance abuse impacts related to the medical cannabis program reported to the Office of Medical Cannabis.

Volunteered responses on health care practitioner surveys have indicated use of medical cannabis acquired through the program has allowed reduction or discontinuation of patients' opioid and benzodiazepine medications. More complete information on this subject will be available when survey results for patients certified for intractable pain become available in 2017.

Some evidence from other jurisdictions that medical cannabis being made an option reduces number of opioid overdose deaths within a state. Though not without methodological controversy, the results of these studies are interesting enough that similar research might be considered within the next few years as the scale of Minnesota's program increases.

Section 6. Access to and Quality of Medical Cannabis

Medical Cannabis Products in Minnesota

Allowable preparations of cannabis are whole plant extractions and resins delivered in the form of liquids, pills, and vaporized liquid or oil.[38] All products available in Minnesota are now produced through high pressure carbon dioxide extraction systems that extract from the

[38] Minn.Stat. § 152.22, subd.6.

cannabis plant a wide variety of its constituent chemicals. The resulting liquid extract is then formulated so that it contains precise amounts of certain chemicals.

Minnesota medical cannabis products are characterized by the amount and relative amount of two cannabinoid chemicals they contain: tetrahydrocannbinol (THC) and cannabidiol (CBD). These are only two of the approximately 100 (or more) cannabinoids found in the cannabis plant, but they are typically the most abundant cannabinoids. THC is psychoactive and it produces the euphoria (and sometimes dysphoria) and other effects that are usually referred to as "getting high." In addition to those psychoactive effects, THC also has analgesic, anti-nausea, anti-vomiting, and other effects that position it for being helpful as a medication. CBD is not psychoactive, and in fact it appears to reduce the psychoactive effect of THC. It has anti-inflammatory, anti-epileptic, and analgesic effects. Over the past 20 years or so it has been discovered that the human body has an important homeostatic mechanism called the endocannabinoid system, made up of molecules that interact with receptors to help regulate appetite, sleep, attention, and more. The reason THC and CBD and other cannabinoids derived from the cannabis plant (phytocannabinoids) have effects on the human body is because they engage with the body's endocannabinoid system together with the molecules made within the body (endocannabinoids).

Products produced by the two manufacturers are independent laboratory tested for cannabinoid content, for presence of contaminants (heavy metals, infectious agents, solvents), and for possible degradation over time. The manufacturers do their own testing during the course of production and storage, but there is also mandated testing by third-party laboratories approved by the Health Department.[39] The Department has recently initiated a rulemaking to clarify laboratory testing requirements for medical cannabis.

The manufacturers must comply with multiple rules related to packaging.[40] Examples include labelling requirements, use of child-resistant and tamper-evident packaging, and design of labels and packaging that has the look of standard prescription medications not likely to appeal to children.

[39] Minn.Stat. § 152.25, subd.1(d); Minn.Rules, part 4770.1900, subp.5.

[40] Minn.Stat. § 152.29, subd.3(c)(5) and Minn.Rules, part 4770.0850.

All medical cannabis marketed in the state undergoes content, contamination, and consistency testing at an MDH-approved third-party laboratory. There are currently two third-party laboratories that have been approved by MDH to test medical cannabis. Medical cannabis that does not pass testing standards cannot be marketed.

Rules adopted by MDH require the registered manufacturers to have procedures in place to recall products under certain conditions.[41] There have been no medical cannabis product recalls issued in the state.

Access to medical cannabis

Access to medical cannabis is limited by a number of factors, some intentional and some unintentional. Most significant among these limitations is the cost of medical cannabis to patients, which is not covered by insurance. High cost of medical cannabis products is the most frequent complaint of enrolled patients about the program. In addition, the costs of getting to a cannabis patient center, the annual registration fee of $200 (reduced to $50 if the patient receives medical assistance), and the costs of certification office visits add to this burden.[42] The Office of Medical Cannabis has the authority to conduct a formal assessment of costs experienced by patients.

The out-of-pocket costs to patients range from a couple of hundred to over a thousand dollars per month. Some patients report using less than they believe would be helpful to them because of the expense. Statements that many patients do not enroll in or choose to drop out of the program because of high product costs are credible, given the magnitude of the expense. A survey patients complete three months after their first medical cannabis purchase asks about affordability on a scale of 1 (very affordable) to 7 (cost is very prohibitive). Over a third answered with a 7 and 73% answered with a 5, 6, or 7.[43]

Another possible factor limiting patient access to medical cannabis include the statutory limit of eight dispensing or distribution facilities statewide.[44] The Office of Medical Cannabis is developing information relating to how far patients need to travel to reach a cannabis patient center.

[41] Minnesota Rules, part 4770.1850.

[42] According to patient comments, some health care practitioners charge patients up to $250 for a "certification visit" and $175 more for quarterly follow-up visits.

[43] "Early Results of Office of Medical Cannabis Surveys, May 2016," accessed on November 1, 2016 at http://www.health.state.mn.us/topics/cannabis/about/surveyresults0516.pdf.

[44] Minnesota Statutes, section 152.29, subdivision 1(a).

Some patients and potential patients have reported difficulty finding a health care practitioner willing to certify their qualifying medical condition. Participation in the program is voluntary for health care practitioners. Many choose not to participate for a variety of reasons. Registration in the program is steadily increasing and as of September 30, 2016 there were 696 health care practitioners registered: 572 (82%) physicians, 86 (12%) APRNs, and 38 (5%) PAs. Nonetheless, many patients remain frustrated that their clinicians will not certify them for the program and asking for a list of health care practitioners who will certify patients. The Office of Medical Cannabis is prohibited from distributing such a list, because by statute the information in the program registry is protected and considered not public data.

A final access issue is that participation in the program is limited to those with a qualifying medical condition.

Adequacy of Product offerings

The manufacturers are responsible for establishing their own product lines. All medical cannabis in Minnesota must be in an allowable form. *See* Minnesota Statutes, section 152.22, subdivision 6. Generally, both manufacturers offer products ranging from products that are high in THC and low in CBD, to products that have a balanced ratio between THC and CBD, to medications that are low in THC and high in CBD.

Some program participants have reported in public meetings and through communications with Task Force members and MDH staff that the products offered by the program are insufficient. These participants have communicated that beneficial elements found in the "whole plant" are lost because only extract products are permitted. It is felt that the components of the whole plant work together and provide an "entourage effect" which yields greater benefits than the individual, extracted components can deliver. However, law enforcement has communicated to Task Force members and to MDH staff during MDH-sponsored training that medical cannabis in "whole plant" form would be difficult or impossible to distinguish from other forms of cannabis on the street.

Moreover, some patients have complained about the manufacturers' failure to produce strain specific medications has left unmet needs. They claim that products derived from different strains of cannabis plants, sativa and indica, produce very different effects in the user.

Finally, many patients and potential patients point to the high cost of the medical cannabis produced in the state as making it unaffordable and therefore inadequate.

Financial status of manufacturers

In order to ensure continued patient access to medical cannabis, MDH has statutory authority to review annual certified financial audits from both medical cannabis manufacturers.[45] Audits filed in 2016 show that both manufacturers lost a significant amount of money in 2015. One manufacturer showed lost $3 million and the other lost $2.1 million. The ability to absorb losses for the first three years was a selection criterion used to select which manufacturers to register.

Section 7. Law Enforcement and Prosecutorial Impacts

Mandatory reports

Minnesota Rules, part 4770.4004 requires peace officers to notify MDH of any serious adverse incident relating to overdose and any case of diversion involving an adverse incident. MDH has not been notified of any reportable incidents.

Investigations and Prosecutions

Patients registered in the medical cannabis program are not protected from penalties associated with "operating, navigating, or being in actual physical control of any motor vehicle, aircraft, train, or motorboat" while under the influence of medical cannabis.[46] MDH has not been informed of any case of a person operating any of the listed vehicles while impaired by medical cannabis.

MDH is not aware of any prosecutions involving medical cannabis. There is one open criminal investigation by the MN Bureau of Criminal Apprehension (BCA) into the alleged diversion of medical cannabis from Minnesota to another state's medical cannabis program. MDH has cooperated fully with the BCA investigation in this matter.

Minnesota Statutes 152.32, subd. 1(a) creates a rebuttable presumption that a patient enrolled in the registry is engaged in the authorized use of medical cannabis. Therefore, law enforcement personnel should not impede a qualifying patient's access to or use of medical cannabis within allowed parameters. Due to limited forms of medical cannabis allowed under state law and the exclusion of whole plant materials, law enforcement has not reported difficulty distinguishing between medical cannabis and other forms of cannabis in the state.

[45] Minnesota Statutes, section 152.37, subdivision 2.

[46] Minnesota Statutes, section 152.23(a)(4).

MDH has hosted trainings for law enforcement across the state and received positive feedback about the law in its current form. Minnesota Rules, part 4770.4010 require licensed peace officers to report any instance of unauthorized possession of medical cannabis. There have been no reports made to MDH of unauthorized possession.

Search warrants

Minnesota Statutes, section 152.32, subdivision 2(e) prohibits law enforcement from accessing patient registry information except when acting pursuant to a search warrant. MDH has received one search warrant seeking access to patient registry information.

Section 8. Public Awareness and Perceptions

Since September 1, 2014, the Office of Medical Cannabis staff have conducted more than 153 presentations around the state. The perception of medical cannabis is still influenced by many factors outside the control of the state program. Overall, perception of the program is colored by its slow and methodical approach to gain greater social acceptance, by stories of program participants and potential participants, and by longstanding preconceived views.

Section 9. Legislation and Case Law

Legislation and laws related to medical cannabis in Minnesota include:

- Laws 2014, Chapter 311
- Laws 2015, Chapter 74
- Laws 2016, Chapter 179

On September 30, 2016, the Ramsey County District Court issued a decision involving Minnesota's medical cannabis program. At issue was the classification of data submitted by an applicant to become a medical cannabis manufacturer and whether those data are "public" or "not public" data under Minnesota law. The court ruled that while section 152.25, subd. 1(a) provides that data on a registered manufacturer is public, this section does not make public the application data of applicants not selected. As a result of the district court's ruling, MDH has removed the names and the applications of the two unsuccessful semi-finalists from our

website. The public will no longer have access to information about unsuccessful medical cannabis manufacturer applicants.[47]

[47] Cross Nurseries, LLC d/b/a AbatinMinnesota v. Minnesota Department of Health, 62-CV-15-7603.

Appendix 1: Membership of the Minnesota Task Force on Medical Cannabis Therapeutic Research

The members are:

James Backstrom – Hastings, MN
Minnesota County Attorneys Association

Duane Bandel – Minneapolis, MN
Consumer Member

Maria Botker – Clinton, MN
Parent Member

Sen. D. Scott Dibble, – Minneapolis, MN
Senate

Ramonna Dohman
Commissioner of Public Safety

Dr. Edward Ehlinger
Commissioner of Health

Dennis Flaherty – St. Paul, MN
Minnesota Police and Peace Officers Association

Karina Forrest-Perkins – White Bear Township, MN
Substance Use Treatment Provider

James Franklin – St. Paul, MN
Minnesota Sheriffs' Association Representative

Rep. Patrick Garofalo – Farmington, MN
House of Representatives

David Hartford – St. Cloud, MN
Substance Use Treatment Provider

Vincent Hayden, PhD. – Minneapolis, MN
Substance Use Treatment Provider

Sen. Bill Ingebrigtsen – Alexandria, MN
Senate

Lucinda Jesson
Commissioner of Human Services

Chief David Kolb – Champlin, MN
Minnesota Chiefs of Police Association

Doreen McIntyre – Champlin, MN
Health Care Provider

Jeremy Pauling – Montevideo, MN
Parent Member

Dr. Charles Reznikoff – Minneapolis, MN
Health Care Provider

Laura Schwartzwald – Aitkin, MN
Pharmacist Member

Sarah Wellington –St. Paul, MN
Consumer Member

Dr. Dawn Wyllie – Bemidji, MN
Health Care Provider

Open positions:

- **House Minority Appointee**
- **Substance Use Treatment Provider**

Former members:

Carly Melin – Hibbing, MN
House of Representatives

Branden Petersen – Andover, MN
Senate

Dr. Pamela Gonzalez – Minneapolis, MN
Substance Use Treatment Provider