MN HOUSE RESEARCH

Minnesota's Medical Cannabis Program

October 2023

Overview

This publication describes Minnesota's medical cannabis program, found in Minnesota Statutes, sections 152.22 to 152.37. Statutes establishing the medical cannabis program were enacted in 2014 and have been amended through the 2023 session. In this program, qualifying patients must enroll in a patient registry in order to use and possess cannabis for medical purposes. This publication also provides a brief history of medical cannabis legislation in Minnesota and a list of changes made to qualifying medical conditions and delivery methods.

Contents

Please note: The House Research Department provides services to the Minnesota House of Representatives; it does not and cannot represent or provide legal services to private individuals, private entities, or other government organizations. This publication is not intended to provide legal advice and should not be used as a substitute for consulting with a private attorney. Serious criminal and civil consequences can follow a possession or distribution of cannabis charge. If readers have any concerns about consequences resulting from the possession or distribution of medical cannabis, they should consult a private attorney.

By **Elisabeth Klarqvist,** 651-296-5043

Overview of the Law

Statutes establishing Minnesota's medical cannabis program were enacted in May 2014.[1] The law established a patient registry program administered by the Minnesota Department of Health (MDH), and allows qualifying patients enrolled in the registry to possess and use cannabis for medical purposes. The medical cannabis program will be transferred to the Office of Cannabis Management on March 1, 2025, and renamed the Division of Medical Cannabis.

The law allows the commissioner of health to register two manufacturers. Each manufacturer must have one manufacturing facility and is permitted to have eight distribution sites throughout the state.

The manufacturers may distribute medical cannabis in the form of dried raw cannabis or as a pill, liquid, topical product, water-soluble cannabinoid multi-particulate, orally dissolvable product, or infused edible product in the form of gummies and chews. Patients may also obtain medical cannabis from a Tribal medical cannabis program manufacturer.

To obtain medical cannabis under the registry program, a patient must be diagnosed with one or more qualifying medical conditions. The following conditions are qualifying medical conditions:

1) Alzheimer's disease
2) Amyotrophic lateral sclerosis (ALS)
3) Autism spectrum disorder
4) Cancer*
5) Chronic motor or vocal tic disorder
6) Chronic pain
7) Glaucoma
8) HIV/AIDS
9) Inflammatory bowel disease, including Crohn's disease
10) Intractable pain
11) Irritable bowel syndrome
12) Obsessive-compulsive disorder
13) Obstructive sleep apnea
14) Post-traumatic stress disorder
15) Seizures
16) Severe and persistent muscle spasms
17) Sickle cell disease
18) Terminal illness with life expectancy of under one year*
19) Tourette's syndrome

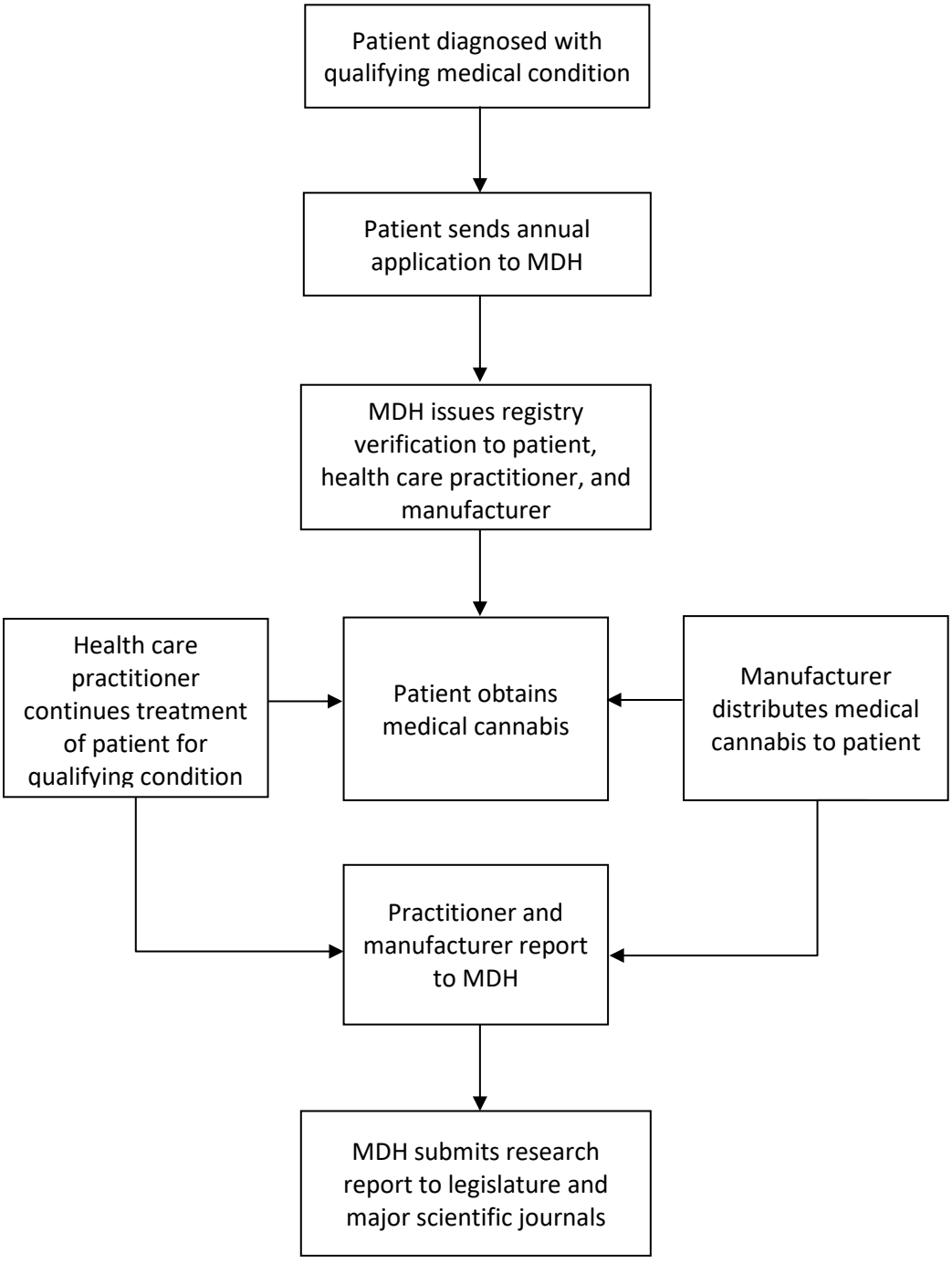
[1] Laws 2014, ch. 311; codified as Minn. Stat. §§ 152.22 to 152.37.

20) Any other condition or its treatment approved by the commissioner (subject to legislative oversight)

* Illness or treatment must produce one or more of the following: (1) severe or chronic pain; (2) nausea or severe vomiting; or (3) cachexia or severe wasting.

The general design of the registry program is as follows:

General Design of the Registry Program



General Design of the Registry Program

The components of the registry program are explained briefly below, but many aspects are more fully detailed in subsequent sections of this publication.

Patient diagnosed with qualifying medical condition

Prior to applying to participate in the registry program, a patient must be diagnosed by a health care practitioner with one or more qualifying medical conditions listed in statute or designated by the Commissioner of Health.

Patient sends annual application to MDH

Once a health care practitioner certifies that the patient has a qualifying medical condition, the patient must apply to the Minnesota Department of Health (MDH) to enroll in the registry program. The patient must submit this application on an annual basis.

MDH issues a registry verification to patient, health care practitioner, and manufacturer

Once the patient has been accepted into the registry program, MDH issues a registry verification listing the patient's information, along with information on the patient's registered designated caregiver or parent, legal guardian, or spouse, if applicable. The registry verification is issued to the patient, the patient's listed health care practitioner, and the manufacturer as proof of the patient's participation in the registry program.

Health care practitioner continues treatment of qualifying medical condition

As part of the health care practitioner's duties, the practitioner must continue to treat the patient's qualifying medical condition.

Manufacturer distributes medical cannabis to patient

A manufacturer may only distribute medical cannabis to a person listed on the patient's registry verification. Final approval for distribution must be made by a licensed pharmacist, and in some cases a pharmacist consultation with the patient must take place. A manufacturer may also distribute medical cannabis to Tribal medical cannabis program patients.

Patient obtains medical cannabis from manufacturer

A patient may only obtain medical cannabis from a registered manufacturer or Tribal medical cannabis program manufacturer. If a patient has a registered designated caregiver or parent, legal guardian, or spouse listed on the patient's registry verification, that person may also obtain medical cannabis from the manufacturer on the patient's behalf.

Reports to MDH

The health care practitioner is required to report the patient's health records to MDH through the registry program. The manufacturer is also required to submit a report to MDH containing various information.

MDH submits reports to legislature and major medical journals

MDH is required to conduct research on the information in the registry program and submit reports to certain legislative committees as well as major medical journals.

The Patient Registry Program

MDH Program Administration

The Office of Medical Cannabis at MDH administers the patient registry program. MDH functions include maintaining the patient registry and issuing registry verifications to enrolled patients, registering and regulating medical cannabis manufacturers, adding or modifying qualifying medical conditions and allowable medical cannabis delivery methods, providing information to health care practitioners, and adopting rules to implement the program.

The Office of Medical Cannabis and the patient registry program will move to the Office of Cannabis Management effective March 1, 2025, and the Office of Medical Cannabis will be renamed the Division of Medical Cannabis. On that date, the statutes in chapter 152 governing the medical cannabis program will be repealed, and the medical cannabis program will be governed by statutes in chapter 342 and accompanying rules.

Manufacturer Registration

Initial registration and reregistration[2]

On December 1, 2014, MDH registered two medical cannabis manufacturers, LeafLine Labs and Minnesota Medical Solutions, to supply medical cannabis to patients in the registry program. Minnesota Medical Solutions is now known as Green Goods Minnesota. LeafLine Labs was acquired by another company, and its cultivation and distribution facilities are operated by RISE. As a condition of initial registration, each manufacturer agreed to begin distribution of medical cannabis to patients by July 1, 2015, and comply with other requirements under the law. Manufacturers are subject to re-registration every two years.

MDH is required to consider the following factors when determining which manufacturers to register or reregister:

- Technical expertise in cultivating medical cannabis and converting it into allowable forms
- The qualifications of the manufacturer's employees

[2] Minn. Stat. § 152.25, subd. 1.

- The long-term financial stability of the manufacturer
- The ability to provide appropriate security measures on the premises of the manufacturer
- Whether the manufacturer has demonstrated an ability to meet the medical cannabis production needs required by the registry program
- The manufacturer's projection and ongoing assessment of patient fees

The commissioner may accept additional applications for manufacturer registration if one of the registered manufacturers ceases to be registered. A registration agreement between the commissioner and a manufacturer is not transferrable.

Enforcement actions against manufacturer registrations[3]

The commissioner has authority to revoke, not renew, or temporarily suspend a manufacturer's registration. The commissioner is authorized to not renew a manufacturer's registration if certain individuals affiliated with the manufacturer intentionally divert medical cannabis to a person other than allowed by law. Before revoking or not renewing a registration, the commissioner must provide written notice to the affected manufacturer, and the manufacturer may request a contested case hearing. In addition, the commissioner may temporarily suspend a manufacturer's registration for up to 90 days in certain circumstances. If the commissioner takes any enforcement action against a manufacturer that affects the ability of patients, designated caregivers, and parents, legal guardians, and spouses to obtain medical cannabis from that manufacturer, the commissioner must give notice of the enforcement action and alternatives for obtaining medical cannabis to affected patients, designated caregivers, and parents, legal guardians, and spouses.

Other methods of enforcement[4]

In addition to taking enforcement action against manufacturer registrations, the commissioner may use the tools and authority in the Health Enforcement Consolidation Act (Minnesota Statutes, sections 144.99 to 144.993) to enforce medical cannabis statutes.

Inspections at least annually[5]

Until a state-centralized seed-to-sale system is implemented, the commissioner must conduct at least one unannounced inspection per year of each manufacturer. In March 2022 the state entered into a contract with Metrc to implement a seed-to-sale inventory tracking system for the registry program.

[3] Minn. Stat. § 152.25, subds. 1, 1a, 1b, 1c.

[4] Minn. Stat. § 144.99, subd. 1.

[5] Minn. Stat. § 152.29, subd. 1, para. (n).

Financial audit and examination[6]

MDH may inspect the manufacturer's financial documents through an examination of its annual certified financial audit or through an examination of its business affairs. (For more on manufacturer financial audits, see page 17).

Changing delivery methods and qualifying medical conditions[7]

The commissioner may add a qualifying medical condition to the list of qualifying medical conditions, modify a condition on the list, or remove a condition from the list. The commissioner may also add to the list of allowable medical cannabis delivery methods. To add a delivery method or to add, remove, or modify a condition, the commissioner must evaluate petitions received and may add, remove, or modify the condition if the commissioner determines that the change is warranted based on evidence and research. The commissioner must then notify the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services as to the reasons for the addition or removal. This notice must include any public comments the commissioner received and any guidance the commissioner received from the Task Force on Medical Cannabis Therapeutic Research. The notification must be given by January 15 of the year the commissioner wishes to make the change. The change becomes effective August 1 of that year unless the legislature provides otherwise by law.[8]

Rulemaking authority[9]

MDH adopted the initial medical cannabis rules using the expedited rulemaking process under Minnesota Statutes, section 14.389. MDH may use the exempt rulemaking process under Minnesota Statutes, section 14.386 to adopt or amend rules to implement the addition of dried raw cannabis as an allowable form of medical cannabis, and these rules do not expire after two years. MDH must use the standard rulemaking process to adopt all other rules.

Reports[10]

The commissioner is required to regularly update the Task Force on Medical Cannabis Therapeutic Research and the chairs and ranking minority members of certain legislative committees regarding any changes in federal law or regulation of medical cannabis or hemp, and market demand and supply in Minnesota for products made from hemp that can be used for medicinal purposes. The commissioner may also submit medical research collected through

[6] Minn. Stat. § 152.37.

[7] Minn. Stat. § 152.27, subd. 2, para. (b).

[8] In 2019 the Commissioner of Health proposed adding age-related macular degeneration as a qualifying medical condition. After this proposal was made, a 2020 law prohibited this condition from being added as a qualifying medical condition. This was the first instance in which a law prohibited the addition of a qualifying medical condition that was proposed by the commissioner. See Laws 2020, ch. 115, art. 1, § 16.

[9] Minn. Stat. §§ 152.26; 152.261.

[10] Minn. Stat. § 152.25, subd. 4.

the registry program to federal agencies with regulatory authority over medical cannabis in order to demonstrate the effectiveness of medical cannabis for treating qualifying medical conditions. The commissioner must also submit findings from the registry program to both the legislature and major scientific journals.

Range of dosages and compounds[11]

MDH must annually review existing medical and scientific literature on the recommended range of dosages and chemical compounds for each qualifying medical condition and must publicly report that review. The most recent review was published in May 2022 and is posted on the MDH website.[12]

Adverse incidents[13]

As required by law, MDH adopted rules to require law enforcement personnel and emergency medical personnel to report incidents when individuals not authorized to use medical cannabis are found in possession of medical cannabis. The department also adopted rules requiring law enforcement personnel, health care professionals, registered patients, caregivers, and manufacturers to report serious adverse incidents involving medical cannabis, including incidents involving an overdose of medical cannabis.

Transportation[14]

Department of Health staff may transport medical cannabis to deliver it to laboratories for testing and for special investigations. The motor vehicle used by the department must be staffed with at least two Department of Health employees.

Patients

Participation in the registry program

For a patient to participate in the registry program, a patient must first be examined by a health care practitioner to determine whether the patient has one or more qualifying medical conditions. The following conditions are qualifying medical conditions:[15]

1) Alzheimer's disease
2) Amyotrophic lateral sclerosis (ALS)
3) Autism spectrum disorder
4) Cancer*
5) Chronic motor or vocal tic disorder

[11] Minn. Stat. § 152.25, subd. 2.

[12] *See* www.health.state.mn.us/people/cannabis/practitioners/docs/dosingreport.pdf.

[13] Minn. Stat. § 152.261; Minn. Rules, parts 4770.4004 and 4770.4010.

[14] Minn. Stat. § 152.29, subd. 3a.

[15] Minn. Stat. § 152.22, subd. 14; additional conditions added by Commissioner of Health.

6) Chronic pain
7) Glaucoma
8) HIV/AIDS
9) Inflammatory bowel disease, including Crohn's disease
10) Intractable pain
11) Irritable bowel syndrome
12) Obsessive-compulsive disorder
13) Obstructive sleep apnea
14) Post-traumatic stress disorder
15) Seizures
16) Severe and persistent muscle spasms
17) Sickle cell disease
18) Terminal illness with life expectancy of under one year*
19) Tourette's syndrome
20) Any other condition or its treatment approved by the commissioner (subject to legislative oversight)

* Illness or treatment must produce one or more of the following: (1) severe or chronic pain; (2) nausea or severe vomiting; or (3) cachexia or severe wasting.

Laws 2014, chapter 311, section 20, required the Commissioner of Health to consider adding intractable pain to the list of qualifying medical conditions before considering adding any other condition to the list. The commissioner added intractable pain[16] to the list of qualifying medical conditions using the procedure in Minnesota Statutes, section 152.27, subdivision 2, paragraph (b). In the following years, the commissioner added post-traumatic stress disorder, autism spectrum disorder, obstructive sleep apnea, Alzheimer's disease, chronic pain,[17] sickle cell disease, chronic motor or vocal tic disorders, irritable bowel syndrome, and obsessive-compulsive order to the list of qualifying medical conditions.

In December 2019, the Commissioner of Health also proposed adding age-related macular degeneration as a qualifying medical condition. This addition was prohibited by law in 2020, and age-related macular degeneration is not a qualifying medical condition.[18]

[16] Intractable pain is defined in Minnesota Statutes, section 152.125, subdivision 1, as a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause or pain is possible, or none has been found after reasonable efforts. According to MDH, intractable pain is a subset of chronic pain.

[17] According to a September 2019 Department of Health issue brief on adding chronic pain as a qualifying medical condition, chronic pain does not have a single definition. The term has been defined as pain that persists beyond the normal time of healing (which may be one month, three months, or six months), or pain that occurs at least half of the days for six months or more. Chronic pain also may trigger central sensitization, which is a prolonged increase in the excitability and firing of neurons in the central nervous system.

[18] Laws 2020, ch. 115, art. 1, § 16.

Following diagnosis of a qualifying medical condition, the patient must submit an application to MDH to enroll in the registry program.[19] The application must include a health care practitioner's certification of diagnosis and other forms required by MDH. The application must also include the name, mailing address, and date of birth of the patient, the designated caregiver if the patient requires assistance with administering or obtaining medical cannabis, and the patient's parent, legal guardian, or spouse if that individual will act as caregiver. Patients were formerly required to submit an application fee, but the application fee was eliminated effective July 1, 2023.

The commissioner must approve or deny an application within 30 days of receiving the application. Once the application is approved by MDH, the patient receives a registry verification.

Reasons to deny enrollment in the registry program[20]

The commissioner is authorized to deny a patient enrollment in the registry program only if the patient:

- does not have a certification from a health care practitioner of a diagnosis with a qualifying medical condition;
- does not provide the required information or signed disclosures;
- has previously been removed from the registry program for a violation of patient duties or for the commission of a crime related to medical cannabis; or
- provides false information.

If a patient is denied enrollment, the commissioner must give the patient a written reason for the denial. A denial is considered a final decision of the commissioner and is subject to judicial review under the Administrative Procedure Act, chapter 14.

Responsibilities during enrollment[21]

To maintain enrollment in the registry program, each year the patient must submit to MDH a copy of the patient's certification of diagnosis. Patients must also continue to receive regularly scheduled treatment for that qualifying medical condition and report changes in that condition to their health care practitioner while enrolled in the registry program.

Registered designated caregivers[22]

A patient is permitted to have a registered designated caregiver if the patient needs assistance in administering medical cannabis or acquiring medical cannabis from a distribution facility. The

[19] Minn. Stat. § 152.27, subd. 3.

[20] Minn. Stat. § 152.27, subd. 6.

[21] Minn. Stat. § 152.30.

[22] Minn. Stat. § 152.27, subd. 4.

registered designated caregiver must agree, in writing, to act as the patient's caregiver. As conditions of registration, the caregiver must:

- be at least 18 years of age;
- agree to only possess the patient's medical cannabis for purposes of assisting the patient; and
- agree to not be a caregiver for more than six patients at once. For purposes of this requirement, patients who live in the same residence count as one patient.

A registered designated caregiver may also be enrolled in the registry program as a patient and may possess medical cannabis for the caregiver's personal use.

Registered designated caregivers are subject to a criminal background check. If the caregiver has a disqualifying felony offense,[23] the commissioner is prohibited from registering that caregiver. Registered designated caregivers are also subject to criminal sanctions for diversion of medical cannabis in the same way as patients. (For more information on that criminal sanction, see page 13).

Parents, legal guardians, and spouses[24]

A patient's parent, legal guardian, or spouse, if listed on the registry verification as a patient's caregiver, may act as a patient's caregiver without having to register as a designated caregiver. Parents, legal guardians, and spouses are also subject to criminal sanctions for diversion of medical cannabis in the same way as patients. (For more information on that criminal sanction, see page 13).

Civil and criminal protections[25]

Presumption

Once a patient enrolls in the registry program, there is a presumption that the patient is engaging in the authorized use of medical cannabis. This presumption also applies to Tribal medical cannabis program patients. It may be rebutted by evidence that the patient's use of medical cannabis was not for the purpose of treating the patient's qualifying medical condition or associated symptoms, or for a purpose authorized by the patient's Tribal medical cannabis program.

Exemption from criminal sanctions for use or possession

Patients and Tribal medical cannabis program patients who use or possess medical cannabis are exempt from criminal sanctions for the use or possession of a controlled substance. Registered

[23] Disqualifying felony offenses are defined as violations of any state or federal controlled substance law that would be a felony in Minnesota, regardless of the sentence imposed, unless the commissioner determines that the conviction was for either the use or assistance with use of medical cannabis. Minn. Stat. § 152.22, subd. 3.

[24] Minn. Stat. § 152.27, subd. 5.

[25] *See generally* Minn. Stat. § 152.32, subds. 1, 2.

designated caregivers who possess medical cannabis, and, if listed on the registry verification, parents, legal guardians, and spouses who possess medical cannabis, are exempt from criminal sanctions for possession of a controlled substance.

Forfeiture

Medical cannabis and associated property are not subject to forfeiture under Minnesota law.

Search warrant needed to access registry

Law enforcement personnel must have a valid search warrant to access the patient registry.

Use of registry verification or application to support a search

A person's possession of a registry verification or registry program application or an equivalent from a Tribal medical cannabis program does not constitute probable cause or reasonable suspicion, and cannot be used to support a search of the person or property.

Circumstances in which penalties apply

The medical cannabis statutes do not prevent the imposition of civil, criminal, or other penalties for:

1) undertaking any task under the influence of medical cannabis that would constitute negligence or professional malpractice;

2) possessing or using medical cannabis:
    i) on a school bus or van;
    ii) on the grounds of any preschool, primary school, or secondary school;
    iii) in any correctional facility; or
    iv) on the grounds of any child care facility or home day care;

3) vaporizing or combusting medical cannabis:
    i) on any form of public transportation;
    ii) where the vapor may be inhaled by a nonpatient minor or where the smoke would be inhaled by a minor; or
    iii) in a public place, including any indoor or outdoor area used by or open to the general public or a place of employment;[26] and

4) operating, navigating, or being in actual physical control of any motor vehicle, aircraft, train, or motorboat, or working on transportation property, equipment, or facilities while under the influence of medical cannabis.[27]

[26] *See* Minn. Stat. § 144.413, subd. 1b, for a definition of place of employment.

[27] Minn. Stat. § 152.23.

Criminal sanctions

Diversion of medical cannabis

A patient or other individual authorized to obtain medical cannabis commits a felony if the patient or individual intentionally sells or transfers medical cannabis to an individual not authorized to obtain medical cannabis. Individuals authorized to obtain medical cannabis are patients, registered designated caregivers, and if listed on the registry verification, the parents, legal guardian, or spouse of a patient. This crime is punishable by imprisonment for not more than two years, payment of a fine of not more than $3,000, or both.[28]

False statements

A person who intentionally makes a false statement to law enforcement personnel about any fact or circumstance relating to the use of medical cannabis in order to avoid arrest or prosecution is guilty of a misdemeanor. This crime is punishable by imprisonment for up to 90 days, payment of a fine of not more than $1,000, or both, in addition to any other applicable penalty in law. A patient or a registered designated caregiver convicted of this crime is disqualified from any further participation in the registry program.[29]

Patient discrimination prohibited[30]

A patient or Tribal medical cannabis program patient is protected from being discriminated against in the following circumstances.

Enrollment in school

A school cannot refuse to enroll a person or otherwise penalize a person solely because the person is enrolled in the registry program or is a Tribal medical cannabis program patient. This prohibition does not apply if enrolling the person would cause the school to violate federal law or cause the school to lose a monetary or licensing-related benefit under federal law.

Leasing

A landlord cannot refuse to lease to a person or otherwise penalize a person solely because the person is enrolled in the registry program or is a Tribal medical cannabis program patient. This prohibition does not apply if leasing to the person would cause the landlord to violate federal law or cause the landlord to lose a monetary or licensing-related benefit under federal law.

Medical care

A patient's use of medical cannabis under the registry program or Tribal medical cannabis program is considered the authorized use of medication for purposes of medical care, including

[28] *See generally* Minn. Stat. § 152.33, subd. 2.

[29] Minn. Stat. § 152.33, subd. 3.

[30] Minn. Stat. § 152.32, subd. 3.

organ transplants. This use of medical cannabis is not the use of an illicit substance and does not disqualify a patient from needed medical care.

Employment

An employer is prohibited from discriminating against a person in hiring, termination, or any term or condition of employment, or otherwise penalize the employee based on:

- the person's status as a patient enrolled in the registry program or as a Tribal medical cannabis program patient; or
- a patient's positive drug test for cannabis components or metabolites, unless the patient used, possessed, or was impaired by medical cannabis while on the employer's premises or during the hours of employment.

An employer is not required to take actions, however, that would violate federal law or cause the employer to lose a federal monetary or licensing-related benefit. If an employee is required to take a drug test for the employer pursuant to section 181.953, the employee may present verification of enrollment in the registry program or verification of being a Tribal medical cannabis program patient as part of the employee's explanation of a positive urine test under section 181.953, subdivision 6.

Custody/Visitation

A person cannot be denied custody of a minor child or visitation rights with a minor child solely based on a person's status as a patient enrolled in the registry program or as a Tribal medical cannabis program patient. The law also provides that there is no presumption of neglect or child endangerment for conduct allowed under the registry program or a Tribal medical cannabis program, unless the person's behavior creates an unreasonable danger to the safety of the child as established by clear and convincing evidence.

Federally approved clinical trials[31]

The Commissioner of Health must provide information to patients about any federally approved clinical trials for the treatment of that patient's qualifying medical condition with medical cannabis. The commissioner may prohibit a patient from enrolling in the registry program if that patient is simultaneously enrolled in a federally approved clinical trial for the treatment of the patient's qualifying condition with medical cannabis.

[31] Minn. Stat. § 152.24.

Manufacturers

Regulation

Fees[32]

The Commissioner of Health must collect from manufacturers an annual fee for the cost incurred by MDH to regulate and inspect the manufacturer for that year. The yearly fee amount is established by the Commissioner of Health. Each manufacturer is allowed to charge patients enrolled in the program a reasonable fee for operating costs of the manufacturer and is allowed to establish a sliding scale of patient fees based on a patient's household income. Manufacturers may also accept private donations in order to reduce patient fees.

Operating documents[33]

A manufacturer's operating documents must include procedures for oversight, procedures to ensure accurate recordkeeping, procedures for appropriate security measures to deter theft and unauthorized entrance into areas that contain medical cannabis, and procedures for the delivery and transportation of hemp and hemp products between hemp growers or processors and manufacturers.

Location and number of facilities[34]

Each manufacturer is permitted to operate eight distribution facilities (also referred to as dispensaries) for distribution of medical cannabis and must operate one production facility for cultivation, harvesting, manufacturing, packaging, and processing of medical cannabis.[35] The production facility may be at the same location as a distribution facility.

The commissioner must designate geographic service areas served by each manufacturer, and a manufacturer cannot have more than two distribution facilities in each assigned service area. No facility may be within 1,000 feet of a public or private school that was in existence prior to the manufacturer's registration with MDH. As of September 2023, distribution facilities are located in Blaine, Bloomington, Burnsville, Duluth/Hermantown, Eagan, Hibbing, Mankato, Minneapolis, Moorhead, New Hope, Rochester, St. Cloud, St. Paul, Willmar, and Woodbury. Green Goods Minnesota operates eight distribution facilities, and RISE operates seven distribution facilities.

[32] Minn. Stat. § 152.35.

[33] Minn. Stat. § 152.29, subd. 1, para. (d).

[34] Minn. Stat. § 152.29, subd. 1, paras. (a) and (k).

[35] Prior to July 2019, each manufacturer was required to operate four distribution facilities and one production facility.

Employees[36]

A manufacturer is prohibited from employing any person under the age of 21 or any person who has been convicted of a disqualifying felony offense.[37] However, a manufacturer may employ a person who has been convicted of a disqualifying felony offense if the Commissioner of Health determines the conviction was for the use of or assistance with the use of medical cannabis. All potential employees must undergo a criminal history background check through the Bureau of Criminal Apprehension prior to working for the manufacturer.

In order to comply with distribution requirements, manufacturers must also employ at least one pharmacist licensed in Minnesota. The pharmacist employees must be the only employees who give final approval for distribution of medical cannabis and, in some cases, must consult with the patient before distributing the medical cannabis.[38] A pharmacist consultation is not required when a manufacturer is distributing medical cannabis according to an established, patient-specific dosage plan and is not changing the dosage or product distributed under the plan.

Any employee of the manufacturer involved in transporting medical cannabis or medical cannabis products from one location to another or to the other manufacturer must carry identification showing that the person is an employee of the manufacturer.[39]

Security[40]

Manufacturers must have certain security measures at all distribution sites and the production site. These security measures must include:

- procedures for the delivery and transportation of hemp or hemp products between hemp growers or hemp processors and manufacturers;
- a fully operational security alarm system;
- facility access controls;
- perimeter intrusion detection systems; and
- a personnel identification system.

[36] Minn. Stat. § 152.29, subd. 1, para. (j).

[37] A disqualifying felony offense is defined as a violation of any state or federal controlled substance crime that would be a felony under Minnesota law, whether or not the offense was committed in Minnesota and regardless of the sentence imposed. Minn. Stat. § 152.22, subd. 3.

[38] Minn. Stat. § 152.29, subd. 3, paras. (a) and (c).

[39] Minn. Stat. § 152.29, subd. 3, para. (d).

[40] Minn. Stat. § 152.29, subd. 1, para. (e).

Testing medical cannabis for content, contamination, consistency[41]

Each manufacturer must contract with an independent laboratory approved by the Commissioner of Health to test the manufacturer's medical cannabis and hemp and hemp products acquired by the manufacturer for content, contamination, and consistency. The cost of this contract must be paid by the manufacturer and is subject to any additional requirements set by the commissioner. The commissioner developed stock solution/final product acceptance criteria, specifying maximum allowed levels for metals, toxins, microbials, and solvents, and testing requirements for pesticides.[42]

Inspections[43]

Manufacturers are subject to reasonable inspections by the Commissioner of Health. In addition, until implementation of a state-centralized, seed-to-sale system, the commissioner must conduct at least one unannounced inspection per year of each manufacturer.

Each manufacturer must keep detailed financial records in a manner approved by the commissioner and make these records available for the commissioner's review. In addition, the manufacturers must submit to the commissioner the results of an annual financial audit conducted by an independent certified public accountant, paid for by the manufacturer. The commissioner may require a second financial audit by a certified public accountant chosen by the commissioner, also at the expense of the manufacturer.

The commissioner or the commissioner's designee may examine the business affairs of a manufacturer, including a review of the manufacturer's financing, budgets, revenues, sales, and pricing. The commissioner may retain outside professionals, such as attorneys and certified public accountants, to conduct or assist with this examination, but may not retain the same certified public accountant as used in the annual audit. If the commissioner conducts this examination, the commissioner must complete a report, provide a copy to the manufacturer, and post a copy on the department's website. All data collected during this examination, except for the public report, are private data on individuals or nonpublic data.

Reports to commissioner[44]

Each manufacturer must submit a monthly report to the Commissioner of Health. The report must include the following information for each patient served in the prior month:

- the amount and dosages of medical cannabis distributed
- the chemical composition of the medical cannabis

[41] Minn. Stat. § 152.29, subd. 1, para. (c).

[42] These acceptance criteria are found at https://www.health.state.mn.us/people/cannabis/docs/safety/mnmcacccriteria.pdf

[43] Minn. Stat. §§ 152.29, subd. 1, paras. (h) and (n); 152.37.

[44] Minn. Stat. § 152.29, subd. 4.

- the tracking number assigned to any medical cannabis distributed

For transactions involving Tribal medical cannabis program patients, manufacturers must report, on a weekly basis, information on Tribal medical cannabis program patients served by the manufacturer and on the medical cannabis distributed to them.

These reports are not public. MDH compares data in the monthly reports to data in the patient registry to ensure that the patient registry has a record of all medical cannabis transactions. MDH has also used these reports to fill in incomplete records in the registry.

Distribution

What may be distributed[45]

A manufacturer may distribute medical cannabis as dried raw cannabis, pills, liquid, topical formulations, water-soluble cannabinoid multi-particulates (including things like granules, powder, and sprinkles), orally dissolvable products (such as a lozenge, gum, mint, buccal tablet, or sublingual tablet), or infused edible products in the form of gummies or chews. A manufacturer is not limited to distributing medical cannabis that was cultivated and processed by that manufacturer, but may also distribute medical cannabis cultivated and processed by the other manufacturer. Manufacturers are allowed, but not required, to distribute medical cannabis products, such as delivery devices and educational material.

All medical cannabis must be assigned a tracking number, packaged in compliance with the United States Poison Prevention Packaging Act,[46] and labeled with the following information:

- All active ingredients
- Individually identifying information, including:
  - the patient's name and date of birth
  - if applicable, the name and date of birth of the patient's registered designated caregiver or parent or legal guardian
  - the patient's registry identification number
  - the chemical composition
  - the dosage

People allowed to receive medical cannabis[47]

A manufacturer may distribute medical cannabis only to a person listed on the patient's registry verification that the manufacturer received from MDH, or to a Tribal medical cannabis program patient. The manufacturer may not distribute any medical cannabis until the patient's registry verification, or equivalent documentation issued by a Tribal medical cannabis program, has been received. The registry verification includes patient information and may also list a

[45] Minn. Stat. §§ 152.22, subd. 6; 152.29, subd. 3.

[46] 15 U.S.C. §§ 1471-1477.

[47] Minn. Stat. § 152.29, subd. 3.

registered designated caregiver or a parent, guardian, or spouse of the patient. If a person is listed on the registry verification, the manufacturer may distribute the medical cannabis after verifying the person's identity by photographic identification, unless the individual distributing the medical cannabis personally knows the recipient.[48]

Medical cannabis in dried raw cannabis form may be distributed only to patients age 21 or older, or to caregivers of patients age 21 or older.[49]

Distribution requirements[50]

Final approval for distribution of medical cannabis must be given by employees of the manufacturer who are licensed pharmacists in Minnesota. In some cases, distribution may only occur after a pharmacist has consulted with the patient to determine the proper dosage and range of chemical compositions for that individual patient. The pharmacist may consult with the patient remotely, as long as the consultation meets certain requirements. A pharmacist consultation is not required when a manufacturer is distributing medical cannabis to a patient according to an established, patient-specific dosage plan and is not modifying the dosage or product distributed under the plan.

A manufacturer may distribute medical cannabis to a patient or caregiver who is at the distribution facility but stays in the motor vehicle, as long as the distribution facility complies with certain requirements for payment, recordkeeping, and storage and distribution of the medical cannabis.

Amount of medical cannabis that can be distributed[51]

A maximum of a 90-day supply of the dosage determined for the individual patient may be distributed at one time.

Other

Relationship with health care practitioners[52]

A manufacturer must not share office space with a health care practitioner. A manufacturer is also prohibited from referring patients to a health care practitioner or having any financial relationship with a health care practitioner.

[48] Minn. Stat. § 152.11, subd. 2d.

[49] Minn. Stat. § 152.29, subd. 3, para. (e).

[50] Minn. Stat. § 152.29, subds. 3, paras. (a) and (c); and 3b.

[51] Minn. Stat. § 152.29, subd. 3, para. (c), cl. (6).

[52] Minn. Stat. § 152.29, subd. 1, para. (f).

Marketing restrictions[53]

Manufacturers must comply with reasonable restrictions set by the Commissioner of Health relating to signage, marketing, display, and advertising of medical cannabis.

Transportation[54]

A manufacturer may staff a motor vehicle with one employee to transport medical cannabis to a certified laboratory to be tested or to a facility for disposal or to transport hemp for any purpose. A manufacturer must staff a motor vehicle with at least two employees when transporting medical cannabis for any other purpose or to any other destination. A manufacturer may also contract with a third party for armored car services to deliver medical cannabis to distribution facilities.

A Tribal medical cannabis program manufacturer may transport medical cannabis to testing laboratories in Minnesota and to other Indian lands. It must staff the motor vehicle transporting medical cannabis with at least two manufacturer employees.

Criminal and civil liability[55]

The law establishes criminal penalties that apply to manufacturers or employees of manufacturers in addition to any other applicable penalty in law. A manufacturer or agent of a manufacturer who intentionally transfers medical cannabis to a person other than one listed on a registry verification, a Tribal medical cannabis program patient, or another registered manufacturer, or who submits false records or documentation required for registration is guilty of a felony punishable by up to two years of imprisonment, a fine of not more than $3,000, or both. If certain individuals affiliated with a manufacturer intentionally divert medical cannabis outside the state to a person other than allowed by law, the commissioner may fine the manufacturer $250,000 and may begin proceedings to revoke the manufacturer's registration. A manufacturer may also be fined up to $1,000, in addition to any other applicable penalty in law, for any violation of laws or regulations relating to the registry program where no penalty is specified.

Criminal protections[56]

Employees of a manufacturer or an independent laboratory that tests medical cannabis are exempted from criminal liability under Minnesota law for the possession, dosage determination, and sale of medical cannabis as permitted under the registry program.

[53] Minn. Stat. § 152.29, subd. 1, para. (l).

[54] Minn. Stat. §§ 152.29, subd. 3a; 152.291.

[55] Minn. Stat. § 152.33, subds. 1, 4, and 6.

[56] Minn. Stat. § 152.32, subd. 2.

Data practices[57]

Data submitted to a medical cannabis manufacturer, and data submitted by a medical cannabis manufacturer to the Commissioner of Health, are classified as private data on individuals or nonpublic data. This data may be used to comply with requirements in chapter 13 and to comply with requests from the legislative auditor or state auditor.

Health Care Practitioners

For purposes of the registry program, a health care practitioner is defined as a Minnesota-licensed doctor of medicine, a Minnesota-licensed physician assistant, or a Minnesota-licensed advanced practice registered nurse, with the primary responsibility for care and treatment of the patient's underlying qualifying medical condition.[58]

Participation

MDH training/notification[59]

The Commissioner of Health must notify all eligible health care practitioners in the state about the registry program. This notice must include an explanation of the purposes and requirements of the program. If a health care practitioner meets the requirements and requests to participate in the program, the commissioner must allow the practitioner to participate. However, no health care practitioner is required to participate in the program.[60] In addition to notification, the commissioner also must provide practitioners with explanatory information and assistance in understanding the therapeutic uses of medical cannabis under the program requirements. The commissioner must provide patient applications to participating health care practitioners, who then may provide those applications to patients.

Certifications and recertifications[61]

In order for a patient to participate in the registry program, a health care practitioner must provide the patient with a certification of diagnosis with at least one qualifying medical condition. The certification must have been given by the practitioner within the 90 days prior to the patient's application. Practitioners must use the certification form developed by the Commissioner of Health. Practitioners must annually reassess patients and recertify diagnoses with a qualifying medical condition. Certifications and recertifications may occur via telehealth.

[57] Minn. Stat. § 152.31.

[58] Minn. Stat. § 152.22, subd. 4.

[59] Minn. Stat. § 152.27, subd. 2, para. (a).

[60] Minn. Stat. § 152.28, subd. 1, para. (d).

[61] Minn. Stat. § 152.28, subd. 1, paras. (a) and (c).

Responsibilities during participation[62]

If a health care practitioner agrees to participate in the registry program, the practitioner must continue to treat the patient for the patient's qualifying medical condition. Throughout that ongoing treatment, the practitioner must report the health records of the patient to the commissioner. The reporting of health records must be made in a manner set by the commissioner and is subject to data privacy provisions.

Advice to patients and others[63]

A health care practitioner working with a patient in the program must provide the patient, registered designated caregiver, and parent, legal guardian, or spouse with information on nonprofit patient support groups or organizations. The practitioner is also required to provide explanatory information provided by MDH disclosing:

- the experimental nature of therapeutic use of medical cannabis;
- the possible risks, benefits, and side effects of the proposed treatment;
- the application for participation in the program;
- other materials from the commissioner; and
- the Tennessen warning.[64]

Medical Assistance/MinnesotaCare reimbursement[65]

Medical Assistance (MA) and MinnesotaCare are not required to reimburse an enrollee or a provider for "costs associated with the medical use of cannabis." Medical cannabis is not listed on the drug formulary for MA and MinnesotaCare, so those programs do not cover medical cannabis.[66] However, MA and MinnesotaCare are required to reimburse health care practitioners for services related to the treatment of the patient's qualifying medical condition if that service is covered under applicable statutes.

Legal Issues

Advertising restrictions[67]

Health care practitioners are prohibited from publishing advertisements that:

[62] Minn. Stat. § 152.28, subd. 1, paras. (a) and (b).

[63] Minn. Stat. § 152.28, subd. 1, para. (a).

[64] The Tennessen warning is a notice provided to individuals asked to provide private or confidential data on the individual to a government entity. *See* Minn. Stat. § 13.04, subd. 2 (explaining the Tennessen warning).

[65] Minn. Stat. § 152.23, para. (b).

[66] *See* Minn. Stat. § 256B.0625, subd. 13d; Minnesota Health Care Programs Provider Manual, www.dhs.state.mn.us

[67] Minn. Stat. § 152.28, subd. 3.

- contain false or misleading statements about medical cannabis or the registry program;
- use colloquial terms to refer to medical cannabis;
- state or imply that a health care practitioner is endorsed by MDH;
- include images of cannabis or of cannabis-smoking paraphernalia; or
- contain medical symbols that may be confused with symbols of medical associations.

A health care practitioner who violates these advertising restrictions cannot certify patients to enroll in the registry.

Civil/disciplinary protections[68]

The law prohibits the Board of Medical Practice, the Board of Nursing, or any other professional licensing board from subjecting a health care practitioner to any civil or disciplinary penalties solely for participation in the registry program. This protection also extends to pharmacists under the Board of Pharmacy. The protection does not prevent a professional licensing board from taking action in response to violations of any other law. The law also does not provide any civil protections for health care practitioners for claims of malpractice, negligence, or any other civil claim.

Criminal liability[69]

Although the law creates exemptions from criminal liability for certain actions by patients, caregivers, and manufacturers, it does not exempt health care practitioners from criminal liability. Under the registry program, a health care practitioner does not possess or distribute medical cannabis and is therefore not exempted from criminal controlled substance possession laws.

A health care practitioner is subject to a misdemeanor penalty, punishable by up to 90 days in jail, payment of a fine up to $1,000, or both, for the following actions:

- knowingly providing patients with referrals to a specific manufacturer or a specific designated caregiver
- advertising as a manufacturer
- issuing a certification that a patient has a qualifying medical condition while holding a financial interest in a manufacturer

A case decided by the federal Court of Appeals for the Ninth Circuit addressed whether a health care practitioner may be criminally liable for aiding and abetting a federal crime for the physician's "recommendation" to a patient to use marijuana for medicinal purposes. In *Conant v. Walters*, the court held that a doctor's "recommendation" alone did not amount to aiding

[68] Minn. Stat. § 152.32, subd. 2, para. (c).

[69] Minn. Stat. § 152.33, subd. 5.

and abetting.[70] The case was based on California law that required a doctor to "recommend" a patient's use of medical marijuana. Minnesota law differs from California law in that respect, as a practitioner in Minnesota is providing a "certification of diagnosis" and not a "recommendation." It is also important to note that the Ninth Circuit Court of Appeals does not have jurisdiction over Minnesota, and therefore this decision is not binding on Minnesota courts.

Firearm possession and applications[71]

Under federal law, a person who is an unlawful user of a controlled substance is prohibited from possessing a firearm.[72] In 2023, state law was amended to provide that the use of medical cannabis by a person in the registry program does not make the person an unlawful user of a controlled substance. It also specifies that participation in the registry program does not make the person ineligible to possess a firearm; a permit to carry a firearm cannot be denied solely because a person is enrolled in the registry program; and standard application forms for a permit to purchase or carry a firearm must authorize a patient in the registry program to refrain from disclosing the patient's use of medical cannabis.

On May 30, 2023, the Bureau of Alcohol, Tobacco, and Firearms and Explosives issued a statement that said "Regardless of the recent changes in Minnesota law related to the legalization of marijuana, an individual who is a current user of marijuana is still federally defined as an 'unlawful user' of a controlled substance and therefore is prohibited from shipping, transporting, receiving, or possessing firearms or ammunition."[73] The statement added that federal law "does not provide any exception allowing the use of marijuana for medicinal…purposes."[74]

Health records[75]

All data collected on patients and reported to the patient registry are health records under the Health Records Act and are classified as private data on individuals. The data may, however, be used or reported in an aggregated, nonidentifiable form as part of the scientific, peer-reviewed publication of research required under the law or in the creation of summary data.

[70] *Conant v. Walters,* 309 F.3d 629 (9th Cir. 2002).

[71] Minn. Stat. §§ 624.713, subd. 1, clause (10), item (iii); 624.714, subd. 6, para. (f); 624.7151; and 624.7152.

[72] 18 U.S.C. § 922(g)(3).

[73] https://www.atf.gov/news/pr/atf-provides-clarification-related-new-minnesota-marijuana-law

[74] Id.

[75] Minn. Stat. §§ 152.28, subd. 2; 152.31.

Other

Health care facilities and home care providers[76]

Under the law, health care facilities and home care providers may adopt reasonable restrictions on the use of medical cannabis by a patient who resides at or is actively seeking care or treatment at the facility or from the provider. For purposes of this provision, health care facilities include those licensed under chapter 144A (nursing homes and hospice facilities); boarding care homes and supervised living facilities licensed under section 144.50; assisted living facilities; facilities owned, controlled, managed, or under common control with hospitals licensed under chapter 144; and other health facilities licensed by the Commissioner of Health. Restrictions may include that the facility or provider will not store or maintain the patient's medical cannabis supply, that the facility or provider is not responsible for providing the medical cannabis for patients, and that medical cannabis may only be used in specified places within the facility. The facilities and providers are not required to adopt any restrictions and are prohibited from unreasonably limiting a patient's access to or use of medical cannabis.

Employees of a health care facility, emergency medical services personnel, and home care providers are not subject to a violation under chapter 152 for possessing medical cannabis during the course of their duties and may distribute medical cannabis to a registered patient who resides at or is seeking active care and treatment at the facility or from the provider. Under this section, employees acting within the course of their duties are not required to register as a designated caregiver.

Prescription Monitoring Program[77]

Medical cannabis is not eligible to be entered into the Prescription Monitoring Program (PMP) database because it is not dispensed under a prescription drug order.[78] Under federal law, cannabis is a Schedule I controlled substance.

Operation of the Program

Appropriations

Money is appropriated by law from the general fund and the state government special revenue fund to the Commissioner of Health to fund the Office of Medical Cannabis. Appropriations from the state government special revenue fund for fiscal years 2015 to 2023 are from annual registration fees collected from manufacturers and annual fees collected from patients for enrollment in the patient registry; beginning in fiscal year 2024, appropriations from the state government special revenue fund are from annual registration fees collected from

[76] Minn. Stat. §§ 144A.4791, subd. 14; 152.34.

[77] Minn. Stat. § 152.126.

[78] The Prescription Monitoring Program (PMP) is codified in Minnesota Statutes, section 152.126. The PMP allows, in some cases, health care practitioners with prescribing authority to check the database for a patient's history of controlled substance prescriptions. The information in the PMP is generally inputted by the pharmacist who delivers the controlled substance. Among the included substances in the PMP are all substances listed on Schedule II, III, IV, or V.

manufacturers. The following table lists appropriations by fund in each fiscal year for the Office of Medical Cannabis.

Appropriations to MDH for the Office of Medical Cannabis

	Appropriations by Fund	
Fiscal Year	General Fund	State Government Special Revenue Fund
FY 2015	$2,795,000	$100,000
FY 2016	$829,000	$834,000
FY 2017	$752,000	$729,000
FY 2018	$708,000	$729,000
FY 2019	$708,000	$729,000
FY 2020	$771,000	$2,116,000
FY 2021	$779,000	$1,984,000
FY 2022	$781,000	$4,717,000
FY 2023	$781,000	$3,424,000
FY 2024	$781,000	$3,424,000
FY 2025	$521,000	$2,283,000

Program Participation

The MDH website provides data on participation in the medical cannabis program by patients, caregivers, and health care practitioners. Weekly updates on registration data specify the numbers of patients, caregivers, and health care practitioners currently participating in the program and the total number of patients who have enrolled since the program began. A medical cannabis dashboard includes other data on patients and health care practitioners, data on qualifying medical conditions, and monthly data on the number of patient visits to a distribution center that resulted in a medical cannabis purchase.

The following table lists the number of patients enrolled in the medical cannabis program; the number of enrolled patients with designated caregivers or registered parents, guardians, or spouses; and the number of health care practitioners approved for the program. A patient may have both designated caregivers and parents, guardians, or a spouse as caregivers, to help them obtain and administer medical cannabis.

Participation in the Medical Cannabis Program

Reporting Date	Patients Enrolled in Program	Enrolled Patients with Registered Designated Caregiver and/or Registered Parent, Legal Guardian, or Spouse	Health Care Practitioners Approved in Program
June 30, 2016	1,520	205 with registered designated caregiver 251 with registered parent/guardian	605
June 30, 2017	6,184	502 with registered designated caregiver 361 with registered parent/guardian	910
June 30, 2018	10,738	1,288 ▪ 833 with registered designated caregiver ▪ 495 with registered parent/guardian	1,234
June 30, 2019	17,202	2,454 ▪ 1,378 with registered designated caregiver ▪ 1,134 with registered parent/guardian	1,560
June 30, 2020	22,233[79]	3,559 ▪ 1,539 with registered designated caregiver[80] ▪ 2,110 with registered parent/guardian/spouse	1,770
August 5, 2021	23,772	3,325 ▪ 1,034 with a registered designated caregiver ▪ 2,398 with a registered parent/guardian/spouse	1,946

[79] According to MDH, the patient enrollment number for the fiscal year ending June 30, 2020, is inflated because Emergency Executive Order 20-26 prevented patient enrollments from expiring during the peacetime emergency due to COVID-19.

[80] Before July 1, 2019, a spouse of a patient was required to register as a designated caregiver in order to assist a patient with obtaining and administering medical cannabis. According to MDH, as of June 30, 2020, some spouses of patients may still be registered as designated caregivers rather than being registered as a spouse caregiver.

Reporting Date	Patients Enrolled in Program	Enrolled Patients with Registered Designated Caregiver and/or Registered Parent, Legal Guardian, or Spouse	Health Care Practitioners Approved in Program
June 3, 2022	35,711	4,462 ▪ 1,372 with a registered designated caregiver ▪ 3,215 with a registered parent/guardian/spouse	2,203
September 8, 2023	40,515	4,850 ▪ 1,255 with a registered designated caregiver ▪ 3,720 with a registered parent/guardian/spouse	2,426

Task Force on Medical Cannabis Therapeutic Research[81]

The Task Force on Medical Cannabis Therapeutic Research was established to conduct an impact assessment of the registry program on Minnesota. The 23-member task force consists of representatives from:

- the House of Representatives and the Senate;
- consumers or patients enrolled in the registry program;
- health care providers;
- law enforcement and prosecutors;
- substance use disorder treatment providers; and
- the commissioners of health, human services, and public safety.

All members, except the members from the House of Representatives and the Senate, are appointed by the governor. Two members of the House of Representatives and two members of the Senate are also members of the task force, with one member of each body serving as a co-chair. The co-chairs are appointed by the Senate majority leader and the Speaker of the House. The second member from each body is appointed by the minority leader of that body. All members serve at the pleasure of their appointing authority. The Commissioner of Health provides administrative and technical support to the task force.

This task force will be eliminated effective March 1, 2025.

[81] Minn. Stat. § 152.36.

Deadline extensions[82]

The task force had authority to extend the deadline to register manufacturers and the distribution deadline by six months if requested by the Commissioner of Health. MDH registered two manufacturers by the December 1, 2014, deadline, and the manufacturers began distributing medical cannabis on the July 1, 2015, deadline, so no extensions were needed.

Cost assessments

Beginning with a report on January 15, 2015, and continuing annually until January 15, 2019, the commissioners of the state agencies impacted by the medical cannabis therapeutic research study were required to report to the co-chairs of the task force the costs incurred by each agency in implementing the study. Agencies were required to report actual costs incurred compared to estimated costs.

Impact assessments

The task force must complete an impact assessment and report it to the legislature every two years beginning in 2017. The impact assessment must be conducted by holding hearings to evaluate the impact of medical cannabis and hemp use and evaluate Minnesota's activities involving medical cannabis and hemp. The impact assessment must include analysis of:

- the program design and implementation;
- the impact on the health care provider community;
- patient experiences;
- the impact on the incidence of substance abuse;
- access to and quality of medical cannabis, hemp, and medical cannabis products;
- the impact on law enforcement and prosecutions;
- public awareness and perception; and
- any unintended consequences.

The task force issued its first impact assessment report February 1, 2017.[83] To date, the task force has not issued any subsequent impact assessment reports.

Additional reports to the legislature

The task force had to report to the legislature by February 1, 2015, on the design and implementation of the registry program, and to submit completed cost assessments. These reporting requirements have expired.

[82] Minn. Stat. § 152.25, subd. 3.

[83] This report may be found on the Minnesota Department of Health's website at www.health.state.mn.us/people/cannabis/docs/taskforce/reportfinal061417.pdf

At any time, the task force may recommend to the legislature whether to add or remove conditions from the list of qualifying medical conditions.

Legislative History of Medical Cannabis Regulation in Minnesota

1980. In 1980, the THC Therapeutic Research Act was adopted and signed into law. The purpose of the act was to research whether cannabis could alleviate the effects of chemotherapy during the treatment of cancer.[84] The act required the Commissioner of the Department of Health to appoint a principal investigator.[85] The principal investigator was required to obtain cannabis only from the National Institute on Drug Abuse and comply with federal laws and regulations while conducting the research program.[86] In 1980, $100,000 was appropriated by the legislature to the Commissioner of Health to administer the act, but the appropriation was vetoed by Governor Al Quie.[87]

2001. In 2001, Representative Phyllis Kahn introduced House File 2164, known as the Compassionate Use Act. That act would have allowed for the medical use of cannabis after a patient had been diagnosed by a physician as having a debilitating medical condition. The House bill, and its companion bill in the Senate, were both introduced but not heard in committee.

2007. In 2007, Representative Thomas Huntley introduced House File 655 and Senator Steve Murphy introduced Senate File 345. Both bills would have allowed the use of medical cannabis for treatment of a debilitating medical condition. The Senate file passed the Senate floor and was referred to the House where it was given a second reading, but not passed.

2009. In 2009, the first medical cannabis law that would have allowed patient possession of medical cannabis passed both bodies of the legislature.[88] The act allowed patients to possess and use cannabis if diagnosed with a terminal illness that was accompanied by a variety of symptoms. The act passed both the House and the Senate and was vetoed by Governor Tim Pawlenty on May 22, 2009.

2013. In 2013, Representative Carly Melin and Senator Scott Dibble introduced House File 1818 and Senate File 1641, respectively, both allowing for the use and possession of medical cannabis by patients with a specified list of conditions. House File 1818 was referred to committee but did not pass the House floor. Senate File 1641 passed the Senate on May 6, 2014, and was referred to the House for consideration, but was not heard in committee.

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[84] Minn. Stat. § 152.21, subd. 1.

[85] Minn. Stat. § 152.21, subd. 4.

[86] Minn. Stat. § 152.21, subd. 5.

[87] Laws 1980, ch. 614, § 30.

[88] Laws 2009, ch. 166; Senate File 97, House File 292.

2014. On April 24, 2014, Senate File 2470, originally a bill relating to education, passed the Senate and was referred to the House for consideration. The bill was heard in the Rules and Administration Committee where an amendment was offered and adopted that allowed for the medical use of cannabis through a clinical trial model. The bill was then heard in the Ways and Means Committee where another amendment was offered and adopted, altering the program to a registry program. The bill was sent to the House floor where it was passed with additional amendments. Because the bill originated in the Senate and already passed the Senate, the Senate was able to either concur on the bill as amended or refuse to concur. The Senate refused to concur and the bill was heard in conference committee and passed by both bodies as amended in conference committee. Governor Mark Dayton signed the bill into law on May 29, 2014.[89]

2015. Laws 2015, chapter 74, amended various sections of the medical cannabis act by:

- modifying the definition of medical cannabis to include possession by a manufacturer or laboratory of any part of the cannabis plant prior to processing the plant into an approved liquid or pill form;
- establishing time limits for the Commissioner of Health to either approve or deny a patient's application for the registry program; and
- adding facilities owned, controlled, managed, or under common control of a hospital to those facilities that may adopt reasonable restrictions on the use of medical cannabis by patients who reside at or are actively receiving care or treatment at the facility.

A provision was also added to allow employees of a health care facility, in the course of their duties, to possess medical cannabis for a registered patient without registering with the commissioner as a designated caregiver.

2016. Laws 2016, chapter 179, amended various sections of the medical cannabis act by:

- expanding the definition of qualifying medical condition to include inflammatory bowel disease;
- requiring the Commissioner of Health to regularly update legislators about certain topics;
- specifying that only manufacturer employees licensed as pharmacists may give final approval for distribution of medical cannabis;
- allowing patient consultations via videoconference to determine dosages;
- allowing the transportation of medical cannabis by only one manufacturer employee in certain circumstances; and
- directing the Commissioner of Health to provide administrative and technical support to the Task Force on Medical Cannabis Therapeutic Research.

A separate provision was added to statutes governing home care providers, allowing home care providers to adopt reasonable restrictions on the use of medical cannabis by patients in the registry program who receive care from home care providers, and to protect home care

[89] Laws 2014, ch. 311.

provider employees from being subject to violations of controlled substance laws for carrying out employment duties and caring for patients in the registry program.

2017. Laws 2017, First Special Session, chapter 6, modified the Commissioner of Health's authority and tools for regulating registered medical cannabis manufacturers and health care practitioners. Regarding manufacturers, the commissioner is authorized to:

- accept additional registration applications from manufacturers if a manufacturer registered before December 1, 2014, ceases to be registered;
- not renew a manufacturer's registration, if an officer, director, or controlling person of a manufacturer diverts medical cannabis to a person other than allowed by law; and
- impose a civil penalty and revoke a manufacturer's registration, if an officer, director, or controlling person of a manufacturer diverts medical cannabis to a person other than allowed by law and transports medical cannabis outside the state.

The law also established procedures for the commissioner to revoke, not renew, deny consent to transfer, or temporarily suspend a registration of a medical cannabis manufacturer. In addition, the law prohibited health care practitioners from including certain terms, images, and symbols in their advertising. A health care practitioner who violates these advertising restrictions cannot certify patients as having qualifying medical conditions, for purposes of participating in the medical cannabis registry.

2019. Laws 2019, First Special Session, chapter 9, included numerous changes to the medical cannabis act and related statutes.

- The commissioner may establish the geographic areas to be served by each manufacturer, and use the tools and authority in the Health Enforcement Consolidation Act to enforce the medical cannabis act.

- Changes for patients and caregivers included lowering the minimum age for registered designated caregivers from 21 to 18, requiring registered designated caregivers to renew their criminal background checks every two years, allowing a spouse of a patient to act as a patient caregiver without registering as a designated caregiver, no longer listing a patient's qualifying medical condition on the patient's registry verification, and allowing a registered designated caregiver to also be a patient enrolled in the registry.

- Changes for manufacturers included increasing the number of distribution facilities operated by each manufacturer from four to eight, increasing the amount of medical cannabis a manufacturer may distribute to a patient from a 30-day supply to a 90-day supply, making a manufacturer registration nontransferable, allowing a manufacturer to obtain hemp from hemp growers and process hemp into an allowable form of medical cannabis, and allowing a manufacturer to transfer medical cannabis and medical cannabis products to the other manufacturer for distribution.

2020. In Laws 2020, chapter 115, article 1, medical cannabis manufacturers were authorized, rather than required, to operate eight distribution facilities. Additionally, the Commissioner of Health was required to conduct at least one unannounced inspection per year of each manufacturer, until a state-centralized, seed-to-sale system is implemented. This law also permits patients receiving veterans disability or railroad disability payments to pay the reduced fee to enroll in the medical cannabis program, and provides that age-related macular degeneration will not be added to the program's list of qualifying medical conditions.

During the peacetime emergency declared due to COVID-19, Governor Walz issued Executive Order 20-26 and authorized certain modifications to the medical cannabis program. Laws 2020, First Special Session, chapter 7, section 2, extended until June 30, 2021, the provisions in Executive Order 20-26 authorizing the use of telemedicine in the medical cannabis program to conduct patient assessments to initially certify patient qualifying medical conditions, and to perform consultations between patients or caregivers and manufacturer employees before the distribution of medical cannabis.

2021. Laws 2021, chapter 30, article 3, sections 28 to 41, changed the laws governing sources, distribution, and allowable forms of medical cannabis; registered designated caregivers; and the authority of the commissioner. An amendment to the definition of medical cannabis allows manufacturers to sell dried raw cannabis to patients age 21 or over and to their caregivers, and allows patients age 21 or over to combust dried raw cannabis. Manufacturers are also permitted to obtain hemp products from licensed hemp processors and process hemp products into allowable forms of medical cannabis.

Patients are no longer required to be at a distribution facility to consult with a pharmacist before obtaining medical cannabis. The consultation may take place by telephone or other remote means, and pharmacist consultations are no longer required when a manufacturer is distributing medical cannabis according to an existing, patient-specific dosage plan. Patients are no longer required to have a health care practitioner certify that they need a designated caregiver, and registered designated caregivers may serve up to six registered patients (instead of one patient), with patients who live in the same residence counting as one patient.

The Commissioner of Health is authorized to remove qualifying medical conditions from the list (in addition to adding or modifying qualifying medical conditions).

2023. Laws 2023, chapter 63, establishes a regulatory system for adult-use cannabis and, as part of that system, moves the medical cannabis program from the Department of Health to a new Office of Cannabis Management effective March 1, 2025. It also authorizes manufacturers in the registry program to distribute medical cannabis to Tribal medical cannabis program patients; permits patients enrolled in the registry program to obtain medical cannabis from Tribal manufacturers; extends certain legal protections to Tribal medical cannabis program patients and others; authorizes transportation of medical cannabis by Tribal manufacturers; and eliminates the patient application fee to enroll in the registry program.

Laws 2023, chapter 70, allows health care practitioner certifications that a patient has a qualifying medical condition to occur via telehealth; allows manufacturers to contract for

armored car services to deliver medical cannabis; and allows Department of Health staff to transport medical cannabis for certain purposes.

Changes to Qualifying Medical Conditions and Delivery Methods

The following table provides information on changes made to the program's list of qualifying medical conditions and allowable delivery methods and the year in which each change went into effect. With one exception, these changes were made by the Commissioner of Health using the commissioner's authority under Minnesota Statutes, section 152.27, subdivision 2, paragraph (b). In 2021, combustion of dried raw cannabis was added by law as an allowable delivery method, and that addition became effective in 2022.

Year Effective	Change to Qualifying Medical Conditions and Allowable Delivery Methods
2016	Addition of intractable pain as qualifying medical condition
2017	Addition of post-traumatic stress disorder (PTSD) as qualifying medical condition Addition of topical formulations (patches, lotions, creams, gels, and ointments) as allowable delivery method
2018	Addition of autism spectrum disorder and obstructive sleep apnea as qualifying medical conditions
2019	Addition of Alzheimer's disease as qualifying medical condition
2020	Addition of chronic pain as qualifying medical condition Addition of water-soluble cannabinoid multi-particulates (granules, powders, and sprinkles) and orally dissolvable products (lozenges, gum, mints, buccal tablets, and sublingual tablets) as allowable delivery methods
2021	Addition of sickle cell disease and chronic motor or vocal tic disorder as qualifying medical conditions
2022	Addition of combustion of dried raw cannabis and infused edible products in the form of gummies and chews as allowable delivery methods
2023	Addition of irritable bowel syndrome and obsessive-compulsive disorder as qualifying medical conditions

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