INFORMATION BRIEF
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Minnesota's Medical Cannabis Therapeutic Research Act

This information brief explains the Medical Cannabis Therapeutic Research Act, Minnesota Statutes, sections 152.22 to 152.37, enacted in 2014 and amended through the 2016 regular legislative session. The act established a patient registry program that allows qualifying patients to use and possess cannabis for medical purposes. A brief history of medical cannabis legislation in Minnesota is also provided.

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Overview of the Law

The Medical Cannabis Therapeutic Research Act was enacted in May 2014.[1] The law established a patient registry program, administered by the Minnesota Department of Health (MDH), which allows qualifying patients to use and possess cannabis for medical use.

The law allows for two manufacturers to be registered in the state. Each manufacturer must have one manufacturing facility and four distribution sites throughout the state.

The manufacturers may only distribute medical cannabis in pill or liquid form, and patients may only possess medical cannabis in those limited forms.

Qualifying medical conditions include:

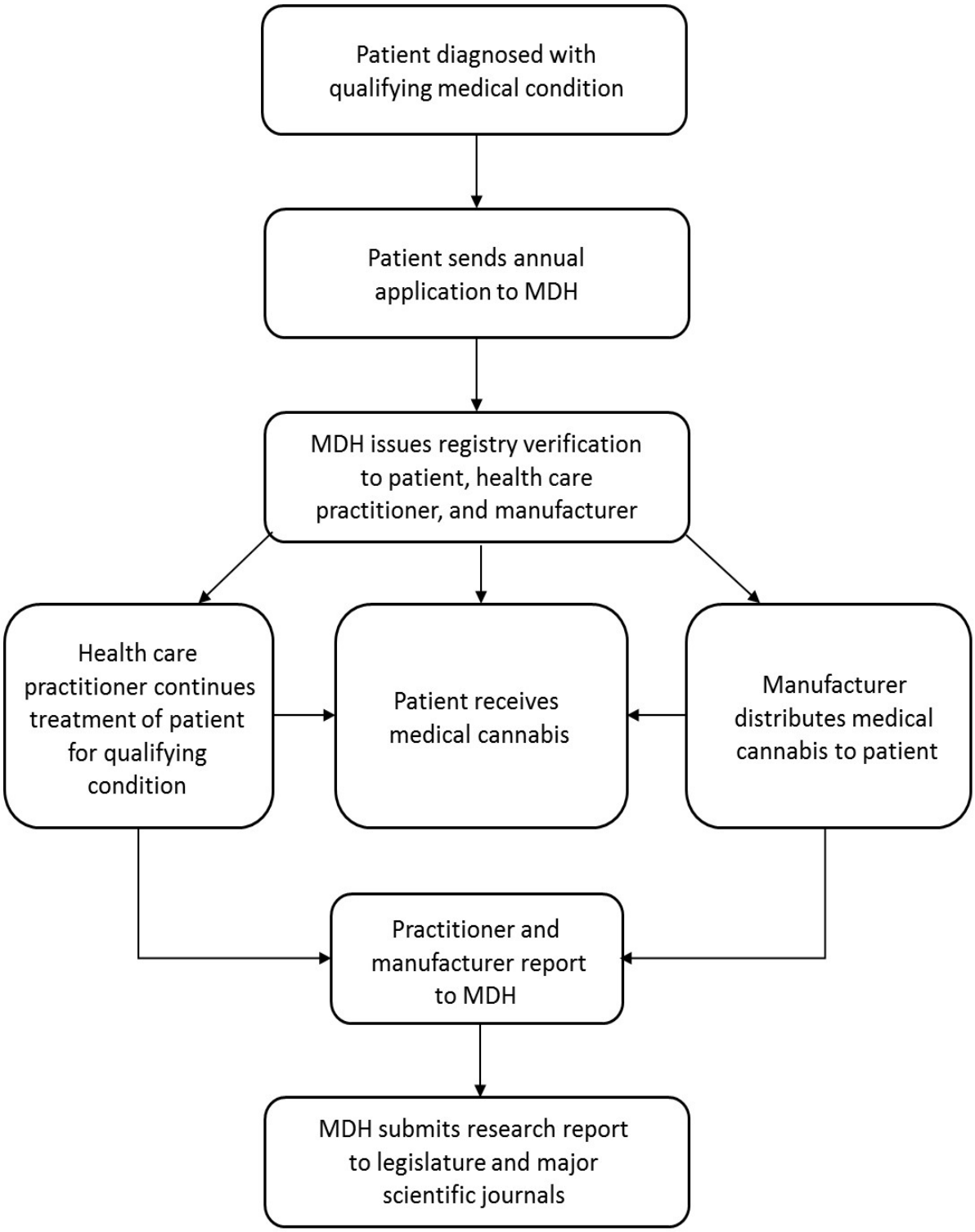
1. Cancer*
2. Glaucoma
3. HIV/AIDS
4. Tourette's syndrome
5. ALS
6. Seizures
7. Severe and persistent muscle spasms
8. Inflammatory bowel disease, including Crohn's disease
9. Terminal illness with life expectancy of under one year*
10. Intractable pain
11. Any other condition or its treatment approved 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:

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

General Design of the Registry Program



General Design of the Registry Program

The general design of the registry program is explained briefly below, but many aspects are more fully detailed in subsequent sections of this information brief.

Patient diagnosed with qualifying medical condition

Prior to applying to be a part of the registry program, a patient must be diagnosed by a health care practitioner with one or more of the qualifying medical conditions.

Patient sends annual application to MDH

Once the patient receives a certification of diagnosis of a qualifying medical condition from a health care practitioner, the patient must apply to be a part of the registry program with the Minnesota Department of Health (MDH). The patient must submit this application, along with an application fee, 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 the information of the registered designated caregiver or parent or legal guardian, 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 condition

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

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 after a consultation with the patient.

Patient obtains medical cannabis from manufacturer

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

MDH and its commissioner are responsible for administering the patient registry program. The commissioner created the Office of Medical Cannabis to implement the program and to ensure patient, health care provider, and manufacturer compliance with the duties imposed by the state statutes and rules governing the program.

Range of compounds[2]

MDH must annually review existing medical and scientific literature on the recommended range of dosages and chemical compounds for each qualifying medical condition and publicly report that review. The most recent review was published in December 2015. The recommended ranges of dosages and chemical compounds are posted on the MDH website.[3]

Rulemaking authority[4]

MDH adopted rules governing medical cannabis using the expedited rulemaking process under Minnesota Statutes, section 14.389. MDH was required to have rules necessary for the manufacturers to begin distributing medical cannabis to patients by July 1, 2015. The rules were adopted January 20, 2015, and are found in Minnesota Rules, chapter 4770.

Adverse incidents[5]

MDH adopted rules to require law enforcement 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, health care professionals, registered patients, caregivers, and manufacturers to report serious adverse incidents involving medical cannabis, including incidents involving an overdose of medical cannabis.

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[2] Minn. Stat. § 152.25, subd. 2.

[3] http://www.health.state.mn.us/topics/cannabis/.

[4] Minn. Stat. § 152.26.

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

Adding additional allowable forms and qualifying medical conditions[6]

The commissioner may add to the list of qualifying medical conditions and also add to the list of allowable forms of medical cannabis. The commissioner is prohibited, however, from adding smoking as an allowable form. To add an additional form or condition, the commissioner must notify the chairs and ranking minority members of the legislative committees having jurisdiction over health and human services as to the reasons for the addition. This notice must include any public comments the commissioner has received and any guidance the commissioner has received from the task force on medical cannabis research. The notification must be given by January 15 of the year the commissioner wishes to make the change. The change will become effective August 1 of that year unless the legislature by law provides otherwise.

Financial audit

MDH may inspect the manufacturer's financial documents through a financial audit by a certified annual audit or through an examination of its business affairs. (For more on manufacturer financial audits, see page 14).

Reports[7]

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

Patients

Qualifying medical conditions

Qualifying medical conditions include:[8]

1. Cancer*
2. Glaucoma
3. HIV/AIDS
4. Tourette's syndrome
5. ALS
6. Seizures
7. Severe and persistent muscle spasms

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

[7] Minn. Stat. § 152.25, subd. 4.

[8] Minn. Stat. § 152.22, subd. 14.

8. Inflammatory bowel disease, including Crohn's disease
9. Terminal illness with life expectancy of under one year*
10. Intractable pain
11. 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.

Intractable pain

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 was required to report to the Task Force on Medical Cannabis Therapeutic Research by July 1, 2016, on the need to add intractable pain. The Commissioner of Health added intractable pain to the list of qualifying medical conditions using the procedure in Minnesota Statutes, section 152.27, subdivision 2, paragraph (b). Patients with intractable pain were eligible to enroll in the registry program beginning July 1, 2016, and to receive medical cannabis beginning August 1, 2016. Intractable pain is defined in Minnesota Statutes, section 152.125, subdivision 1.

Participation in the registry program

A patient's first step is to consult with a health care practitioner regarding whether or not the patient has one or more of the qualifying medical conditions. If the patient has been diagnosed with a qualifying medical condition, the patient must submit an application and application fee to MDH to enroll in the registry program.[9] The application must include a doctor'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 is unable to self-administer medication, and the patient's parent or legal guardian if the parent or legal guardian will be acting as caregiver.

As part of the yearly application, the patient is required to pay an application fee of $200. If the patient attests to receiving Social Security disability or Supplemental Security Insurance payments, or being enrolled in Medical Assistance or MinnesotaCare, the patient's yearly fee is $50.[10]

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

[9] Minn. Stat. § 152.27, subd. 3.

[10] Minn. Stat. § 152.35.

Reasons for denial of participation in the registry program[11]

The commissioner is authorized to deny a patient entry into the registry program only if the patient:

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

If a patient is denied entry, 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, pursuant to chapter 14.

Responsibilities during participation[12]

To maintain enrollment in the registry program, the patient must resubmit a copy of the certification of diagnosis to MDH on a yearly basis and pay a yearly application fee. 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 throughout enrollment in the registry program.

Registered designated caregivers[13]

A patient is permitted to have a registered designated caregiver if the patient's health care practitioner certifies that the patient has a developmental or physical disability that prevents the patient from either self-administering the medication or acquiring the medication from a distribution facility. The registered designated caregiver must agree, in writing, to act as the patient's caregiver. As conditions of registration, the caregiver must:

- be at least 21 years of age;
- agree to only possess medical cannabis for purposes of assisting the patient; and
- agree to not be a caregiver for more than one patient, unless the patients reside in the same residence.

[11] Minn. Stat. § 152.27, subd. 6.

[12] Minn. Stat. § 152.30.

[13] Minn. Stat. § 152.27, subd. 4.

Registered designated caregivers are subject to a criminal background check. If the caregiver has a disqualifying felony offense,[14] 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 10).

Parents or legal guardians[15]

A parent or legal guardian, 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 and legal guardians 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 10).

Civil and criminal protections[16]

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 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.

Exemption from criminal sanctions for use or possession. Patients who use or possess medical cannabis, and registered designated caregivers and parents and legal guardians who possess medical cannabis, are exempt from criminal sanctions for use or 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 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 still apply. Although a patient is exempt from criminal sanctions for possession under Minnesota law, the patient is not exempt from penalties for:

[14] 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.

[15] Minn. Stat. § 152.27, subd. 5.

[16] *See generally* Minn. Stat. § 152.32, subd. 2.

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

(2) possessing or using medical cannabis:

a. on a school bus or van;
b. on the grounds of any preschool, primary school, or secondary school;
c. in any correctional facility; or
d. on the grounds of any child care facility or home daycare;

(3) vaporizing medical cannabis:

a. on any form of public transportation
b. where the vapor may be inhaled by a nonpatient minor child; or
c. in a public place, including any indoor or outdoor area used by or open to the general public or a place of employment;[17] 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.[18]

Criminal sanctions

Diversion of medical cannabis. A patient, registered designated caregiver, or, if listed on the registry verification, a parent or legal guardian of a patient who intentionally sells or otherwise transfers medical cannabis to a person other than a patient, registered designated caregiver, or, if listed on the registry verification, a parent or legal guardian, is guilty of a felony. This crime is punishable by imprisonment for not more than two years or payment of a fine of not more than $3,000, or both.[19]

False statements. A person who intentionally makes a false statement to law enforcement 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 under the law. A patient or a registered designated caregiver convicted of this crime is disqualified from any further participation in the registry program.[20]

[17] *See* Minn. Stat. § 144.413, subd. 1b.

[18] Minn. Stat. § 152.23.

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

[20] Minn. Stat. § 152.33, subd. 3.

Patient discrimination prohibited[21]

A patient is protected from discrimination in a variety of 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 medical cannabis registry program. 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 medical cannabis registry program. 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 is considered the authorized use of medication for purposes of medical care, including organ transplants. This use of medical cannabis is not 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 in the registry program; 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 patient registry 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. The law also requires that there is no presumption of neglect or child endangerment for conduct allowed under the registry program, unless the person's behavior creates an unreasonable danger to the safety of the child as established by clear and convincing evidence.

[21] Minn. Stat. § 152.32, subd. 3.

Federally approved clinical trials[22]

The Commissioner of Health must provide information to all patients about the existence of any federally approved clinical trials for the treatment of that patient's qualifying condition with medical cannabis. The commissioner may prohibit enrollment of a patient 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.

Manufacturers

Registration[23]

On December 1, 2014, MDH registered two medical cannabis manufacturers: LeafLine Labs and Minnesota Medical Solutions. Manufacturers are subject to re-registration every two years. 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.

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

- Technical expertise in cultivation and conversion into allowable forms of medical cannabis
- The qualifications of the manufacturer's employees
- 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 fees on patients

Regulation

Fees[24]

Manufacturers will be charged an annual fee for the cost incurred by MDH for the regulation and inspection of the manufacturer for that year. The yearly fee will be established and collected 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. Manufacturers are allowed

[22] Minn. Stat. § 152.24.

[23] Minn. Stat. § 152.25, subd. 1.

[24] Minn. Stat. § 152.35.

to establish a sliding scale of patient fees based on a patient's household income but are not required to establish the scale. Manufacturers may also accept private donations in order to reduce patient fees.

Operating documents[25]

A manufacturer's operating documents must include procedures for oversight, procedures to ensure accurate recordkeeping, and procedures for appropriate security measures to deter theft and unauthorized entrance.

Location of facilities[26]

Each manufacturer was required to have four distribution facilities in operation by July 1, 2016, and one production facility (the production facility may be at the same location as a distribution facility). The distribution facilities must be located throughout the state based on geographical need in order to improve patient access. 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. Distribution facilities are currently located in Bloomington, Eagan, Hibbing, Minneapolis, Moorhead, Rochester, St. Cloud, and St. Paul.

Employees[27]

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.[28] 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 with the manufacturer.

Due to 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 must consult with the patient before distributing the medical cannabis.[29]

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

[26] Minn. Stat. § 152.29, subd. 1, paras. (a) and (j).

[27] Minn. Stat. § 152.29, subd. 1, para. (i).

[28] 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.

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

Any employee of the manufacturer involved in delivering medical cannabis or medical cannabis products from one location to another must carry identification showing that the person is an employee of the manufacturer.[30]

Security[31]

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

- a fully operational security alarm system;
- facility access controls;
- perimeter intrusion detection systems; and
- a personnel identification system.

Contract with an independent laboratory[32]

Each manufacturer must contract with an independent laboratory that has been approved by the Commissioner of Health. The laboratory tests the manufacturers' medical cannabis for content, contamination, and consistency in order to verify that it meets the requirements under the law. The cost of this contract must be paid by the manufacturer and is subject to any additional requirements set by the Commissioner of Health.

Inspections[33]

Manufacturers are subject to reasonable inspections by the Commissioner of Health. 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 the manufacturer, including, but not limited to, review of the 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 and provide a copy to the manufacturer

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

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

[32] Minn. Stat. § 152.29, subd. 1, para. (b).

[33] Minn. Stat. §§ 152.29, subd. 1, para. (g); 152.37.

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.

Monthly report to MDH[34]

Each manufacturer must submit a monthly report to MDH. The report must include:

- the amount and dosages of medical cannabis distributed;
- the chemical composition of the medical cannabis; and
- the tracking number assigned to any medical cannabis distributed.

Production

Requirements[35]

Each manufacturer must produce a reliable and ongoing supply of medical cannabis to patients and process the medical cannabis into an allowed form prior to its distribution. Production of medical cannabis must be done in one location and must be in an enclosed and locked facility.

Allowable forms[36]

Medical cannabis may only be distributed as a pill or liquid, including oil.

The Commissioner of Health may allow other forms, except smoking. Any addition by the commissioner must follow the procedure in Minnesota Statutes, section 152.27, subdivision 2, paragraph (b), and is subject to legislative oversight.

Deadlines[37]

Each manufacturer had to begin distribution to patients from at least one distribution site by July 1, 2015. Distribution had to occur from all four of the manufacturer's distribution sites by July 1, 2016.

[34] Minn. Stat. § 152.29, subd. 4.

[35] Minn. Stat. § 152.29, subd. 2.

[36] Minn. Stat. § 152.22, subd. 6.

[37] Minn. Stat. § 152.29, subd. 1, para. (a).

Distribution

What may be distributed[38]

A manufacturer may only distribute medical cannabis as a pill or liquid. The 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 and be packaged in compliance with the United States Poison Prevention Packaging Act.[39] All medical cannabis must also be 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[40]

A manufacturer may distribute medical cannabis only to a person listed on the patient's registry verification that the manufacturer received from MDH. The manufacturer may not distribute any medical cannabis until the registry verification has been received. The registry verification includes patient information and may also include a registered designated caregiver or a parent or guardian of the patient. If a person is listed on the registry verification, the manufacturer may distribute the medical cannabis after verifying the person's identification by photographic identification, unless the individual distributing the medical cannabis personally knows the recipient.[41]

Who may distribute the medical cannabis[42]

Only employees of the manufacturer who are licensed pharmacists in Minnesota may give final approval for distribution of medical cannabis. Distribution may only occur after a pharmacist has consulted with the patient to determine the proper dosage and range of chemical compositions

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

[39] 15 U.S.C. §§ 1471-1477. (The United States Poison Prevention Packaging Act, P.L. 91-601, was enacted to protect children from unintended ingestion of medicines and common household products.)

[40] Minn. Stat. § 152.29, subd. 3.

[41] Minn. Stat. § 152.11, subd. 2d.

[42] Minn. Stat. § 152.29, subd. 3, para. (a).

for that individual patient. The pharmacist may consult with the patient via videoconference, as long as the consolation meets certain requirements.

Amount of medical cannabis that can be distributed[43]

A maximum of a 30-day supply of the dosage determined for the individual patient may be distributed at one time.

Other

Relationship with health care practitioners[44]

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.

Marketing restrictions[45]

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

Transportation[46]

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. 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.

Criminal and civil liability[47]

The law establishes several new criminal penalties applicable to manufacturers or employees of manufacturers in addition to any other applicable penalty in law. Any manufacturer or agent of a manufacturer who intentionally transfers medical cannabis to a person other than one listed on a registry verification or submits false records or documentation required by MDH to register as a manufacturer is guilty of a felony punishable by up to two years of imprisonment, a fine of not more than $3,000, or both. A manufacturer may also be fined up to $1,000, in addition to any

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

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

[45] Minn. Stat. § 152.29, subd. 1, para. (k).

[46] Minn. Stat. section 152.29, subd. 3a.

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

other applicable penalty in law, for any violation of laws or regulations relating to the registry program where no penalty is specified.

Criminal protections[48]

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

Health Care Practitioners

A health care practitioner, for purposes of the registry program, is defined as a Minnesota-licensed doctor of medicine, a Minnesota-licensed physician assistant acting within the scope of practice, or a Minnesota-licensed advanced practice registered nurse, with the primary responsibility for care and treatment of the underlying qualifying medical condition.[49]

Participation

MDH training/notification[50]

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 that participation. However, no health care practitioner is required to participate in the program.[51] 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 practitioner will receive the patient applications from the commissioner in order to provide those applications to patients.

Advice to patients[52]

Once a health care practitioner is working with a patient in the program, the law requires the practitioner to provide the patient, registered designated caregiver, or parent or legal guardian with information on nonprofit support groups or organizations. The practitioner is also required

[48] Minn. Stat. § 152.32, subd. 2.

[49] Minn. Stat. § 152.22, subd. 4.

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

[51] Minn. Stat. § 152.28, subd. 1, para. (c).

[52] Minn. Stat. § 158.28, subd. 1, para. (a), cls. (3) and (4).

to provide the explanatory information that was received from MDH. The law requires the explanatory information to disclose:

- 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.[53]

Certifications[54]

In order for a patient to participate in the registry program, a health care practitioner must provide a certification of diagnosis for at least one of the qualifying medical conditions. The patient's application must include this certification in order to participate in the registry program, and the certification must have been given by the practitioner within the previous 90 days of the patient's application. Practitioners must use the certification form developed by the Commissioner of Health.

In certain circumstances, the practitioner may also provide a certification of a patient's disability. The law allows for patients in the registry program to have a registered designated caregiver if the patient is either unable to self-administer medication or is unable to acquire medical cannabis from a distribution facility due to a developmental or physical disability. If the practitioner determines that the disability prevents the patient from doing either one of those activities, the practitioner will provide that determination on the patient's certification of diagnosis.

Responsibilities during participation[55]

The law requires that if a health care practitioner agrees to participate in the registry program, the practitioner must continue treatment of the patient for the qualifying medical condition. The practitioner must report the health records of the patient throughout that ongoing treatment 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. Each year, the practitioner also must determine if the patient continues to suffer from a qualifying medical condition and, if so, issue a new certification of that diagnosis.

[53] *See* Minn. Stat. § 13.04, subd. 2 (explaining the Tennessen warning).

[54] Minn. Stat. § 152.28, subd. 1, para. (a), cls. (1) and (2).

[55] Minn. Stat. § 152.28, subd. 1, paras. (a), cl. (5), and (b).

Medical Assistance/MinnesotaCare reimbursement[56]

Medical Assistance (MA) and MinnesotaCare are not required to reimburse an enrollee or a provider for "costs associated with the medical use of cannabis." MA and MinnesotaCare are, however, still required to reimburse for services related to the treatment of the patient's qualifying medical condition if that service is covered under applicable statutes.

Legal Issues

Health records[57]

All data collected on patients and reported to the patient registry are health records under the Health Records Act and are considered 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.

Civil/disciplinary protections[58]

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 section of 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[59]

Although the law creates exemptions from criminal liability for certain actions by patients, caregivers, and manufacturers, it does not create criminal liability exemptions for health care practitioners. 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 or 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

[56] Minn. Stat. § 152.23, para. (b).

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

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

[59] Minn. Stat. § 152.33, subd. 5.

- advertising as a manufacturer
- issuing a certification 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 his or her "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 and abetting.[60] 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 would not be binding on Minnesota courts.

Other

Prescription Monitoring Program[61]

Medical cannabis is not eligible to be entered into the Prescription Monitoring Program (PMP).[62] Under Minnesota and federal law, cannabis is a Schedule I controlled substance, and therefore the medical cannabis is not dispensed under a prescription drug order, as required by statute to be entered in the PMP.

Discrimination for purposes of medical care prohibited[63]

The law prohibits discrimination against patients for the purpose of medical care. The law states that a patient's use of medical cannabis is considered the equivalent to the authorized use of any other medication and does not constitute the use of an illicit substance or otherwise disqualify a patient from needed medical care, including organ transplants.

Health care facilities and home care providers[64]

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

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

[61] Minn. Stat. § 152.126.

[62] The Prescription Monitoring Program (PMP) is codified in Minnesota Statutes, section 152.126. The PMP allows 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 classified as a Schedule II through V.

[63] Minn. Stat. § 152.32, subd. 3, para. (b).

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

those 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. 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 this chapter 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.

Operation of the Program

Appropriations[65]

Health Department

MDH was appropriated $2,795,000 from the general fund for fiscal year 2015. The base of that appropriation in fiscal year 2016 is $829,000 and in fiscal year 2017 is $752,000. The fiscal year 2017 appropriation from the general fund includes $24,000 for the Commissioner of Health to administer the Task Force on Medical Cannabis Therapeutic Research and for the task force to conduct an impact assessment on the use of cannabis for medicinal purposes. In 2016, the legislature cancelled a $24,000 appropriation from the general fund to the Legislative Coordinating Commission for these purposes and reallocated the funds to the Commissioner of Health.

MDH was also appropriated $100,000 from the state government special revenue fund in fiscal year 2015. The base for that appropriation in fiscal year 2016 is $834,000 and in fiscal year 2017 is $729,000.

Appropriations to MDH

	Appropriations by Fiscal Year		
Fund	**FY 2015**	**FY 2016**	**FY 2017**
General Fund	$2,795,000	$829,000	$752,000
State Government Special Revenue Fund	$100,000	$834,000	$729,000

[65] Laws 2014, ch. 311, § 21; Laws 2016, ch. 179, §§ 40, 41.

Task Force on Medical Cannabis Therapeutic Research[66]

The Task Force on Medical Cannabis Therapeutic Research was established to conduct an impact assessment of the registry program on Minnesota. The task force is also involved in certain deadline extensions for the program. 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 appointed, 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.

Deadline extensions[67]

The task force could have extended the deadline to register manufacturers and the distribution deadline by six months if requested by the Commissioner of Health. MDH did register two manufacturers by the December 1, 2014, deadline, and the manufacturers began distributing medical cannabis on the July 1, 2015, deadline, so no extension was needed.

Cost assessment

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

[66] Minn. Stat. § 152.36.

[67] Minn. Stat. § 152.25, subd. 3.

Impact assessment

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 use and evaluate Minnesota's activities involving medical cannabis. 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 and medical cannabis products;
- the impact on law enforcement and prosecutions;
- public awareness and perception; and
- any unintended consequences.

Additional reports to the legislature

In addition, the task force must make the following reports to the legislature:

- February 1, 2015: report on the design and implementation of the registry program
- Reports based on the biennial cost assessments from the state agencies

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 in Minnesota

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.[68] The act required the Commissioner of the Department of Health to appoint a principal investigator.[69] 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.[70] 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.[71]

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.

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.

In 2009, the first medical cannabis law that would have allowed patient possession of medical cannabis passed both bodies of the legislature.[72] 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 Gov. Tim Pawlenty on May 22, 2009.

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.

[68] Minn. Stat. § 152.21, subd. 1 (2014).

[69] Minn. Stat. § 152.21, subd. 4 (2014).

[70] Minn. Stat. § 152.21, subd. 5 (2014).

[71] Laws 1980, ch. 614, § 30.

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

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.[73]

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.

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.

[73] Laws 2014, ch. 311.

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

For more information about health issues, visit the health and human services area of our website, www.house.mn/hrd/.