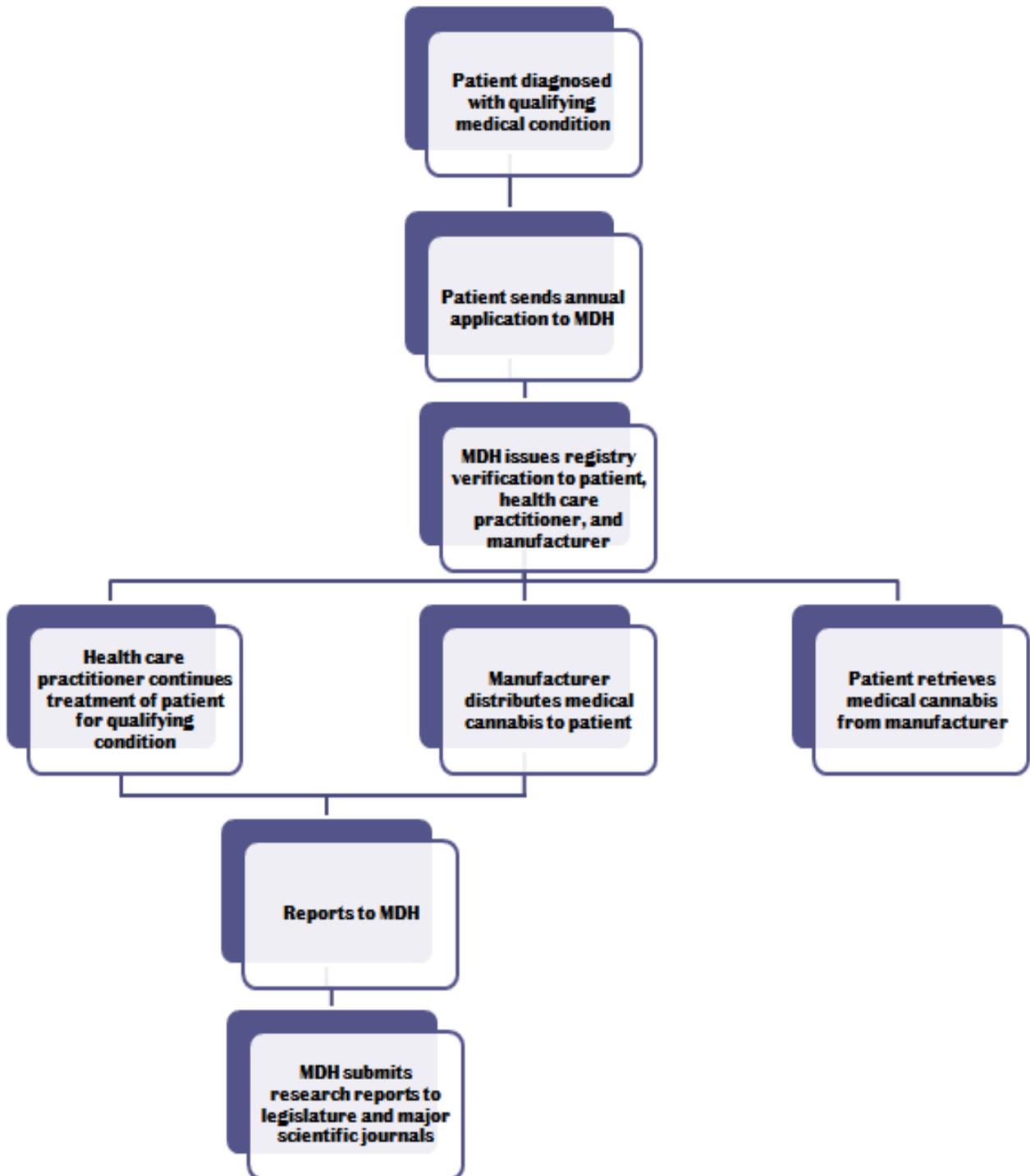


Minnesota Medical Cannabis Registry Program: An Overview

General Design of the Registry Program



Qualifying medical conditions

1. Cancer*
2. Glaucoma
3. HIV/AIDS
4. Tourette's
5. ALS
6. Seizures
7. Severe and persistent muscle spasms
8. Crohn's disease
9. Terminal illness with life expectancy of under one year*
10. Any other condition or its treatment approved by the commissioner (subject to legislative overview)

*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.

Allowable forms of medical cannabis

Medical cannabis is only allowed to be distributed in two forms: pill or liquid (including oil). The commissioner of health may add additional delivery methods, subject to legislative oversight, but may not add smoking as an allowable delivery method.

Patients

Participation in the registry program

A patient's first step is to consult with a health care practitioner regarding whether or not the patient suffers from 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 to the Minnesota Department of Health (MDH) in order to be enrolled in the registry program. The application must include a doctor's certification of diagnosis and other forms required by MDH.

Responsibilities during participation

The patient is required to resubmit a copy of the certification of diagnosis to MDH on a yearly basis. The patient 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.

Civil and criminal protections

Once a patient is enrolled in the registry program, the patient is presumed to be engaging in the authorized use of medical cannabis. Possession of medical cannabis by a patient, registered designated caregiver, or, in some cases, the parent or legal guardian of the patient, is now exempt from criminal sanctions under Minnesota law. Medical cannabis and associated property is also not subject to forfeiture under Minnesota law. A patient's possession of a registry verification or application does not constitute probable cause or reasonable suspicion and cannot be used to support a search of the person or property. Note that the statutory definition of medical cannabis

currently excludes any form of medical cannabis other than pills or liquids. If a patient is found in possession of any other form of cannabis, the patient may be subject to criminal penalties.

Health Care Practitioners

Participation in the registry program

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 of care and treatment of the underlying qualifying medical condition. Prior to a patient's registration in the program, the health care practitioner must certify that the patient has been diagnosed with a qualifying medical condition and agree to continue treatment for that qualifying medical condition. The health care practitioner must also determine whether the patient is developmentally or physically disabled so as to be unable to self-administer medication or acquire medical cannabis from a distribution facility. No health care practitioner is required to participate in the registry program.

Responsibilities during participation

Once the health care practitioner's patient has been enrolled in the registry program, the health care practitioner must continue treatment of the qualifying medical condition and report health records to MDH.

Civil and criminal protections

Health care practitioners are not included in the exemptions for criminal liability for possession as the health care practitioner does not come in contact with the medical cannabis under the design of the program. The health care practitioner is not subject to any civil or disciplinary penalties by any professional licensing board for participation in the registry program.

Manufacturers - Registration

By December 1, 2014, the MDH is required to register two medical cannabis manufacturers that are subject to an annual re-registration and a one-time \$20,000 non-refundable application fee. As a condition of registration, a manufacturer must agree to begin distribution of medical cannabis to patients by July 1, 2015, and comply with other requirements under the law

MDH is required under the law to take certain factors into consideration when determining which manufacturers to register. Those factors are:

- 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; and
- the manufacturer's projection and ongoing assessment of fees on patients.

Manufacturers – Regulation

Fees

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

Operating documents

Procedures for oversight must be included in the manufacturer’s operating documents to ensure accurate record-keeping and that appropriate security measures are in place to deter theft.

Location of facilities

Each manufacturer will have four distribution facilities and one production facility (the production facility may be at the same location as a distribution facility). The distribution facilities are required to be located throughout the state based on geographical need in order to improve patient access. No facility is allowed to be within 1,000 feet of a school, public or private, that was in existence prior to the manufacturer’s registration with MDH.

Employees

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. For purposes of manufacturer employment, a disqualifying felony offense includes 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. 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 employee(s) must be the only employee(s) distributing medical cannabis after a consultation with the patient.

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

Security

Manufacturers are required to have certain security measures on all distribution sites as well as the production site. These security measures include:

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

Contract with an independent laboratory

Each manufacturer is required to contract with an independent laboratory that has been approved by the commissioner of health. The laboratory will conduct testing on medical cannabis produced by the manufacturer as to content, contamination, and consistency in order to verify the medical cannabis meets the requirements under the law. The cost of this contract will be paid by the manufacturer and is subject to any additional requirements set by the commissioner of health.

Inspections

Manufacturers are subject to reasonable inspections by the commissioner of health. Each manufacturer is also required to keep detailed financial records in a manner approved by the commissioner and keep these records available for the commissioner's review. In addition, the manufacturers are required to 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 is permitted to require a second financial audit by a certified public accountant chosen by the commissioner which would also be at the expense of the manufacturer.

The commissioner or a designee is permitted under the law to examine the business affairs of the manufacturer, including, but not limited to, review of the financing, budgets, revenues, sales, and pricing. The commissioner is permitted to retain outside professionals, such as attorneys and certified public accountants, but may not retain the same certified public accountant as used in the annual audit. If the commissioner conducts this examination, the commissioner is required to complete a report and 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.

Monthly report to MDH

Each manufacturer is required to 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.

Manufacturers – Production

Requirements

Each manufacturer is required to produce a reliable and ongoing supply of medical cannabis to patients and is required to produce medical cannabis in the forms allowed under the law prior to any distribution. Production of medical cannabis is required to be in one location and must be in an enclosed and locked facility.

Allowable forms

Medical cannabis is prohibited from being distributed in any form other than:

- Pill; or
- Liquid, including oil.

The commissioner of health may allow other forms, except smoking. Any addition by the commissioner is subject to legislative oversight.

Deadlines

Each manufacturer is required to begin distribution to patients from at least one distribution site by July 1, 2015. Distribution must occur from all four distribution sites by July 1, 2016.

Manufacturers – Distribution

What may be distributed

A manufacturer is only permitted to distribute medical cannabis in the form of a pill or liquid. The manufacturers are allowed, but not required, to distribute medical cannabis products, including, but not limited to, delivery devices and educational material.

All medical cannabis is required to be assigned a tracking number and to be in packaging that is in compliance with the United States Poison Prevention Packing Act. All medical cannabis is also required to 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

To whom may medical cannabis be distributed

A manufacturer is permitted to 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 will include 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 person is known to the person distributing (*see* MN Stat. §152.11, subd. 2d).

Who may distribute the medical cannabis

Only employees of the manufacturer who are licensed pharmacists in Minnesota may distribute medical cannabis. Distribution by the pharmacist may only occur after the pharmacist has consulted with the patient to determine the proper dosage and range of chemical compositions for that individual patient.

How much medical cannabis can be distributed

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

Manufacturers – Other

Relationship with health care practitioners

A manufacturer is prohibited from sharing 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

Manufacturers are required to comply with reasonable restrictions set by the commissioner of health relating to signage, marketing, display, and advertising of medical cannabis.

Criminal and civil liability

The law establishes several new criminal penalties that may apply 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 not more than two years of imprisonment, a fine of not more than \$3,000, or both. A manufacturer will 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

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.