State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-NINTH SESSION

H. F. No. 1482

03/05/2015 Authored by Albright, Schoen, Garofalo, Melin and Zerwas
The bill was read for the first time and referred to the Committee on Health and Human Services Reform
04/07/2015 Adoption of Report: Amended and re-referred to the Committee on Health and Human Services Finance

A bill for an act

relating to health; changing provisions in the medical cannabis program; amending Minnesota Statutes 2014, sections 152.25, subdivision 1; 152.27, subdivision 6; 152.29, subdivision 1; 152.37, subdivision 2; Laws 2014, chapter 311, section 20.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2014, section 152.25, subdivision 1, is amended to read:

Subdivision 1. **Medical cannabis manufacturer registration.** (a) The commissioner shall register two in-state manufacturers for the production of all medical cannabis within the state by December 1, 2014, unless the commissioner obtains an adequate supply of federally sourced medical cannabis by August 1, 2014. The commissioner shall register new manufacturers or reregister the existing manufacturers by December 1 ~~of each year~~ every three years, using the factors described in paragraph (c). The commissioner shall continue to accept applications after December 1, 2014, if two manufacturers that meet the qualifications set forth in this subdivision do not apply before December 1, 2014. The commissioner's determination that no manufacturer exists to fulfill the duties under sections 152.22 to 152.37 is subject to judicial review in Ramsey County District Court. Data submitted during the application process are private data on individuals or nonpublic data as defined in section 13.02 until the manufacturer is registered under this section. Data on a manufacturer that is registered are public data, unless the data are trade secret or security information under section 13.37.

(b) As a condition for registration, a manufacturer must agree to:

(1) begin supplying medical cannabis to patients by July 1, 2015; and

(2) comply with all requirements under sections 152.22 to 152.37.

(c) The commissioner shall consider the following factors when determining which manufacturer to register:

(1) the technical expertise of the manufacturer in cultivating medical cannabis and converting the medical cannabis into an acceptable delivery method under section 152.22, subdivision 6;

(2) the qualifications of the manufacturer's employees;

(3) the long-term financial stability of the manufacturer;

(4) the ability to provide appropriate security measures on the premises of the manufacturer;

(5) whether the manufacturer has demonstrated an ability to meet the medical cannabis production needs required by sections 152.22 to 152.37; and

(6) the manufacturer's projection and ongoing assessment of fees on patients with a qualifying medical condition.

(d) The commissioner shall require each medical cannabis manufacturer to contract with an independent laboratory to test medical cannabis produced by the manufacturer. The commissioner shall approve the laboratory chosen by each manufacturer and require that the laboratory report testing results to the manufacturer in a manner determined by the commissioner.

Sec. 2. Minnesota Statutes 2014, section 152.27, subdivision 6, is amended to read:

Subd. 6. **Patient enrollment.** (a) After receipt of a patient's application, application fees, and signed disclosure, the commissioner shall enroll the patient in the registry program and issue the patient and patient's registered designated caregiver or parent or legal guardian, if applicable, a registry verification. The commissioner shall approve or deny a patient's application for participation in the registry program within 30 days after the commissioner receives the patient's application and application fee. The commissioner may approve applications up to 60 days after the receipt of a patient's application and application fees until January 1, 2016. A patient's enrollment in the registry program shall only be denied if the patient:

(1) does not have certification from a health care practitioner that the patient has been diagnosed with a qualifying medical condition;

(2) has not signed and returned the disclosure form required under subdivision 3, paragraph (c), to the commissioner;

(3) does not provide the information required;

(4) has previously been removed from the registry program for violations of section 152.30 or 152.33; or

(5) provides false information.

(b) The commissioner shall give written notice to a patient of the reason for denying enrollment in the registry program.

(c) Denial of enrollment into the registry program is considered a final decision of the commissioner and is subject to judicial review under the Administrative Procedure Act pursuant to chapter 14.

(d) A patient's enrollment in the registry program may only be revoked upon the death of the patient or if a patient violates a requirement under section 152.30 or 152.33.

(e) The commissioner shall develop a registry verification to provide to the patient, the health care practitioner identified in the patient's application, and to the manufacturer. The registry verification shall include:

(1) the patient's name and date of birth;

(2) the patient registry number assigned to the patient;

(3) the patient's qualifying medical condition as provided by the patient's health care practitioner in the certification; and

(4) the name and date of birth of the patient's registered designated caregiver, if any, or the name of the patient's parent or legal guardian if the parent or legal guardian will be acting as a caregiver.

Sec. 3. Minnesota Statutes 2014, section 152.29, subdivision 1, is amended to read:

Subdivision 1. **Manufacturer; requirements.** (a) A manufacturer shall operate four distribution facilities, which may include the manufacturer's single location for cultivation, harvesting, manufacturing, packaging, and processing but is not required to include that location. A manufacturer is required to begin distribution of medical cannabis from at least one distribution facility by July 1, 2015. All distribution facilities must be operational and begin distribution of medical cannabis by July 1, 2016. The distribution facilities shall be located based on geographical need throughout the state to improve patient access. A manufacturer shall disclose the proposed locations for the distribution facilities to the commissioner during the registration process. A manufacturer shall operate only one location where all cultivation, harvesting, manufacturing, packaging, and processing shall be conducted. Any additional distribution facilities may dispense medical cannabis and medical cannabis products but may not contain any medical cannabis in a form other than those forms allowed under section 152.22, subdivision 6, and the manufacturer shall not conduct any cultivation, harvesting, manufacturing, packaging, or processing at an additional distribution facility site. Any distribution facility operated by the manufacturer

is subject to all of the requirements applying to the manufacturer under sections 152.22 to 152.37, including, but not limited to, security and distribution requirements.

(b) A medical cannabis manufacturer shall contract with a laboratory approved by the commissioner, subject to ~~the commissioner's approval of the laboratory and~~ any additional requirements set by the commissioner, for purposes of testing medical cannabis manufactured by the medical cannabis manufacturer as to content, contamination, and consistency to verify the medical cannabis meets the requirements of section 152.22, subdivision 6. The cost of laboratory testing shall be paid by the manufacturer.

(c) The operating documents of a manufacturer must include:

(1) procedures for the oversight of the manufacturer and procedures to ensure accurate record keeping; and

(2) procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabis and unauthorized entrance into areas containing medical cannabis.

(d) A manufacturer shall implement security requirements, including requirements for protection of each location by a fully operational security alarm system, facility access controls, perimeter intrusion detection systems, and a personnel identification system.

(e) A manufacturer shall not share office space with, refer patients to a health care practitioner, or have any financial relationship with a health care practitioner.

(f) A manufacturer shall not permit any person to consume medical cannabis on the property of the manufacturer.

(g) A manufacturer is subject to reasonable inspection by the commissioner.

(h) For purposes of sections 152.22 to 152.37, a medical cannabis manufacturer is not subject to the Board of Pharmacy licensure or regulatory requirements under chapter 151.

(i) A medical cannabis manufacturer may not employ any person who is under 21 years of age or who has been convicted of a disqualifying felony offense. An employee of a medical cannabis manufacturer must submit a completed criminal history records check consent form, a full set of classifiable fingerprints, and the required fees for submission to the Bureau of Criminal Apprehension before an employee may begin working with the manufacturer. The bureau must conduct a Minnesota criminal history records check and the superintendent is authorized to exchange the fingerprints with the Federal Bureau of Investigation to obtain the applicant's national criminal history record information. The bureau shall return the results of the Minnesota and federal criminal history records checks to the commissioner.

(j) A manufacturer may not operate in any location, whether for distribution or cultivation, harvesting, manufacturing, packaging, or processing, within 1,000 feet of a

public or private school existing before the date of the manufacturer's registration with the commissioner.

(k) A manufacturer shall comply with reasonable restrictions set by the commissioner relating to signage, marketing, display, and advertising of medical cannabis.

Sec. 4. Minnesota Statutes 2014, section 152.37, subdivision 2, is amended to read:

Subd. 2. **Certified annual audit.** A medical cannabis manufacturer shall submit the results of an annual certified financial audit to the commissioner no later than May 1 of each year for the calendar year beginning January 2015. The annual audit shall be conducted by an independent certified public accountant and the costs of the audit are the responsibility of the medical cannabis manufacturer. Results of the audit shall be provided to the medical cannabis manufacturer and the commissioner. The commissioner may also require another audit of the medical cannabis manufacturer by a certified public accountant chosen by the commissioner with the costs of the audit paid by the medical cannabis manufacturer.

Sec. 5. Laws 2014, chapter 311, section 20, is amended to read:

Sec. 20. **INTRACTABLE PAIN.**

The commissioner of health shall consider the addition of intractable pain, as defined in Minnesota Statutes, section 152.125, subdivision 1, to the list of qualifying medical conditions under Minnesota Statutes, section 152.22, subdivision 14, prior to the consideration of any other new qualifying medical conditions. The commissioner shall report findings on the need for adding intractable pain to the list of qualifying medical conditions to the task force established under Minnesota Statutes, section 152.36, no later than ~~July~~ January 1, 2016.