# SENATE
## STATE OF MINNESOTA
## NINETIETH SESSION

# S.F. No. 1723

(SENATE AUTHORS: ABELER)

| DATE | D-PG | OFFICIAL STATUS |
|---|---|---|
| 03/02/2017 | | Introduction and first reading<br>Referred to Health and Human Services Finance and Policy |

A bill for an act

relating to health; modifying provisions in the Medical Cannabis Therapeutic Research Act; amending Minnesota Statutes 2016, sections 144.99, subdivision 1; 152.25, subdivision 1, by adding a subdivision; 152.29, subdivisions 1, 3; proposing coding for new law in Minnesota Statutes, chapter 152; repealing Minnesota Statutes 2016, section 152.33, subdivision 6.

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

Section 1. Minnesota Statutes 2016, section 144.99, subdivision 1, is amended to read:

Subdivision 1. **Remedies available.** The provisions of chapters 103I and 157 and sections 115.71 to 115.77; 144.12, subdivision 1, paragraphs (1), (2), (5), (6), (10), (12), (13), (14), and (15); 144.1201 to 144.1204; 144.121; 144.1222; 144.35; 144.381 to 144.385; 144.411 to 144.417; 144.495; 144.71 to 144.74; 144.9501 to 144.9512; 144.97 to 144.98; 144.992; 152.22 to 152.37; 326.70 to 326.785; 327.10 to 327.131; and 327.14 to 327.28 and all rules, orders, stipulation agreements, settlements, compliance agreements, licenses, registrations, certificates, and permits adopted or issued by the department or under any other law now in force or later enacted for the preservation of public health may, in addition to provisions in other statutes, be enforced under this section.

Sec. 2. Minnesota Statutes 2016, 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 every two 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 medical cannabis manufacturer 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~~ commissioner makes a final decision regarding registration. The application of a registered manufacturer and its contents become public data, unless the data are trade secret or security information under section 13.37. The application of a nonselected applicant and its contents shall remain private data on individuals or nonpublic data as defined in section 13.02.

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

(1) begin supplying medical cannabis to patients ~~by July 1, 2015~~ by a date specified by the commissioner in the commissioner's decision regarding registration of the new manufacturer; and

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

(c) The commissioner ~~shall~~ may consider the following factors when determining ~~which manufacturer to register~~ whether to register a new manufacturer, approve or deny a reregistration application from a current registered manufacturer, or revoke the registration of a current registered manufacturer:

(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; and

(7) the manufacturer's history of past violations, including their number, willfulness, gravity, and any economic benefit derived by the manufacturer related to documented violations.

(d) Registrations issued under this section are nontransferable without prior written consent of the commissioner.

~~The commissioner shall require~~ (e) Each medical cannabis manufacturer ~~to~~ shall contract with an independent laboratory to test medical cannabis produced by the manufacturer. The commissioner ~~shall~~ must approve ~~the~~ a laboratory ~~chosen by each manufacturer and~~ before it may test medical cannabis. The commissioner shall require that the laboratory report testing results to the manufacturer and directly to the commissioner in a manner determined by the commissioner.

(f) When necessary to investigate an imminent threat to the health or safety of patients or the public, employees of a laboratory approved by the commissioner to test medical cannabis may, at the request of the commissioner, collect samples and transport cannabis plant material, cannabis extracts, medical cannabis, and excipients and diluents used in producing medical cannabis from a manufacturer's production facility to the testing laboratory. The transport motor vehicle must be staffed with a minimum of two employees of the laboratory.

Sec. 3. Minnesota Statutes 2016, section 152.25, is amended by adding a subdivision to read:

Subd. 1a. **Medical cannabis manufacturer revocation, nonrenewal, or denial of consent to transfer.** (a) If the commissioner intends to revoke, not renew, or deny consent to transfer a registration issued under this section, the commissioner must first notify in writing the manufacturer against whom the action is to be taken and provide the manufacturer with an opportunity to request a hearing under the contested case provisions of chapter 14. If the manufacturer does not request a hearing by notifying the commissioner in writing within 20 days after receipt of the notice of proposed action, the commissioner may proceed with the action without a hearing. The registration of a manufacturer is considered revoked either on the date the manufacturer's current registration expires or as of the effective date as stated on the commissioner's written notice of revocation.

(b) Upon the revocation of a manufacturer's registration, the commissioner shall notify in writing each patient and the patient's registered designated caregiver or registered parent or legal guardian two or more business days prior to the revocation's effective date, about the outcome of the proceeding and information regarding alternative registered manufacturers.

Sec. 4. Minnesota Statutes 2016, 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.~~ If the commissioner is registering a new manufacturer under section 152.25, the commissioner shall specify the date by which the new manufacturer is required to begin distribution of medical cannabis from at least one distribution facility, and the date by which all distribution facilities must be operational and distributing medical cannabis. 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 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. If, based on test results, the commissioner determines the presence of contaminating substances in any medical cannabis product in sufficient quantities to present a likely threat to patient health or safety, the manufacturer, upon order of the commissioner, shall destroy all quantities of the contaminated medical cannabis product so identified and provide the commissioner proof of the product's destruction. 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.

(l) A manufacturer must use a seed-to-sale tracking system that will create and maintain records relating to cannabis and medical cannabis inventory at every stage of the medical cannabis life cycle, from plant stage through cultivation, extraction, final processing, transportation, distribution, and sale.

(m) A manufacturer must notify the commissioner of any assignment or transfer of an ownership interest in the manufacturer of five percent or more. The transferee 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 prior to any transfer or assignment. 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 transferee's national criminal history records information. The bureau shall return the results of the Minnesota and federal criminal history records checks to the commissioner.

Sec. 5. Minnesota Statutes 2016, section 152.29, subdivision 3, is amended to read:

Subd. 3. **Manufacturer; distribution.** (a) A manufacturer shall require that employees licensed as pharmacists pursuant to chapter 151 be the only employees to give final approval for the distribution of medical cannabis to a patient.

(b) A manufacturer may dispense medical cannabis products, whether or not the products have been manufactured by the manufacturer, but is not required to dispense medical cannabis products.

(c) Prior to distribution of any medical cannabis, the manufacturer shall:

(1) verify that the manufacturer has received the registry verification from the commissioner for that individual patient;

(2) verify that the person requesting the distribution of medical cannabis is the patient, the patient's registered designated caregiver, or the patient's parent or legal guardian listed in the registry verification using the procedures described in section 152.11, subdivision 2d;

(3) assign a tracking number to any medical cannabis distributed from the manufacturer;

(4) ensure that any employee of the manufacturer licensed as a pharmacist pursuant to chapter 151 has consulted with the patient to determine the proper dosage for the individual patient after reviewing the ranges of chemical compositions of the medical cannabis and the ranges of proper dosages reported by the commissioner. For purposes of this clause, a consultation may be conducted remotely using a videoconference, so long as the employee providing the consultation is able to confirm the identity of the patient, the consultation occurs while the patient is at a distribution facility, and the consultation adheres to patient privacy requirements that apply to health care services delivered through telemedicine;

(5) properly package medical cannabis in compliance with the United States Poison Prevention Packing Act regarding child-resistant packaging and exemptions for packaging for elderly patients, and label distributed medical cannabis with a list of all active ingredients and individually identifying information, including:

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

(ii) the name and date of birth of the patient's registered designated caregiver or, if listed on the registry verification, the name of the patient's parent or legal guardian, if applicable;

(iii) the patient's registry identification number;

(iv) the chemical composition of the medical cannabis; and

(v) the dosage recommended for that patient; and

(6) ensure that the medical cannabis distributed contains a maximum of a 30-day supply of the dosage determined for that patient.

(d) A manufacturer shall require any employee of the manufacturer who is transporting medical cannabis or medical cannabis products to a distribution facility to carry identification showing that the person is an employee of the manufacturer.

Sec. 6. **[152.291] TEMPORARY SUSPENSION OF A MEDICAL CANNABIS MANUFACTURER.**

Subdivision 1. **Suspension proceedings.** The commissioner of health may institute proceedings to temporarily suspend the registration of a medical cannabis manufacturer for a period of up to 90 days by notifying the manufacturer in writing if any action by an officer, director, or controlling person of the manufacturer:

(1) violates any of the requirements of sections 152.21 to 152.37 or the rules adopted thereunder;

(2) permits, aids, or abets the commission of any violation of state law at the manufacturer's location for cultivation, harvesting, manufacturing, packaging, and processing or at any site for distribution of medical cannabis;

(3) performs any act contrary to the welfare of a patient or registered designated caregiver; or

(4) obtains, or attempts to obtain, a registration by fraudulent means or misrepresentation.

Subd. 2. **Notice to patients.** Within five working days after proceedings are initiated by the commissioner to suspend a manufacturer's registration, the commissioner shall notify

each patient and the patient's registered designated caregiver or registered parent or legal guardian about the proceedings and potential patient impacts.

Subd. 3. **Notice and hearing.** No manufacturer registration may be suspended without a hearing held as a contested case under chapter 14. The hearing must commence within 60 days after the proceedings are initiated.

Subd. 4. **Expedited suspension.** When the commissioner determines the operations or medical cannabis of a registered manufacturer presents an imminent threat to the health or safety of patients or the public, the commissioner may immediately suspend the registration of a medical cannabis manufacturer by bringing an action in the district court in Ramsey or Hennepin County or in the district in which a manufacturer is located to enjoin employees of the manufacturer from illegally engaging in activities regulated by sections 152.21 to 152.37. A temporary restraining order may be granted by the court in the proceeding if continued activity by the manufacturer would create an imminent risk of harm to patients.

Sec. 7. **REPEALER.**

Minnesota Statutes 2016, section 152.33, subdivision 6, is repealed.

**152.33 VIOLATIONS.**

Subd. 6. **Other violations; civil penalty.** A manufacturer shall be fined up to $1,000 for any violation of sections 152.22 to 152.37, or the regulations issued pursuant to them, where no penalty has been specified. This penalty is in addition to any other applicable penalties in law.