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

A bill for an act

relating to health; changing provisions in the medical cannabis program; amending Minnesota Statutes 2014, sections 144.99, subdivision 1; 152.22, subdivision 4; 152.25, subdivision 1; 152.26; 152.27, subdivisions 2, 6; 152.29, subdivisions 1, 2, 3; 152.32, subdivision 2; Laws 2014, chapter 311, section 20; proposing coding for new law in Minnesota Statutes, chapter 152.

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

Section 1. Minnesota Statutes 2014, 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 2014, section 152.22, subdivision 4, is amended to read:

Subd. 4. **Health care practitioner.** "Health care practitioner" means a person who has the primary responsibility for the care and treatment of the qualifying medical condition of a person diagnosed with a qualifying medical condition and who is a Minnesota licensed ~~doctor of medicine, a Minnesota licensed physician assistant acting within the scope of authorized practice, or a Minnesota licensed advanced practice~~

~~registered nurse who has the primary responsibility for the care and treatment of the qualifying medical condition of a person diagnosed with a qualifying medical condition.~~:

(1) doctor of medicine;

(2) physician assistant acting within the scope of authorized practice; or

(3) advanced practice registered nurse.

Sec. 3. 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 approved by the commissioner 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. 4. Minnesota Statutes 2014, section 152.26, is amended to read:

152.26 RULEMAKING.

The commissioner may adopt rules to implement sections 152.22 to 152.37. Rules for which notice is published in the State Register before January 1, 2015, may be adopted using the process in section 14.389. Rules for implementing additional qualifying medical conditions may be adopted using the process in section 14.389.

Sec. 5. Minnesota Statutes 2014, section 152.27, subdivision 2, is amended to read:

Subd. 2. **Commissioner duties.** (a) The commissioner shall:

(1) give notice of the program to health care practitioners in the state who are eligible to serve as health care practitioners and explain the purposes and requirements of the program;

(2) allow each health care practitioner who meets or agrees to meet the program's requirements and who requests to participate, to be included in the registry program to collect data for the patient registry;

(3) provide explanatory information and assistance to each health care practitioner in understanding the nature of therapeutic use of medical cannabis within program requirements;

(4) create and provide a certification to be used by a health care practitioner for the practitioner to certify whether a patient has been diagnosed with a qualifying medical condition and include in the certification an option for the practitioner to certify whether the patient, in the health care practitioner's medical opinion, is developmentally or physically disabled and, as a result of that disability, the patient is unable to self-administer medication or acquire medical cannabis from a distribution facility;

(5) supervise the participation of the health care practitioner in conducting patient treatment and health records reporting in a manner that ensures stringent security and record-keeping requirements and that prevents the unauthorized release of private data on individuals as defined by section 13.02;

(6) develop safety criteria for patients with a qualifying medical condition as a requirement of the patient's participation in the program, to prevent the patient from undertaking any task under the influence of medical cannabis that would constitute negligence or professional malpractice on the part of the patient; and

(7) conduct research and studies based on data from health records submitted to the registry program and submit reports on intermediate or final research results to the legislature and major scientific journals. The commissioner may contract with a third party to complete the requirements of this clause. Any reports submitted must comply with section 152.28, subdivision 2.

(b) If the commissioner wishes to add a delivery method under section 152.22, subdivision 6, or a qualifying medical condition under section 152.22, subdivision 14, the commissioner must notify the chairs and ranking minority members of the legislative policy committees having jurisdiction over health and public safety of the addition and the reasons for its addition, including any written comments received by the commissioner from the public and any guidance received from the task force on medical cannabis research, by January 15 of the year in which the commissioner wishes to make the change. The change shall be effective on August 1 of that year, unless the legislature by law provides otherwise.

(c) If the commissioner authorizes additional distribution facilities or additional distribution options for patients to improve patient access to medical cannabis pursuant to section 152.29, subdivision 1, the commissioner shall provide notice by publishing notice of the change in the State Register and must notify the chairs and ranking minority members of the legislative policy committees having jurisdiction over health and public safety of the addition, including any written comments received by the commissioner from the public and any guidance received from the task force on medical cannabis research. The change shall become effective upon publication in the State Register.

Sec. 6. 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. 7. 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. The commissioner may

authorize additional distribution facilities and additional distribution options for patients in order to improve patient access if the commissioner determines existing distribution facility locations do not adequately serve patient need. 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. 8. Minnesota Statutes 2014, section 152.29, subdivision 2, is amended to read:

Subd. 2. **Manufacturer; production.** (a) A manufacturer of medical cannabis shall provide a reliable and ongoing supply of all medical cannabis needed for the registry program.

(b) All cultivation, harvesting, manufacturing, packaging, and processing of medical cannabis must take place in an enclosed, locked facility at a physical address provided to the commissioner during the registration process.

(c) A manufacturer must process and prepare any medical cannabis plant material into a form allowable under section 152.22, subdivision 6, prior to distribution of any medical cannabis.

(d) A manufacturer may transfer cannabis plants prior to the plant having been processed into an allowable form, as defined under section 152.22, subdivision 6, to another manufacturer registered under section 152.25, subdivision 1, after receiving approval from the commissioner.

Sec. 9. Minnesota Statutes 2014, 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 distribute the~~ consult with the patient prior to the initial distribution of medical cannabis to a ~~patient~~ person listed on the patient's registry verification and prior to distribution at any time the dosage or range of chemical compositions changes for the individual patient.

(b) A manufacturer may distribute medical cannabis manufactured by any medical cannabis manufacturer registered under section 152.25, subdivision 1.

~~(b)~~ (c) 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)~~ (d) 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~~ or is a person listed on the patient's registry verification;

(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;

(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; and

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

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

Sec. 10. Minnesota Statutes 2014, section 152.32, subdivision 2, is amended to read:

Subd. 2. **Criminal and civil protections.** (a) Subject to section 152.23, the following are not violations under this chapter:

(1) use or possession of medical cannabis or medical cannabis products by a patient enrolled in the registry program, or possession by a registered designated caregiver or the parent or legal guardian of a patient if the parent or legal guardian is listed on the registry verification;

(2) possession, dosage determination, or sale of medical cannabis or medical cannabis products by a medical cannabis manufacturer, employees of a manufacturer, a laboratory conducting testing on medical cannabis, or employees of the laboratory; ~~and~~

(3) possession of cannabis prior to the cannabis having been processed into an allowable form as defined under section 152.22, subdivision 6, while engaged in employment duties, by a manufacturer, employee of a manufacturer, a laboratory conducting testing, or an employee of the laboratory; and

~~(3)~~ (4) possession of medical cannabis or medical cannabis products by any person while carrying out the duties required under sections 152.22 to 152.37.

(b) Medical cannabis obtained and distributed pursuant to sections 152.22 to 152.37 and associated property is not subject to forfeiture under sections 609.531 to 609.5316.

(c) The commissioner, the commissioner's staff, the commissioner's agents or contractors, and any health care practitioner are not subject to any civil or disciplinary penalties by the Board of Medical Practice, the Board of Nursing, or by any business, occupational, or professional licensing board or entity, solely for the participation in the registry program under sections 152.22 to 152.37. A pharmacist licensed under chapter 151 is not subject to any civil or disciplinary penalties by the Board of Pharmacy when acting in accordance with the provisions of sections 152.22 to 152.37. Nothing in this section affects a professional licensing board from taking action in response to violations of any other section of law.

(d) Notwithstanding any law to the contrary, the commissioner, the governor of Minnesota, or an employee of any state agency may not be held civilly or criminally liable for any injury, loss of property, personal injury, or death caused by any act or omission while acting within the scope of office or employment under sections 152.22 to 152.37.

(e) Federal, state, and local law enforcement authorities are prohibited from accessing the patient registry under sections 152.22 to 152.37 except when acting pursuant to a valid search warrant.

(f) Notwithstanding any law to the contrary, neither the commissioner nor a public employee may release data or information about an individual contained in any report,

document, or registry created under sections 152.22 to 152.37 or any information obtained about a patient participating in the program, except as provided in sections 152.22 to 152.37.

(g) No information contained in a report, document, or registry or obtained from a patient under sections 152.22 to 152.37 may be admitted as evidence in a criminal proceeding unless independently obtained or in connection with a proceeding involving a violation of sections 152.22 to 152.37.

(h) Notwithstanding section 13.09, any person who violates paragraph (e) or (f) is guilty of a gross misdemeanor.

(i) An attorney may not be subject to disciplinary action by the Minnesota Supreme Court or professional responsibility board for providing legal assistance to prospective or registered manufacturers or others related to activity that is no longer subject to criminal penalties under state law pursuant to sections 152.22 to 152.37.

(j) Possession of a registry verification or application for enrollment in the program by a person entitled to possess or apply for enrollment in the registry program does not constitute probable cause or reasonable suspicion, nor shall it be used to support a search of the person or property of the person possessing or applying for the registry verification, or otherwise subject the person or property of the person to inspection by any governmental agency.

Sec. 11. **[152.38] TITLE.**

Sections 152.21 to 152.38 may be cited as the "Medical Cannabis Therapeutic Research Act."

Sec. 12. 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.