HF1993 FIRST ENGROSSMENT

REVISOR

This Document can be made available in alternative formats upon request

1.1

State of Minnesota

A bill for an act

H1993-1

HOUSE OF REPRESENTATIVES 1993 NINETIETH SESSION H. F. No.

03/02/2017

Authored by Hamilton and Murphy, E., The bill was read for the first time and referred to the Committee on Health and Human Services Reform Adoption of Report: Amended and re-referred to the Committee on Civil Law and Data Practices Policy 03/15/2017

1.2 1.3 1.4 1.5	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; repealing Minnesota Statutes 2016, section 152.33, subdivision 6.
1.6	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:
1.7	Section 1. Minnesota Statutes 2016, section 144.99, subdivision 1, is amended to read:
1.8	Subdivision 1. Remedies available. The provisions of chapters 103I and 157 and sections
1.9	115.71 to 115.77; 144.12, subdivision 1, paragraphs (1), (2), (5), (6), (10), (12), (13), (14),
1.10	and (15); 144.1201 to 144.1204; 144.121; 144.1222; 144.35; 144.381 to 144.385; 144.411
1.11	to 144.417; 144.495; 144.71 to 144.74; 144.9501 to 144.9512; 144.97 to 144.98; 144.992;
1.12	<u>152.22 to 152.37;</u> 326.70 to 326.785; 327.10 to 327.131; and 327.14 to 327.28 and all rules,
1.13	orders, stipulation agreements, settlements, compliance agreements, licenses, registrations,
1.14	certificates, and permits adopted or issued by the department or under any other law now
1.15	in force or later enacted for the preservation of public health may, in addition to provisions
1.16	in other statutes, be enforced under this section.
1.17	Sec. 2. Minnesota Statutes 2016, section 152.25, subdivision 1, is amended to read:
1.18	Subdivision 1. Medical cannabis manufacturer registration. (a) The commissioner
1.19	shall register two in-state manufacturers for the production of all medical cannabis within
1.20	the state by December 1, 2014, unless the commissioner obtains an adequate supply of
1.21	federally sourced medical cannabis by August 1, 2014. The commissioner shall register
1.22	new manufacturers or reregister the existing manufacturers by December 1 every two years,
1.23	using the factors described in paragraph (c). The commissioner shall continue to accept

HF1993 FIRST ENGROSSMENT

SGS

2.1	applications after December 1, 2014, if two manufacturers that meet the qualifications set
2.2	forth in this subdivision do not apply before December 1, 2014. The commissioner's
2.3	determination that no manufacturer exists to fulfill the duties under sections 152.22 to 152.37
2.4	is subject to judicial review in Ramsey County District Court. Data submitted during the
2.5	medical cannabis manufacturer application process are private data on individuals or
2.6	nonpublic data as defined in section 13.02 until the manufacturer is registered under this
2.7	section. Data on a manufacturer that is registered are commissioner makes a final decision
2.8	regarding registration. The application of a registered manufacturer and its contents become
2.9	public data, unless the data are trade secret or security information under section 13.37. The
2.10	application of a nonselected applicant and its contents shall remain private data on individuals
2.11	or nonpublic data as defined in section 13.02.
2.12	(b) As a condition for registration, a manufacturer must agree to:
2.13	(1) begin supplying medical cannabis to patients by July 1, 2015 by a date specified by
2.14	the commissioner in the commissioner's decision regarding registration of the new
2.15	manufacturer; and
2.16	(2) comply with all requirements under sections 152.22 to 152.37.
2.17	(c) The commissioner shall consider the following factors when determining which
2.18	manufacturer to register whether to register a new manufacturer, approve or deny a
2.18 2.19	manufacturer to register whether to register a new manufacturer, approve or deny a reregistration application from a current registered manufacturer, or revoke the registration
2.19	reregistration application from a current registered manufacturer, or revoke the registration
2.19 2.20	reregistration application from a current registered manufacturer, or revoke the registration of a current registered manufacturer:
2.192.202.21	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
2.192.202.212.22	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,
2.192.202.212.222.23	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;
 2.19 2.20 2.21 2.22 2.23 2.24 	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;
 2.19 2.20 2.21 2.22 2.23 2.24 2.25 	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;
 2.19 2.20 2.21 2.22 2.23 2.24 2.25 2.26 	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
 2.19 2.20 2.21 2.22 2.23 2.24 2.25 2.26 2.27 	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;
 2.19 2.20 2.21 2.22 2.23 2.24 2.25 2.26 2.27 2.28 2.29 	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
 2.19 2.20 2.21 2.22 2.23 2.24 2.25 2.26 2.27 2.28 	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

SGS

(7) the manufacturer's history of past violations, including their number, willfulness, 3.1 gravity, and any economic benefit derived by the manufacturer related to documented 3.2 3.3 violations. (d) Registrations issued under this section are nontransferable without prior written 3.4 3.5 consent of the commissioner. The commissioner shall require (e) Each medical cannabis manufacturer to shall contract 3.6 with an independent laboratory to test medical cannabis produced by the manufacturer. The 37 commissioner shall must approve the a laboratory chosen by each manufacturer and before 3.8 it may test medical cannabis. The commissioner shall require that the laboratory report 3.9 3.10 testing results to the manufacturer and directly to the commissioner in a manner determined by the commissioner. 3.11 (f) When necessary to investigate an imminent threat to the health or safety of patients 3.12 or the public, employees of a laboratory approved by the commissioner to test medical 3.13 cannabis may, at the request of the commissioner, collect samples and transport cannabis 3.14 plant material, cannabis extracts, medical cannabis, and excipients and diluents used in 3.15 producing medical cannabis from a manufacturer's production facility to the testing 3.16 laboratory. The transport motor vehicle must be staffed with a minimum of two employees 3.17 of the laboratory. 3.18 Sec. 3. Minnesota Statutes 2016, section 152.25, is amended by adding a subdivision to 3.19 read: 3.20 Subd. 1a. Medical cannabis manufacturer revocation, nonrenewal, or denial of 3.21 consent to transfer. (a) If the commissioner intends to revoke, not renew, or deny consent 3.22 to transfer a registration issued under this section, the commissioner must first notify in 3.23 writing the manufacturer against whom the action is to be taken and provide the manufacturer 3.24 with an opportunity to request a hearing under the contested case provisions of chapter 14. 3.25 If the manufacturer does not request a hearing by notifying the commissioner in writing 3.26 within 20 days after receipt of the notice of proposed action, the commissioner may proceed 3.27 with the action without a hearing. The registration of a manufacturer is considered revoked 3.28 either on the date the manufacturer's current registration expires or as of the effective date 3.29 3.30 as stated on the commissioner's written notice of revocation. (b) Upon the revocation of a manufacturer's registration, the commissioner shall notify 3.31 in writing each patient and the patient's registered designated caregiver or registered parent 3.32 or legal guardian two or more business days prior to the revocation's effective date, about 3.33 the outcome of the proceeding and information regarding alternative registered manufacturers. 3.34

3

Sec. 3.

4.1

Sec. 4. Minnesota Statutes 2016, section 152.29, subdivision 1, is amended to read:

H1993-1

Subdivision 1. Manufacturer; requirements. (a) A manufacturer shall operate four 42 distribution facilities, which may include the manufacturer's single location for cultivation, 4.3 harvesting, manufacturing, packaging, and processing but is not required to include that 4.4 4.5 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 4.6 begin distribution of medical cannabis by July 1, 2016. If the commissioner is registering 4.7 a new manufacturer under section 152.25, the commissioner shall specify the date by which 4.8 the new manufacturer is required to begin distribution of medical cannabis from at least 4.9 one distribution facility, and the date by which all distribution facilities must be operational 4.10 and distributing medical cannabis. The distribution facilities shall be located based on 4.11 geographical need throughout the state to improve patient access. A manufacturer shall 4.12 disclose the proposed locations for the distribution facilities to the commissioner during the 4.13 registration process. A manufacturer shall operate only one location where all cultivation, 4.14 harvesting, manufacturing, packaging, and processing shall be conducted. Any additional 4.15 distribution facilities may dispense medical cannabis and medical cannabis products but 4.16 may not contain any medical cannabis in a form other than those forms allowed under 4.17 section 152.22, subdivision 6, and the manufacturer shall not conduct any cultivation, 4.18 harvesting, manufacturing, packaging, or processing at an additional distribution facility 4.19 site. Any distribution facility operated by the manufacturer is subject to all of the 4.20 requirements applying to the manufacturer under sections 152.22 to 152.37, including, but 4.21 not limited to, security and distribution requirements. 4.22

(b) A medical cannabis manufacturer shall contract with a laboratory approved by the 4.23 commissioner, subject to any additional requirements set by the commissioner, for purposes 4.24 of testing medical cannabis manufactured by the medical cannabis manufacturer as to 4.25 content, contamination, and consistency to verify the medical cannabis meets the 4.26 requirements of section 152.22, subdivision 6. If, based on test results, the commissioner 4.27 determines the presence of contaminating substances in any medical cannabis product in 4.28 4.29 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 4.30 cannabis product so identified and provide the commissioner proof of the product's 4.31 destruction. The cost of laboratory testing shall be paid by the manufacturer. 4.32

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

4.34 (1) procedures for the oversight of the manufacturer and procedures to ensure accurate4.35 record keeping; and

4

Sec. 4.

H1993-1

SGS

- 5.1 (2) procedures for the implementation of appropriate security measures to deter and
 5.2 prevent the theft of medical cannabis and unauthorized entrance into areas containing medical
 5.3 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.
- 5.7 (e) A manufacturer shall not share office space with, refer patients to a health care
 5.8 practitioner, or have any financial relationship with a health care practitioner.
- (f) A manufacturer shall not permit any person to consume medical cannabis on theproperty of the manufacturer.
- 5.11 (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 5.14 of age or who has been convicted of a disqualifying felony offense. An employee of a 5.15 medical cannabis manufacturer must submit a completed criminal history records check 5.16 consent form, a full set of classifiable fingerprints, and the required fees for submission to 5.17 the Bureau of Criminal Apprehension before an employee may begin working with the 5.18 manufacturer. The bureau must conduct a Minnesota criminal history records check and 5.19 the superintendent is authorized to exchange the fingerprints with the Federal Bureau of 5.20 Investigation to obtain the applicant's national criminal history record information. The 5.21 bureau shall return the results of the Minnesota and federal criminal history records checks 5 22 to the commissioner. 5.23
- (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.
- 5.27 (k) A manufacturer shall comply with reasonable restrictions set by the commissioner
 5.28 relating to signage, marketing, display, and advertising of medical cannabis.
- (1) 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,
- 5.32 <u>transportation, distribution, and sale.</u>

H1993-1

SGS

(m) A manufacturer must notify the commissioner of any assignment or transfer of an 6.1 ownership interest in the manufacturer of five percent or more. The transferee must submit 6.2 6.3 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 6.4 transfer or assignment. The bureau must conduct a Minnesota criminal history records check 6.5 and the superintendent is authorized to exchange the fingerprints with the Federal Bureau 6.6 of Investigation to obtain the transferee's national criminal history records information. The 6.7 bureau shall return the results of the Minnesota and federal criminal history records checks 6.8 to the commissioner. 6.9

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

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

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

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

6.18 (1) verify that the manufacturer has received the registry verification from the6.19 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;

6.24 (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 6.25 chapter 151 has consulted with the patient to determine the proper dosage for the individual 6.26 patient after reviewing the ranges of chemical compositions of the medical cannabis and 6.27 the ranges of proper dosages reported by the commissioner. For purposes of this clause, a 6.28 consultation may be conducted remotely using a videoconference, so long as the employee 6.29 providing the consultation is able to confirm the identity of the patient, the consultation 6.30 occurs while the patient is at a distribution facility, and the consultation adheres to patient 6.31 privacy requirements that apply to health care services delivered through telemedicine; 6.32

SGS

- 7.2 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:
- 7.5 (i) the patient's name and date of birth;
- 7.6 (ii) the name and date of birth of the patient's registered designated caregiver or, if listed
- 7.7 on the registry verification, the name of the patient's parent or legal guardian, if applicable;
- 7.8 (iii) the patient's registry identification number;
- 7.9 (iv) the chemical composition of the medical cannabis; and
- 7.10 (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.

- 7.16 Sec. 6. **REPEALER.**
- 7.17 Minnesota Statutes 2016, section 152.33, subdivision 6, is repealed.

APPENDIX Repealed Minnesota Statutes: H1993-1

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.