SENATE
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NINETY-SECOND SESSION

S.F. No. 1179

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DATE	D-PG	OFFICIAL STATUS
02/18/2021	458	Introduction and first reading
		Referred to Health and Human Services Finance and Policy
03/01/2021	629	Author added Abeler
03/04/2021	641a	Comm report: To pass as amended
	674	Second reading
03/17/2021	960	Author added Bigham
05/15/2021	4255	Author added Howe
	4795	Rule 47, returned to Health and Human Services Finance and Policy
		See HF2128, Art. 3, Sec. 28-29, 37-41

A bill for an act

relating to health; modifying operation of the medical cannabis program; allowing combustion of dried raw cannabis by patients age 21 or older; adding opiate addiction as a qualifying medical condition for participation in the medical cannabis registry program; modifying the process for adding or modifying a delivery method or qualifying medical condition; amending Minnesota Statutes 2020, sections 152.22, subdivisions 6, 14, by adding a subdivision; 152.27, subdivision 2; 152.29, subdivisions 1, 3, by adding subdivisions; 152.31.

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

Section 1. Minnesota Statutes 2020, section 152.22, is amended by adding a subdivision to read:

Subd. 5c. **Hemp processor.** "Hemp processor" means a person or business licensed by the commissioner of agriculture under chapter 18K to convert raw hemp into a product.

Sec. 2. Minnesota Statutes 2020, section 152.22, subdivision 6, is amended to read:

Subd. 6. **Medical cannabis.** (a) "Medical cannabis" means any species of the genus cannabis plant, or any mixture or preparation of them, including whole plant extracts and resins, and is delivered in the form of:

(1) liquid, including, but not limited to, oil;

(2) pill;

(3) vaporized delivery method with use of liquid or oil ~~but which does not require the use of dried leaves or plant form; or~~;

(4) combustion with use of dried raw cannabis; or

~~(4)~~ (5) any other method~~, excluding smoking,~~ approved by the commissioner.

(b) This definition includes any part of the genus cannabis plant prior to being processed into a form allowed under paragraph (a), that is possessed by a person while that person is engaged in employment duties necessary to carry out a requirement under sections 152.22 to 152.37 for a registered manufacturer or a laboratory under contract with a registered manufacturer. This definition also includes any hemp acquired by a manufacturer by a hemp grower as permitted under section 152.29, subdivision 1, paragraph (b).

Sec. 3. Minnesota Statutes 2020, section 152.22, subdivision 14, is amended to read:

Subd. 14. **Qualifying medical condition.** "Qualifying medical condition" means a diagnosis of any of the following conditions:

(1) cancer, if the underlying condition or treatment produces one or more of the following:

(i) severe or chronic pain;

(ii) nausea or severe vomiting; or

(iii) cachexia or severe wasting;

(2) glaucoma;

(3) human immunodeficiency virus or acquired immune deficiency syndrome;

(4) Tourette's syndrome;

(5) amyotrophic lateral sclerosis;

(6) seizures, including those characteristic of epilepsy;

(7) severe and persistent muscle spasms, including those characteristic of multiple sclerosis;

(8) inflammatory bowel disease, including Crohn's disease;

(9) terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:

(i) severe or chronic pain;

(ii) nausea or severe vomiting; or

(iii) cachexia or severe wasting; or

(10) ~~any other medical condition or its treatment approved by the commissioner~~ opiate addiction.

Sec. 4. Minnesota Statutes 2020, 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 requires assistance in administering medical cannabis or obtaining 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) Effective August 1, 2021, the commissioner may ~~add a~~ recommend to the legislature an addition or modification to the delivery ~~method~~ methods under section 152.22, subdivision 6, or ~~add or modify a~~ an addition or modification to the qualifying medical ~~condition~~ conditions under section 152.22, subdivision 14, ~~upon~~ based on a petition from a member

of the public or the task force on medical cannabis therapeutic research or as directed by law. The commissioner shall evaluate all petitions submitted to add a qualifying medical condition or modify an existing qualifying medical condition ~~submitted by the task force on medical cannabis therapeutic research~~ or as directed by law and ~~shall make~~ may recommend to the legislature the addition or modification if the commissioner determines the addition or modification is warranted based on the best available evidence and research. If the commissioner ~~wishes to add~~ recommends the addition or modification of 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~~ recommendation and the reasons for ~~its addition~~ the recommendation, 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 recommended change shall ~~be~~ not become effective ~~on August 1 of that year, unless the legislature by law provides otherwise~~ unless the change is enacted into law. Any addition or modification of a delivery method or qualifying medical condition made by the commissioner that is in effect on January 1, 2021, shall remain in effect unless removed or modified by law, and any addition or modification that the commissioner has proposed to make and has notified the legislature of the proposed change by January 1, 2021, shall become effective on August 1, 2021, unless otherwise provided by law.

Sec. 5. Minnesota Statutes 2020, section 152.29, subdivision 1, is amended to read:

Subdivision 1. **Manufacturer; requirements.** (a) A manufacturer may operate eight 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. The commissioner shall designate the geographical service areas to be served by each manufacturer based on geographical need throughout the state to improve patient access. A manufacturer shall not have more than two distribution facilities in each geographical service area assigned to the manufacturer by the commissioner. A manufacturer shall operate only one location where all cultivation, harvesting, manufacturing, packaging, and processing of medical cannabis shall be conducted. This location may be one of the manufacturer's distribution facility sites. The 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 the other distribution facility sites. 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 manufacturer may acquire hemp grown in this state from a hemp grower, and may acquire hemp products produced by a hemp processor. A manufacturer may manufacture or process hemp and hemp products into an allowable form of medical cannabis under section 152.22, subdivision 6. Hemp and hemp products acquired by a manufacturer under this paragraph ~~is~~ are subject to the same quality control program, security and testing requirements, and other requirements that apply to medical cannabis under sections 152.22 to 152.37 and Minnesota Rules, chapter 4770.

(c) 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 or hemp or hemp products acquired 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.

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

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

(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; and

(3) procedures for the delivery and transportation of hemp between hemp growers and manufacturers and for the delivery and transportation of hemp products between hemp processors and manufacturers.

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

(f) 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.

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

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

(i) 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.

(j) 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.

(k) 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.

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

(m) Before a manufacturer acquires hemp from a hemp grower or hemp products from a hemp processor, the manufacturer must verify that the hemp grower or hemp processor has a valid license issued by the commissioner of agriculture under chapter 18K.

(n) Until a state-centralized, seed-to-sale system is implemented that can track a specific medical cannabis plant from cultivation through testing and point of sale, the commissioner shall conduct at least one unannounced inspection per year of each manufacturer that includes inspection of:

(1) business operations;

(2) physical locations of the manufacturer's manufacturing facility and distribution facilities;

(3) financial information and inventory documentation, including laboratory testing results; and

(4) physical and electronic security alarm systems.

Sec. 6. Minnesota Statutes 2020, 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. A manufacturer may transport medical cannabis or medical cannabis products that have been cultivated, harvested, manufactured, packaged, and processed by that manufacturer to another registered manufacturer for the other manufacturer to distribute.

(b) A manufacturer may distribute medical cannabis products, whether or not the products have been manufactured by that manufacturer.

(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, legal guardian, or spouse 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~~ by secure videoconference, telephone, or other remote means, 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. A pharmacist consultation under this clause is not required when a manufacturer is distributing medical cannabis to a patient according to a patient-specific dosage plan established with that manufacturer and is not modifying the dosage or product being distributed under that plan;

(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 90-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 or to another registered manufacturer to carry identification showing that the person is an employee of the manufacturer.

(e) A manufacturer shall distribute medical cannabis in dried raw cannabis form only to a patient age 21 or older, or to the registered designated caregiver, parent, legal guardian, or spouse of a patient age 21 or older.

Sec. 7. Minnesota Statutes 2020, section 152.29, is amended by adding a subdivision to read:

Subd. 3b. **Distribution to recipient in a motor vehicle.** A manufacturer may distribute medical cannabis to a patient, registered designated caregiver, or parent, legal guardian, or spouse of a patient who is at the distribution facility but remains in a motor vehicle, provided:

(1) distribution facility staff receive payment and distribute medical cannabis in a designated zone that is as close as feasible to the front door of the distribution facility;

(2) the manufacturer ensures that the receipt of payment and distribution of medical cannabis are visually recorded by a closed-circuit television surveillance camera at the distribution facility and provides any other necessary security safeguards;

(3) the manufacturer does not store medical cannabis outside a restricted access area at the distribution facility, and distribution facility staff transport medical cannabis from a restricted access area at the distribution facility to the designated zone for distribution only after confirming that the patient, designated caregiver, or parent, guardian, or spouse has arrived in the designated zone;

(4) the payment and distribution of medical cannabis take place only after a pharmacist consultation takes place, if required under subdivision 3, paragraph (c), clause (4);

(5) immediately following distribution of medical cannabis, distribution facility staff enter the transaction in the state medical cannabis registry information technology database; and

(6) immediately following distribution of medical cannabis, distribution facility staff take the payment received into the distribution facility.

Sec. 8. Minnesota Statutes 2020, section 152.29, is amended by adding a subdivision to read:

Subd. 3c. **Disposal of medical cannabis plant root balls.** Notwithstanding Minnesota Rules, part 4770.1200, subpart 2, item C, a manufacturer is not required to grind root balls of medical cannabis plants or incorporate them with a greater quantity of nonconsumable solid waste before transporting root balls to another location for disposal. For purposes of this subdivision, "root ball" means a compact mass of roots formed by a plant and any attached growing medium.

Sec. 9. Minnesota Statutes 2020, section 152.31, is amended to read:

152.31 DATA PRACTICES.

(a) Government data in patient files maintained by the commissioner and the health care practitioner, and data submitted to or by a medical cannabis manufacturer, are private data on individuals, as defined in section 13.02, subdivision 12, or nonpublic data, as defined in section 13.02, subdivision 9, but may be used for purposes of complying with chapter 13 and complying with a request from the legislative auditor or the state auditor in the performance of official duties. The provisions of section 13.05, subdivision 11, apply to a registration agreement entered between the commissioner and a medical cannabis manufacturer under section 152.25.

(b) Not public data maintained by the commissioner may not be used for any purpose not provided for in sections 152.22 to 152.37, and may not be combined or linked in any manner with any other list, dataset, or database.

(c) The commissioner may execute data sharing arrangements with the commissioner of agriculture to verify licensing, inspection, and compliance information related to hemp growers and hemp processors under chapter 18K.