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State of Minnesota

HOUSE OF REPRESENTATIVES

A bill for an act

Minnesota Statutes 2020, sections 152.22, subdivision 8; 152.25, subdivision 1;

relating to health; changing certain medical cannabis provisions; amending

NINETY-SECOND SESSION

н. ғ. №. 3876

03/03/2022

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Authored by Edelson
The bill was read for the first time and referred to the Committee on Health Finance and Policy

1.4 1.5	152.30; 152.32, subdivision 2; 152.36; Minnesota Statutes 2021 Supplement, sections 152.27, subdivision 2; 152.29, subdivisions 1, 3.
1.6	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:
1.7	Section 1. Minnesota Statutes 2020, section 152.22, subdivision 8, is amended to read:
1.8	Subd. 8. Medical cannabis product paraphernalia. "Medical cannabis product
1.9	paraphernalia" means any delivery device or related supplies and educational materials used
1.10	in the administration of medical cannabis for a patient with a qualifying medical condition
1.11	enrolled in the registry program.
1.12	Sec. 2. Minnesota Statutes 2020, section 152.25, subdivision 1, is amended to read:
1.13	Subdivision 1. Medical cannabis manufacturer registration. (a) The commissioner
1.14	shall register two in-state manufacturers for the production of all medical cannabis within
1.15	the state. A registration agreement between the commissioner and a manufacturer is
1.16	nontransferable. The commissioner shall register new manufacturers or reregister the existing
1.17	manufacturers by December 1 every two years, using the factors described in this subdivision.
1.18	The commissioner shall accept applications after December 1, 2014, if one of the
1.19	manufacturers registered before December 1, 2014, ceases to be registered as a manufacturer.
1.20	The commissioner's determination that no manufacturer exists to fulfill the duties under
1.21	sections 152.22 to 152.37 is subject to judicial review in Ramsey County District Court.
1.22	Data submitted during the application process are private data on individuals or nonpublic
1.23	data as defined in section 13.02 until the manufacturer is registered under this section. Data

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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 within eight months 2.4 2.5 of its initial registration; and
- (2) comply with all requirements under sections 152.22 to 152.37. 2.6

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- (c) The commissioner shall consider the following factors when determining which 2.7 manufacturer to register: 2.8
 - (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; 2.13
- (4) the ability to provide appropriate security measures on the premises of the 2.14 manufacturer; 2.15
- (5) whether the manufacturer has demonstrated an ability to meet the medical cannabis 2.16 production needs required by sections 152.22 to 152.37; and 2.17
 - (6) the manufacturer's projection and ongoing assessment of fees on patients with a qualifying medical condition.
 - (d) If an officer, director, or controlling person of the manufacturer pleads or is found guilty of intentionally diverting medical cannabis to a person other than allowed by law under section 152.33, subdivision 1, the commissioner may decide not to renew the registration of the manufacturer, provided the violation occurred while the person was an officer, director, or controlling person of the manufacturer.
 - (e) 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.
- (f) The commissioner shall implement a state-centralized medical cannabis electronic 2.30 database to monitor and track the manufacturers' medical cannabis inventories from the seed or clone source through cultivation, processing, testing, and distribution or disposal.

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The inventory tracking database must allow for information regarding medical cannabis to
be updated instantaneously. Any manufacturer or third-party laboratory licensed under this
chapter must submit to the commissioner any information the commissioner deems necessary
for maintaining the inventory tracking database. The commissioner may contract with a
separate entity to establish and maintain all or any part of the inventory tracking database.

The provisions of section 13.05, subdivision 11, apply to a contract entered between the
commissioner and a third party under this paragraph.

- Sec. 3. Minnesota Statutes 2021 Supplement, section 152.27, subdivision 2, is amended to read:
 - Subd. 2. Commissioner duties. (a) The commissioner shall:

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- (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

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(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.

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- (b) The commissioner may add a delivery method under section 152.22, subdivision 6, or add, remove, or modify a qualifying medical condition under section 152.22, subdivision 14, upon 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 to add a qualifying medical condition or to remove or modify an existing qualifying medical condition submitted by the task force on medical cannabis therapeutic research or as directed by law and may make the addition, removal, or modification if the commissioner determines the addition, removal, or modification is warranted based on the best available evidence and research. If the commissioner wishes to add a delivery method under section 152.22, subdivision 6, or add or remove 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 or removal and the reasons for its addition or removal, 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.
- Sec. 4. Minnesota Statutes 2021 Supplement, 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 paraphernalia but may not contain any

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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.

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- (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 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.

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(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.

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- (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;
- 6.32 (2) physical locations of the manufacturer's manufacturing facility and distribution 6.33 facilities;

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

(4) physical and electronic security alarm systems.

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- 7.4 Sec. 5. Minnesota Statutes 2021 Supplement, 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 <u>products paraphernalia</u> 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 <u>products</u> <u>paraphernalia</u>, whether or not the <u>products</u> <u>medical cannabis paraphernalia</u> 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 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 and the consultation adheres to patient privacy requirements that apply to health care services delivered through telehealth. 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

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modifying the dosage or product being distributed under that plan and the medical cannabis is distributed by a pharmacy technician;

- (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
- 8.12 (v) the dosage; and

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- 8.13 (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 <u>products paraphernalia</u> 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. 6. Minnesota Statutes 2020, section 152.30, is amended to read:

152.30 PATIENT DUTIES.

- (a) A patient shall apply to the commissioner for enrollment in the registry program by submitting an application as required in section 152.27 and an annual registration fee as determined under section 152.35.
- (b) As a condition of continued enrollment, patients shall agree to:
- 8.28 (1) continue to receive regularly scheduled treatment for their qualifying medical condition from their health care practitioner; and
- 8.30 (2) report changes in their qualifying medical condition to their health care practitioner.

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(c) A patient shall only receive medical cannabis from a registered manufacturer but is not required to receive medical cannabis <u>products paraphernalia</u> from only a registered manufacturer.

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- Sec. 7. Minnesota Statutes 2020, 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, legal guardian, or spouse of a patient if the parent, legal guardian, or spouse 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 medical cannabis or medical cannabis <u>products paraphernalia</u> 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.

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(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.

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- (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. 8. Minnesota Statutes 2020, section 152.36, is amended to read:

10.21 **152.36 IMPACT ASSESSMENT OF MEDICAL CANNABIS THERAPEUTIC**10.22 **RESEARCH.**

- Subdivision 1. **Task force on medical cannabis therapeutic research.** (a) A 23-member task force on medical cannabis therapeutic research is created to conduct an impact assessment of medical cannabis therapeutic research. The task force shall consist of the following members:
- (1) two members of the house of representatives, one selected by the speaker of the house, the other selected by the minority leader;
- 10.29 (2) two members of the senate, one selected by the majority leader, the other selected by the minority leader;
- 10.31 (3) four members representing consumers or patients enrolled in the registry program, 10.32 including at least two parents of patients under age 18;

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(4) four members representing health care providers, including one licensed pharmacist; 11.1 (5) four members representing law enforcement, one from the Minnesota Chiefs of 11.2 Police Association, one from the Minnesota Sheriff's Association, one from the Minnesota 11.3 Police and Peace Officers Association, and one from the Minnesota County Attorneys 11.4 11.5 Association; (6) four members representing substance use disorder treatment providers; and 11.6 11.7 (7) the commissioners of health, human services, and public safety. (b) Task force members listed under paragraph (a), clauses (3), (4), (5), and (6), shall 11.8 be appointed by the governor under the appointment process in section 15.0597. Members 11.9 shall serve on the task force at the pleasure of the appointing authority. All members must 11.10 be appointed by July 15, 2014, and the commissioner of health shall convene the first meeting 11.11 of the task force by August 1, 2014. 11.12 (c) There shall be two cochairs of the task force chosen from the members listed under 11.13 paragraph (a). One cochair shall be selected by the speaker of the house and the other cochair 11.14 shall be selected by the majority leader of the senate. The authority to convene meetings 11.15 shall alternate between the cochairs. 11.16 (d) Members of the task force other than those in paragraph (a), clauses (1), (2), and (7), 11.17 shall receive expenses as provided in section 15.059, subdivision 6. 11.18 Subd. 1a. Administration. The commissioner of health shall provide administrative and 11.19 technical support to the task force. 11.20 Subd. 2. Impact assessment. The task force shall hold hearings to evaluate the impact 11.21 of the use of medical cannabis and hemp and Minnesota's activities involving medical 11.22 cannabis and hemp, including, but not limited to: 11.23 (1) program design and implementation; 11.24 (2) the impact on the health care provider community; 11.25 11.26 (3) patient experiences; (4) the impact on the incidence of substance abuse; 11.27 (5) access to and quality of medical cannabis, hemp, and medical cannabis products 11.28 paraphernalia; 11.29 (6) the impact on law enforcement and prosecutions; 11.30

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(7) public awareness and perception; and

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(8) any unintended consequences.

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Subd. 3. Cost assessment. By January 15 of each year, beginning January 15, 2015, and ending January 15, 2019, the commissioners of state departments impacted by the medical cannabis therapeutic research study shall report to the cochairs of the task force on the costs incurred by each department on implementing sections 152.22 to 152.37. The reports must compare actual costs to the estimated costs of implementing these sections and must be submitted to the task force on medical cannabis therapeutic research.

- Subd. 4. **Reports to the legislature.** (a) The cochairs of the task force shall submit the following reports an impact assessment report to the chairs and ranking minority members of the legislative committees and divisions with jurisdiction over health and human services, public safety, judiciary, and civil law:
- (1) by February 1, 2015, a report on the design and implementation of the registry program; and every two years thereafter, a complete impact assessment report; and.
- 12.14 (2) upon receipt of a cost assessment from a commissioner of a state agency, the
 12.15 completed cost assessment.
 - (b) The task force may make recommendations to the legislature on whether to add or remove conditions from the list of qualifying medical conditions.
- Subd. 5. **No expiration.** The task force on medical cannabis therapeutic research does not expire.

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