SENATE
STATE OF MINNESOTA
EIGHTY-EIGHTH SESSION

S.F. No. 2470

(SENATE AUTHORS: DIBBLE and Tomassoni)

DATE	D-PG	OFFICIAL STATUS
03/10/2014	6070	Introduction and first reading
		Referred to Education
03/24/2014	6530a	Comm report: To pass as amended
	6801	Second reading
04/24/2014	8273a	Special Order: Amended
	8273	Third reading Passed
05/08/2014	8877	Chief author stricken, shown as co-author Tomassoni
		Chief author added Dibble
05/13/2014	9126	Returned from House with amendment
	9126	Senate not concur, conference committee of 3 requested
	9135	Senate conferees Dibble; Lourey; Petersen, B.
	9310	House conferees Melin; Murphy, E.; Hamilton
05/16/2014	9903c	Conference committee report, delete everything
		Senate adopted CC report and repassed bill
	9922	Third reading
	9923	House adopted SCC report and repassed bill
		Presentment date 05/17/14
	10403	Governor's action Approval 05/29/14
	10404	Secretary of State Chapter 311 05/29/14
		Effective date 05/30/14

A bill for an act

relating to health; providing for medical cannabis registry program; authorizing rulemaking; establishing duties of patients, health care practitioners, and manufacturer of medical cannabis; establishing patient protections; imposing penalties; establishing fees; requiring impact assessment of medical cannabis therapeutic research; requiring audits; appropriating money; amending Minnesota Statutes 2012, sections 13.3806, by adding a subdivision; 256B.0625, subdivision 13d; 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 2012, section 13.3806, is amended by adding a subdivision to read:

Subd. 22. **Medical use of cannabis data.** Data collected under the registry program authorized under sections 152.22 to 152.37 are governed by sections 152.25, subdivision 1; 152.28, subdivision 2; and 152.37, subdivision 3.

Sec. 2. **[152.22] DEFINITIONS.**

Subdivision 1. **Applicability.** For purposes of sections 152.22 to 152.37, the terms defined in this section have the meanings given them.

Subd. 2. **Commissioner.** "Commissioner" means the commissioner of health.

Subd. 3. **Disqualifying felony offense.** "Disqualifying felony offense" means a violation of a state or federal controlled substance law that is a felony under Minnesota law, or would be a felony if committed in Minnesota, regardless of the sentence imposed, unless the commissioner determines that the person's conviction was for the medical use of cannabis or assisting with the medical use of cannabis.

Subd. 4. **Health care practitioner.** "Health care practitioner" means 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.

Subd. 5. **Health records.** "Health records" means health records as defined in section 144.291, subdivision 2, paragraph (c).

Subd. 6. **Medical cannabis.** "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) any other method, excluding smoking, approved by the commissioner.

Subd. 7. **Medical cannabis manufacturer.** "Medical cannabis manufacturer" or "manufacturer" means an entity registered by the commissioner to cultivate, acquire, manufacture, possess, prepare, transfer, transport, supply, or dispense medical cannabis, delivery devices, or related supplies and educational materials.

Subd. 8. **Medical cannabis product.** "Medical cannabis product" means any delivery device or related supplies and educational materials used in the administration of medical cannabis for a patient with a qualifying medical condition enrolled in the registry program.

Subd. 9. **Patient.** "Patient" means a Minnesota resident who has been diagnosed with a qualifying medical condition by a health care practitioner and who has otherwise met any other requirements for patients under sections 152.22 to 152.37 to participate in the registry program under sections 152.22 to 152.37.

Subd. 10. **Patient registry number.** "Patient registry number" means a unique identification number assigned by the commissioner to a patient enrolled in the registry program.

Subd. 11. **Registered designated caregiver.** "Registered designated caregiver" means a person who:

(1) is at least 21 years old;

(2) does not have a conviction for a disqualifying felony offense;

(3) has been approved by the commissioner to assist a patient who has been identified by a health care practitioner as developmentally or physically disabled and therefore unable to self-administer medication or acquire medical cannabis from a distribution facility due to the disability; and

(4) is authorized by the commissioner to assist the patient with the use of medical cannabis.

Subd. 12. **Registry program.** "Registry program" means the patient registry established sections 152.22 to 152.37.

Subd. 13. **Registry verification.** "Registry verification" means the verification provided by the commissioner that a patient is enrolled in the registry program and that includes the patient's name, registry number, and qualifying medical condition and, if applicable, the name of the patient's registered designated caregiver or parent or legal guardian.

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) 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.

Sec. 3. **[152.23] LIMITATIONS.**

(a) Nothing in sections 152.22 to 152.37 permits any person to engage in and does not prevent the imposition of any civil, criminal, or other penalties for:

(1) undertaking any task under the influence of medical cannabis that would constitute negligence or professional malpractice;

(2) possessing or engaging in the use of medical cannabis:

(i) on a school bus or van;

(ii) on the grounds of any preschool or primary or secondary school;

(iii) in any correctional facility; or

(iv) on the grounds of any child care facility or home daycare;

(3) vaporizing medical cannabis pursuant to section 152.22, subdivision 6:

(i) on any form of public transportation;

(ii) where the vapor would be inhaled by a nonpatient minor child; or

(iii) in any public place, including any indoor or outdoor area used by or open to the general public or a place of employment as defined under section 144.413, subdivision 1b; and

(4) operating, navigating, or being in actual physical control of any motor vehicle, aircraft, train, or motorboat, or working on transportation property, equipment, or facilities while under the influence of medical cannabis.

(b) Nothing in sections 152.22 to 152.37 require the medical assistance and MinnesotaCare programs to reimburse an enrollee or a provider for costs associated with the medical use of cannabis. Medical assistance and MinnesotaCare shall continue to provide coverage for all services related to treatment of an enrollee's qualifying medical condition if the service is covered under chapter 256B or 256L.

Sec. 4. **[152.24] FEDERALLY APPROVED CLINICAL TRIALS.**

The commissioner may prohibit enrollment of a patient in the registry program if the patient is simultaneously enrolled in a federally approved clinical trial for the treatment of a qualifying medical condition with medical cannabis. The commissioner shall provide information to all patients enrolled in the registry program on the existence of federally approved clinical trials for the treatment of the patient's qualifying medical condition with medical cannabis as an alternative to enrollment in the patient registry program.

Sec. 5. **[152.25] COMMISSIONER DUTIES.**

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, 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 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.

Subd. 2. **Range of compounds and dosages; report.** The commissioner shall review and publicly report the existing medical and scientific literature regarding the range of recommended dosages for each qualifying condition and the range of chemical compositions of any plant of the genus cannabis that will likely be medically beneficial for each of the qualifying medical conditions. The commissioner shall make this information available to patients with qualifying medical conditions beginning December 1, 2014, and update the information annually. The commissioner may consult with the independent laboratory under contract with the manufacturer or other experts in reporting the range

of recommended dosages for each qualifying medical condition, the range of chemical compositions that will likely be medically beneficial, and any risks of noncannabis drug interactions. The commissioner shall consult with each manufacturer on an annual basis on medical cannabis offered by the manufacturer. The list of medical cannabis offered by a manufacturer shall be published on the Department of Health Web site.

Subd. 3. **Deadlines.** (a) The commissioner shall adopt rules necessary for the manufacturer to begin distribution of medical cannabis to patients under the registry program by July 1, 2015, and have notice of proposed rules published in the State Register prior to January 1, 2015.

(b) The commissioner shall, by November 1, 2014, advise the public and the cochairs of the task force on medical cannabis therapeutic research established under section 152.36 if the commissioner is unable to register two manufacturers by the December 1, 2014, deadline. The commissioner shall provide a written statement as to the reason or reasons the deadline will not be met. Upon request of the commissioner, the task force shall extend the deadline by six months, but may not extend the deadline more than once.

(c) If notified by a manufacturer that distribution to patients may not begin by the July 1, 2015, deadline, the commissioner shall advise the public and the cochairs of the task force on medical cannabis therapeutic research. Upon notification by the commissioner, the task force shall extend the deadline by six months, but may not extend the deadline more than once.

Subd. 4. **Reports.** (a) The commissioner shall provide regular updates to the task force on medical cannabis therapeutic research regarding any changes in federal law or regulatory restrictions regarding the use of medical cannabis.

(b) The commissioner may submit medical research based on the data collected under sections 152.22 to 152.37 to any federal agency with regulatory or enforcement authority over medical cannabis to demonstrate the effectiveness of medical cannabis for treating a qualifying medical condition.

Sec. 6. **[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.

Sec. 7. **[152.27] PATIENT REGISTRY PROGRAM ESTABLISHED.**

Subdivision 1. **Patient registry program; establishment.** (a) The commissioner shall establish a patient registry program to evaluate data on patient demographics,

effective treatment options, clinical outcomes, and quality-of-life outcomes for the purpose of reporting on the benefits, risks, and outcomes regarding patients with a qualifying medical condition engaged in the therapeutic use of medical cannabis.

(b) The establishment of the registry program shall not be construed or interpreted to condone or promote the illicit recreational use of marijuana.

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.

Subd. 3. **Patient application.** (a) The commissioner shall develop a patient application for enrollment into the registry program. The application shall be available to the patient and given to health care practitioners in the state who are eligible to serve as health care practitioners. The application must include:

(1) the name, mailing address, and date of birth of the patient;

(2) the name, mailing address, and telephone number of the patient's health care practitioner;

(3) the name, mailing address, and date of birth of the patient's designated caregiver, if any, or the patient's parent or legal guardian if the parent or legal guardian will be acting as a caregiver;

(4) a copy of the certification from the patient's health care practitioner that is dated within 90 days prior to submitting the application which certifies that the patient has been diagnosed with a qualifying medical condition and, if applicable, that, in the health care practitioner's medical opinion, the patient 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; and

(5) all other signed affidavits and enrollment forms required by the commissioner under sections 152.22 to 152.37, including, but not limited to, the disclosure form required under paragraph (c).

(b) The commissioner shall require a patient to resubmit a copy of the certification from the patient's health care practitioner on a yearly basis and shall require that the recertification be dated within 90 days of submission.

(c) The commissioner shall develop a disclosure form and require, as a condition of enrollment, all patients to sign a copy of the disclosure. The disclosure must include:

(1) a statement that, notwithstanding any law to the contrary, the commissioner, 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; and

(2) the patient's acknowledgement that enrollment in the patient registry program is conditional on the patient's agreement to meet all of the requirements of sections 152.22 to 152.37.

Subd. 4. **Registered designated caregiver.** (a) The commissioner shall register a designated caregiver for a patient if the patient's health care practitioner has certified that 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 and the caregiver has agreed, in writing, to be the patient's designated caregiver. As a condition of registration as a designated caregiver, the commissioner shall require the person to:

(1) be at least 21 years of age;

(2) agree to only possess any medical cannabis for purposes of assisting the patient; and

(3) agree that if the application is approved, the person will not be a registered designated caregiver for more than one patient, unless the patients reside in the same residence.

(b) The commissioner shall conduct a criminal background check on the designated caregiver prior to registration to ensure that the person does not have a conviction for a disqualifying felony offense. Any cost of the background check shall be paid by the person seeking registration as a designated caregiver.

Subd. 5. **Parents or legal guardians.** A parent or legal guardian of a patient may act as the caregiver to the patient without having to register as a designated caregiver. The parent or legal guardian shall follow all of the requirements of parents and legal guardians listed in sections 152.22 to 152.37. Nothing in sections 152.22 to 152.37 limits any legal authority a parent or legal guardian may have for the patient under any other law.

Subd. 6. **Patient enrollment.** (a) After receipt of a patient's application 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. 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 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.

Subd. 7. **Notice requirements.** Patients and registered designated caregivers shall notify the commissioner of any address or name change within 30 days of the change having occurred. A patient or registered designated caregiver is subject to a $100 fine for failure to notify the commissioner of the change.

Sec. 8. **[152.28] HEALTH CARE PRACTITIONER DUTIES.**

Subdivision 1. **Health care practitioner duties.** (a) Prior to a patient's enrollment in the registry program, a health care practitioner shall:

(1) determine, in the health care practitioner's medical judgment, whether a patient suffers from a qualifying medical condition, and, if so determined, provide the patient with a certification of that diagnosis;

(2) determine whether a patient 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, and, if so determined, include that determination on the patient's certification of diagnosis;

(3) advise patients, registered designated caregivers, and parents or legal guardians who are acting as caregivers of the existence of any nonprofit patient support groups or organizations;

(4) provide explanatory information from the commissioner to patients with qualifying medical conditions, including disclosure to all patients about the experimental nature of therapeutic use of medical cannabis; the possible risks, benefits, and side effects of the proposed treatment; the application and other materials from the commissioner; and provide patients with the Tennessen warning as required by section 13.04, subdivision 2; and

(5) agree to continue treatment of the patient's qualifying medical condition and report medical findings to the commissioner.

(b) Upon notification from the commissioner of the patient's enrollment in the registry program, the health care practitioner shall:

(1) participate in the patient registry reporting system under the guidance and supervision of the commissioner;

(2) report health records of the patient throughout the ongoing treatment of the patient to the commissioner in a manner determined by the commissioner and in accordance with subdivision 2;

(3) determine, on a yearly basis, if the patient continues to suffer from a qualifying medical condition and, if so, issue the patient a new certification of that diagnosis; and

(4) otherwise comply with all requirements developed by the commissioner.

(c) Nothing in this section requires a health care practitioner to participate in the registry program.

Subd. 2. **Data.** Data collected on patients by a health care practitioner and reported to the patient registry are health records under section 144.291, and are private data on individuals under section 13.02, but may be used or reported in an aggregated, nonidentifiable form as part of a scientific, peer-reviewed publication of research conducted under section 152.25 or in the creation of summary data, as defined in section 13.02, subdivision 19.

Sec. 9. **[152.29] MANUFACTURER OF MEDICAL CANNABIS DUTIES.**

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. 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, 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.

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.

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 medical cannabis to a patient.

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

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

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

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

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

(4) ensure that any employee of the manufacturer licensed as a pharmacist pursuant to chapter 151 has consulted with the patient to determine the proper dosage for the individual patient after reviewing the ranges of chemical compositions of the medical cannabis and the ranges of proper dosages reported by the commissioner;

(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) 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.

Subd. 4. **Report.** Each manufacturer shall report to the commissioner on a monthly basis the following information on each individual patient for the month prior to the report:

(1) the amount and dosages of medical cannabis distributed;

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

(3) the tracking number assigned to any medical cannabis distributed.

Sec. 10. **[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:

(1) continue to receive regularly scheduled treatment for their qualifying medical condition from their health care practitioner; and

(2) report changes in their qualifying medical condition to their health care practitioner.

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

Sec. 11. **[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.

Sec. 12. **[152.32] PROTECTIONS FOR REGISTRY PROGRAM PARTICIPATION.**

Subdivision 1. **Presumption.** (a) There is a presumption that a patient enrolled in the registry program under sections 152.22 to 152.37 is engaged in the authorized use of medical cannabis.

(b) The presumption may be rebutted by evidence that conduct related to use of medical cannabis was not for the purpose of treating or alleviating the patient's qualifying medical condition or symptoms associated with the patient's qualifying medical condition.

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 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, 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.

Subd. 3. **Discrimination prohibited.** (a) No school or landlord may refuse to enroll or lease to and may not otherwise penalize a person solely for the person's status as a patient enrolled in the registry program under sections 152.22 to 152.37, unless failing to do so would violate federal law or regulations or cause the school or landlord to lose a monetary or licensing-related benefit under federal law or regulations.

(b) For the purposes of medical care, including organ transplants, a registry program enrollee's use of medical cannabis under sections 152.22 to 152.37 is considered the equivalent of the authorized use of any other medication used at the discretion of a physician and does not constitute the use of an illicit substance or otherwise disqualify a patient from needed medical care.

(c) Unless a failure to do so would violate federal law or regulations or cause an employer to lose a monetary or licensing-related benefit under federal law or regulations, an employer may not discriminate against a person in hiring, termination, or any term or condition of employment, or otherwise penalize a person, if the discrimination is based upon either of the following:

(1) the person's status as a patient enrolled in the registry program under sections 152.22 to 152.37; or

(2) a patient's positive drug test for cannabis components or metabolites, unless the patient used, possessed, or was impaired by medical cannabis on the premises of the place of employment or during the hours of employment.

(d) An employee who is required to undergo employer drug testing pursuant to section 181.953 may present verification of enrollment in the patient registry as part of the employee's explanation under section 181.953, subdivision 6.

(e) A person shall not be denied custody of a minor child or visitation rights or parenting time with a minor child solely based on the person's status as a patient enrolled in the registry program under sections 152.22 to 152.37. There shall be no presumption of neglect or child endangerment for conduct allowed under sections 152.22 to 152.37, unless the person's behavior is such that it creates an unreasonable danger to the safety of the minor as established by clear and convincing evidence.

Sec. 13. **[152.33] VIOLATIONS.**

Subdivision 1. **Intentional diversion; criminal penalty.** In addition to any other applicable penalty in law, a manufacturer or an agent of a manufacturer who intentionally transfers medical cannabis to a person other than a patient, a registered designated caregiver or, if listed on the registry verification, a parent or legal guardian of a patient is guilty of a felony punishable by imprisonment for not more than two years or by payment of a fine of not more than $3,000, or both. A person convicted under this subdivision may not continue to be affiliated with the manufacturer and is disqualified from further participation under sections 152.22 to 152.37.

Subd. 2. **Diversion by patient, registered designated caregiver, or parent; criminal penalty.** In addition to any other applicable penalty in law, a patient, registered designated caregiver or, if listed on the registry verification, a parent or legal guardian of a patient who intentionally sells or otherwise transfers medical cannabis to a person other than a patient, designated registered caregiver or, if listed on the registry verification, a parent or legal guardian of a patient is guilty of a felony punishable by imprisonment for not more than two years or by payment of a fine of not more than $3,000, or both.

Subd. 3. **False statement; criminal penalty.** A person who intentionally makes a false statement to a law enforcement official about any fact or circumstance relating to the medical use of cannabis to avoid arrest or prosecution is guilty of a misdemeanor punishable by imprisonment for not more than 90 days or by payment of a fine of not more than $1,000, or both. The penalty is in addition to any other penalties that may apply for making a false statement or for the possession, cultivation, or sale of cannabis not protected by sections 152.22 to 152.37. If a person convicted of violating this subdivision is a patient or a registered designated caregiver, the person is disqualified from further participation under sections 152.22 to 152.37.

Subd. 4. **Submission of false records; criminal penalty.** A person who knowingly submits false records or documentation required by the commissioner to register as a manufacturer of medical cannabis under sections 152.22 to 152.37 is guilty of a felony and may be sentenced to imprisonment for not more than two years or by payment of a fine of not more than $3,000, or both.

Subd. 5. **Violation by health care practitioner; criminal penalty.** A health care practitioner who knowingly refers patients to a manufacturer or to a designated caregiver, who advertises as a manufacturer, or who issues certifications while holding a financial interest in a manufacturer is guilty of a misdemeanor and may be sentenced to imprisonment for not more than 90 days or by payment of a fine of not more than $1,000, or both.

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.

Sec. 14. **[152.34] NURSING FACILITIES.**

Nursing facilities licensed under chapter 144A, boarding care homes licensed under section 144.50, and assisted living facilities may adopt reasonable restrictions on the use of medical cannabis by a patient enrolled in the registry program who resides at the facility. The restrictions may include a provision that the facility will not store or maintain the patient's supply of medical cannabis, that the facility is not responsible for providing the medical cannabis for patients, and that medical cannabis be used only in a place specified by the facility. Nothing contained in this section shall require the facilities to adopt such restrictions and no facility shall unreasonably limit a patient's access to or use of medical cannabis to the extent that use is authorized by the patient under sections 152.22 to 152.37.

Sec. 15. **[152.35] FEES; DEPOSIT OF REVENUE.**

(a) The commissioner shall collect an enrollment fee of $200 from patients enrolled under this section. If the patient attests to receiving Social Security disability, Supplemental Security Insurance payments, or being enrolled in medical assistance or MinnesotaCare, then the fee shall be $50. The fees shall be payable annually and are due on the anniversary date of the patient's enrollment. The fee amount shall be deposited in the state treasury and credited to the state government special revenue fund.

(b) The commissioner shall collect an application fee of $20,000 from each entity submitting an application for registration as a medical cannabis manufacturer. Revenue from the fee shall be deposited in the state treasury and credited to the state government special revenue fund.

(c) The commissioner shall establish and collect an annual fee from a medical cannabis manufacturer equal to the cost of regulating and inspecting the manufacturer in that year. Revenue from the fee amount shall be deposited in the state treasury and credited to the state government special revenue fund.

(d) A medical cannabis manufacturer may charge patients enrolled in the registry program a reasonable fee for costs associated with the operations of the manufacturer. The manufacturer may establish a sliding scale of patient fees based upon a patient's household income and may accept private donations to reduce patient fees.

Sec. 16. **[152.36] IMPACT ASSESSMENT OF MEDICAL CANNABIS THERAPEUTIC 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;

(2) two members of the senate, one selected by the majority leader, the other selected by the minority leader;

(3) four members representing consumers or patients enrolled in the registry program, including at least two parents of patients under age 18;

(4) four members representing health care providers, including one licensed pharmacist;

(5) four members representing law enforcement, one from the Minnesota Chiefs of Police Association, one from the Minnesota Sheriff's Association, one from the Minnesota Police and Peace Officers Association, and one from the Minnesota County Attorneys Association;

(6) four members representing substance use disorder treatment providers; and

(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 be appointed by the governor under the appointment process in section 15.0597. Members shall serve on the task force at the pleasure of the appointing authority. All members must be appointed by July 15, 2014, and the commissioner of health shall convene the first meeting of the task force by August 1, 2014.

(c) There shall be two cochairs of the task force chosen from the members listed under paragraph (a). One cochair shall be selected by the speaker of the house and the other cochair shall be selected by the majority leader of the senate. The authority to convene meetings shall alternate between the cochairs.

(d) Members of the task force other than those in paragraph (a), clauses (1), (2), and (7), shall receive expenses as provided in section 15.059, subdivision 6.

Subd. 2. **Impact assessment.** The task force shall hold hearings to conduct an assessment that evaluates the impact of the use of medical cannabis and evaluates Minnesota's activities and other states' activities involving medical cannabis, and offer analysis of:

(1) program design and implementation;

(2) the impact on the health care provider community;

(3) patient experiences;

(4) the impact on the incidence of substance abuse;

(5) access to and quality of medical cannabis and medical cannabis products;

(6) the impact on law enforcement and prosecutions;

(7) public awareness and perception; and

(8) any unintended consequences.

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 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

(2) upon receipt of a cost assessment from a commissioner of a state agency, the 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. **Expiration.** The task force on medical cannabis therapeutic research does not expire.

Sec. 17. **[152.37] FINANCIAL EXAMINATIONS; PRICING REVIEWS.**

Subdivision 1. **Financial records.** A medical cannabis manufacturer shall maintain detailed financial records in a manner and format approved by the commissioner, and shall keep all records updated and accessible to the commissioner when requested.

Subd. 2. **Certified annual audit.** A medical cannabis manufacturer shall submit the results of an annual certified financial audit to the commissioner no later than May 1 of each year. The annual audit shall be conducted by an independent certified public accountant and the costs of the audit are the responsibility of the medical cannabis manufacturer. Results of the audit shall be provided to the medical cannabis manufacturer and the commissioner. The commissioner may also require another audit of the medical cannabis manufacturer by a certified public accountant chosen by the commissioner with the costs of the audit paid by the medical cannabis manufacturer.

Subd. 3. **Power to examine.** (a) The commissioner or designee may examine the business affairs and conditions of any medical cannabis manufacturer, including but not limited to a review of the financing, budgets, revenues, sales, and pricing.

(b) An examination may cover the medical cannabis manufacturer's business affairs, practices, and conditions including but not limited to a review of the financing, budgets, revenues, sales, and pricing. The commissioner shall determine the nature and scope of each examination and in doing so shall take into account all available relevant factors concerning the financial and business affairs, practices, and conditions of the examinee. The costs incurred by the department in conducting an examination shall be paid for by the medical cannabis manufacturer.

(c) When making an examination under this section, the commissioner may retain attorneys, appraisers, independent economists, independent certified public accountants, or other professionals and specialists as designees. A certified public accountant retained by the commissioner may not be the same certified public accountant providing the certified annual audit in subdivision 2.

(d) The commissioner shall make a report of an examination conducted under this section and provide a copy to the medical cannabis manufacturer. The commissioner shall then post a copy of the report on the department's Web site. All working papers, recorded information, documents, and copies produced by, obtained by, or disclosed to the commissioner or any other person in the course of an examination, other than the information contained in any commissioner official report, made under this section are private data on individuals or nonpublic data, as defined in section 13.02.

Sec. 18. Minnesota Statutes 2012, section 256B.0625, subdivision 13d, is amended to read:

Subd. 13d. **Drug formulary.** (a) The commissioner shall establish a drug formulary. Its establishment and publication shall not be subject to the requirements of the Administrative Procedure Act, but the Formulary Committee shall review and comment on the formulary contents.

(b) The formulary shall not include:

(1) drugs, active pharmaceutical ingredients, or products for which there is no federal funding;

(2) over-the-counter drugs, except as provided in subdivision 13;

(3) drugs or active pharmaceutical ingredients used for weight loss, except that medically necessary lipase inhibitors may be covered for a recipient with type II diabetes;

(4) drugs or active pharmaceutical ingredients when used for the treatment of impotence or erectile dysfunction;

(5) drugs or active pharmaceutical ingredients for which medical value has not been established; ~~and~~

(6) drugs from manufacturers who have not signed a rebate agreement with the Department of Health and Human Services pursuant to section 1927 of title XIX of the Social Security Act~~.~~; and

(7) medical cannabis as defined in section 152.22, subdivision 6.

(c) If a single-source drug used by at least two percent of the fee-for-service medical assistance recipients is removed from the formulary due to the failure of the manufacturer to sign a rebate agreement with the Department of Health and Human Services, the commissioner shall notify prescribing practitioners within 30 days of receiving notification from the Centers for Medicare and Medicaid Services (CMS) that a rebate agreement was not signed.

Sec. 19. **RULES; ADVERSE INCIDENTS.**

(a) The commissioner of health shall adopt rules to establish requirements for reporting incidents when individuals who are not authorized to possess medical cannabis under Minnesota Statutes, sections 152.22 to 152.37, are found in possession of medical cannabis. The rules must identify professionals required to report, the information they are required to report, and actions the reporter must take to secure the medical cannabis.

(b) The commissioner of health shall adopt rules to establish requirements for law enforcement officials and health care professionals to report incidents involving an overdose of medical cannabis to the commissioner of health.

(c) Rules must include the method by which the commissioner will collect and tabulate reports of unauthorized possession and overdose.

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 1, 2016.

Sec. 21. **APPROPRIATIONS; MEDICAL CANNABIS RESEARCH.**

Subdivision 1. **Health Department.** $2,795,000 is appropriated in fiscal year 2015 from the general fund to the commissioner of health for the costs of administering Minnesota Statutes, sections 152.22 to 152.37. The base for this appropriation is $829,000 in fiscal year 2016 and $728,000 in fiscal year 2017.

Subd. 2. **Legislative Coordinating Commission.** $24,000 is appropriated in fiscal year 2015 from the general fund to the Legislative Coordinating Commission to administer the task force on medical cannabis therapeutic research under Minnesota Statutes, section 152.36, and for the task force to conduct the impact assessment on the use of cannabis for medicinal purposes.

Subd. 3. **Health Department.** $100,000 is appropriated in fiscal year 2015 from the state government special revenue fund to the commissioner of health for the costs of implementing Minnesota Statutes, sections 152.22 to 152.37. The base for this appropriation is $834,000 in fiscal year 2016 and $729,000 in fiscal year 2017.

Sec. 22. **EFFECTIVE DATE.**

Sections 1 to 21 are effective the day following final enactment.