HOUSE RESEARCH

Bill Summary

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Overview

This amendment creates a patient registry under the Department of Health relating to the therapeutic use of medical cannabis. It provides for the use of medical cannabis in limited forms for certain qualifying medical conditions and regulates the distribution and manufacture of the medical cannabis products. It also creates a task force to conduct an impact assessment on medical cannabis therapeutic research and provides for certain criminal and civil protections for parties involved in the registry program.

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1 **Medical Cannabis Therapeutic Research Study.** Adds § 1552.22.

Subd. 1. Definitions. (a) Defines terms used in this section.

(b) "Commissioner" is defined as the commissioner of health.

(c) "Health care practitioner" is defined as a doctor, physician assistant, or advanced practice nurse, licensed in Minnesota, who has the primary responsibility of care and treatment of the qualifying medical condition of the patient.

(d) "Health records" is defined as health records as defined in section 144.291 (Minnesota Health Records Act).

(e) "Medical cannabis" is defined as the flowers of any species of the genus cannabis plant which contain a chemical composition determined to likely be medically beneficial by the commissioner and delivered only in the form of: (1) liquid, including oils; (2) pill; (3) vaporized delivery method using only liquid or oil; or (4) any other

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method approved by the commissioner but which does not include smoking.

(f) "Medical cannabis manufacturer" or "manufacturer" is defined as an entity registered with the commissioner to, among other things, cultivate, prepare, and supply medical cannabis, delivery devices, and education materials to patients in the registry program.

(g) "Medical cannabis product" is defined as medical cannabis, delivery devices, or related supplies and education materials.

(h) "Patient" is defined as a Minnesota resident who has been diagnosed with a qualifying medical condition and who has met other requirements necessary for participation in the registry program.

(i) "Patient registry number" is defined as a unique identification number assigned to a patient by the commissioner after the patient has been enrolled in the registry program.

(j) "Registered designated caregiver" is defined as a person who meets listed requirements in order to assist a patient enrolled in the registry program in the administration of medical cannabis.

(k) "Registry program" is defined as the patient registry established under this section.

(l) "Registry verification" is defined as the verification provided by the commissioner to the health care practitioner and the manufacturer that a patient has been enrolled in the registry program and contains listed information.

(m) Qualifying medical condition" is defined as the diagnosis of one of the following conditions:

- Cancer
- Glaucoma
- HIV/AIDS
- Tourette's syndrome
- Amyotrophic lateral sclerosis
- Seizures, including those characteristic of epilepsy
- Severe and persistent muscle spasms, including those characteristic of multiple sclerosis
- Crohn's disease
- Any other medical condition or its treatment approved by the commissioner

Subd. 2. Limitations. States this section does not permit and does not prevent civil, criminal, or other penalties for the listed activities, including, but not limited to, possessing or engaging in the use of medical cannabis in certain locations, vaporizing medical cannabis in any public place or where the smoke would be inhaled by a nonpatient minor child, and operating a monitor vehicle while under the influence of

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medical cannabis. Also adds punishments for possession of use on a school van or on the grounds of a child care facility or home daycare.

Subd. 3. Federally approved clinical trials. Allows the commissioner to prohibit enrollment of a patient in the registry program if the patient is enrolled in a federally-approved clinical trial for the treatment of a qualifying condition with medical cannabis and requires the commissioner to inform patients of federally-approved clinical trials.

Subd. 4. Commissioner duties. (a) Requires the commissioner to, among other things, register and provide regulations for one in-state manufacturer for the production of all medical cannabis products by December 1, 2014 and to register a new manufacturer or reregister the same manufacturer by December 1 of each year. Allows the commissioner to obtain federally-sourced medical cannabis instead of registering a manufacturer if an adequate supply of the federally-sourced medical cannabis is obtained by August 1, 2014. Requires the commissioner to require the manufacturer to supply medical cannabis products to patients by July 1, 2015, and comply with other requirements, as a condition of registration.

(b) Requires the commissioner to consider factors when determining which manufacturer to register, including, but not limited to, the qualifications of employees, the technical expertise of the manufacturer, and the long-term financial stability of the manufacturer.

(c) Requires the commissioner to require the manufacturer to contract with an independent laboratory, approved by the commissioner, for purposes of testing medical cannabis produced by the manufacturer and requires the laboratory to report testing results to the commissioner.

(d) Requires the commissioner to review and publicly report existing medical and scientific literature on the range of recommended dosages for each condition and the range of chemical compositions likely to be medically beneficial for each condition. Requires the information to be available by December 1, 2014, and allows the commissioner to consult with an independent laboratory. Requires the commissioner to consult with the manufacturer on an annual basis to determine which medical cannabis products will be offered by the manufacturer and to publish a list of those products on the Health Department Web site.

(e) Requires the commissioner to complete rulemaking necessary for distribution to begin by July 1, 2015 and have notice published of those rules prior to January 1, 2015.

(f) Requires the commissioner to advise the public and the co-chairs of the task force on medical cannabis therapeutic research if the commissioner is unable to meet deadlines and provides for deadline extensions.

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(g) Requires the commissioner to provide regular updates to the task force on changes in federal law regarding medical cannabis.

(h) Allows the commissioner to submit medical research based on data collected to any federal agency with authority over medical cannabis to demonstrate the efficacy of medical cannabis for treating qualifying medical conditions.

Subd. 5. Rulemaking. Allows the commissioner to adopt rules to implement this section and allows rules for which notice is published before January 1, 2015, to use the expedited rulemaking process.

Subd. 6. Patient registry program established. (a) Requires the commissioner of health to establish a patient registry program to evaluate data on, among other things, effective treatment options for the purpose of reporting on the benefits, risks, and outcomes regarding the use of medical cannabis on a patient's qualifying medical condition.

(b) Requires the commissioner to:

(1) give notice and explanation of the registry program to health care practitioners;

(2) allow participation in the registry program by each health care practitioner in the state who meets qualifications and requests to participate in the registry program;

(3) provide explanatory information to health care practitioners;

(4) create a certification for the health care practitioner to use when certifying a patient's qualifying medical condition and include an option for the health care practitioner to certify that the patient, as the result of the patient's disability, is unable to self-administer medication;

(5) supervise the participation of the health care practitioner in conducting patient treatment and health records reporting;

(6) develop safety criteria for patients; and

(7) conduct research and studies based on data from submitted health records.

(c) Requires the commissioner to develop a patient application for enrollment in the registry program that includes listed information, including, but not limited to, a health care practitioner's certification of a diagnosis for a qualifying medical condition.

(d) Requires the commissioner to register a single designated caregiver if the patient's health care practitioner certified that the patient has a disability that prevents the patient from being able to self-administer medication and lists conditions of registration for the caregiver, including, but not limited to, agreement to supervise only one patient.

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(e) Requires the commissioner to develop a disclosure form that contains information on, among other things, the patient's agreement to meet the requirements of patient duties.

(f) Requires the commissioner to enroll the patient in the registry program after receipt of the application and disclosure form and allows denial of enrollment under certain circumstances, including, but not limited to, the patient's previous removal from the registry program for violations of patient duties or the patient providing false information.

(g) Requires the commissioner to provide written notice to the patient of the reason for denial of enrollment into the patient registry.

(h) States denial of enrollment is a final decision and is subject to judicial review under the Administrative Procedure Act pursuant to chapter 14.

(i) States a patient's enrollment may only be revoked for a patient's violation of a requirement of patient duties (subdivision 9).

(j) Requires the commissioner to develop a registry verification to provide to the health care provider and the manufacturer that includes, among other things, the patient's name, the patient's qualifying condition, and the names of the health care provider and, if applicable, the registered qualifying caregiver or parent.

(k) Provides for a procedure for the commissioner to add a delivery form or qualifying medical condition that includes the legislature's ability to prevent the addition.

(l) States nothing in this section requires medical assistance or MinnesotaCare to reimburse for costs associated with the medical use of cannabis but that reimbursement must continue for covered services related to the recipient's qualifying medical condition.

(m) States that the establishment of the registry program is not intended in any manner to condone or promote the illicit recreational use of marijuana.

Subd. 7. Health care practitioner duties. (a) Requires a health care practitioner, prior to patient enrollment in the registry program, to, among other things, determine whether the patient suffers from a qualifying medical condition and whether the patient has a disability which prevents the patient from self-administering medication and agree to continue treatment of the patient's qualifying medical condition and report findings to the commissioner.

(b) Requires the health care practitioner, after notice that the patient has been enrolled in the registry program, to, among other things, report health records to the commissioner in accordance with paragraph (c).

(c) States that data collected and reported to the patient registry are health records under section 144.291 (Minnesota Health Records Act) and are private data. Allows

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the data to be used or reported in an aggregated, non-identifiable form as part of a scientific, peer-reviewed publication or in the creation of summary data.

(d) States that nothing in this section requires a health care practitioner to enroll a patient in the registry.

Subd. 8. Manufacturer of medical cannabis duties. (a) Requires the manufacturer to provide a reliable and ongoing supply of medical cannabis for the registry program.

(b) Requires all cultivation, harvesting, manufacturing, and packing of cannabis to be in an enclosed, locked facility, at the address of the manufacturer provided during the registration process.

(c) Allows the manufacturer to operate up to two satellite distribution centers located throughout the state. Requires the manufacturer to disclosure the proposed locations of the centers during the registration process and does not allow cannabis in any form other than those allowed under this section. Prohibits, among other things, cultivation and harvesting at a distribution site. States that all distribution centers are subject to the same requirements applying to the manufacturer.

(d) Requires the manufacturer to produce medical cannabis with the chemical compositions determined by the commissioner.

(e) Requires the manufacturer to contract with a laboratory, subject to the commissioner's approval and additional requirements, for purposes of testing medical cannabis. Requires the costs for testing to be paid by the manufacturer.(f) Requires the manufacturer to process the cannabis plant into liquid, including oil, pill, or vaporized delivery method using a liquid or oil, prior to distribution.

(g) Requires the manufacturer to require any employee who is a licensed pharmacist be the only employees to distribute medical cannabis to a patient.

(h) Requires the manufacturer to only distribute medical cannabis products to the patient or, if the patient is under age 18, to the patient's parent or legal guardian.

(i) Requires the manufacturer, prior to distribution, to, among other things, verify the patient's identity and registration in the program, have an employee who is a licensed pharmacist determine dosage for the individual patient, properly label each product, and ensure distribution is only for a 30-day supply of the dosage determined for that patient.

(j) Requires the manufacturer to deliver medical cannabis products to a patient who has a registered designated caregiver and provides for verification procedures upon delivery. Prohibits the manufacturer from distributing medical cannabis products to a registered designated caregiver at any place, including the premises of the manufacturer, other than the patient's primary place of residence.

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(k) Requires the manufacturer to submit a monthly report to the commissioner containing information on, among other things, the amount and dosages distributed and the chemical composition of the medical cannabis.

(l) Lists the requirements for the manufacturer's operating documents.

(m) Prohibits the manufacturer from, among other things, having any financial relationship with a health care practitioner.

(n) Prohibits the manufacturer from allowing any person to consume cannabis on the property of the manufacturer.

(o) States the manufacturer is subject to reasonable inspection by the commissioner.

(p) States for purposes of this section, the manufacturer is not subject to the Board of Pharmacy licensure or regulatory requirements under chapter 151.

(q) Prohibits a manufacturer from employing anyone under the age of 18 or someone who has a disqualifying felony offense, and defines a disqualifying felony offense. Requires employees of the manufacturer to submit a completed criminal history records check both to Minnesota and the FBI.

Subd. 9. Patient duties. (a) Requires the patient to apply to the commissioner for enrollment in the registry program and pay an annual fee.

(b) Requires the patient, as a condition of enrollment, to continue to receive regularly scheduled treatment for their qualifying medical condition from the health care practitioner and report changes in their qualifying medical condition to the health care practitioner.

Subd. 10. Data practices. (a) States that government data in patient's files maintained by the commissioner or health care practitioner, and data submitted to or by the medical cannabis manufacturer, are private data or nonpublic data. Allows the data to be used for purposes complying with chapter 13 and complying with a request from the legislative auditor. Applies section 13.05, subdivision 11 for the agreement entered into between the commissioner and a medical cannabis manufacturer.

(b) Prohibits not public data maintained by the commissioner from being used for any purpose not provided in this section and prohibits it from being combined or linked in any manner with any other list, dataset, or database.

Subd. 11. Protections for registry program participation; criminal and civil. (a) States there is a presumption that a patient enrolled in the registry program is engaged in the authorized use of medical cannabis.

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

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(c) States the following, subject to the conditions listed in subdivision 2, are not violations under chapter 152:

(1) use or possession of medical cannabis products by a patient, or possession by the parent or guardian of a patient under age 18;

(2) possession of medical cannabis products by a registered designated caregiver but only if the caregiver is in possession within the primary residence of the patient;

(3) possession, dosage determination, administering, or dispensing medical cannabis by the manufacturer, employees of the manufacturer, the laboratory contracted by the manufacturer for testing of medical cannabis products, or employees of the laboratory; and

(4) possession of medical cannabis products by any person while carrying out the duties required under this section.

(d) States medical cannabis obtained pursuant to this section and associated property is not subject to forfeiture under sections 609.531 to 609.5316.

(e) Precludes the commissioner, the commissioner's staff, the commissioner's agents or contractors, and any health care practitioner from being subject to any civil or disciplinary penalties by a business, occupational, or professional licensing board or entity based solely for participation in the registry program. States nothing prohibits a licensing board from sanctioning for actions outside of those actions allowed under this section.

(f) States that the commissioner, the governor of Minnesota, or employees of a state agency may not be held civilly or criminally liable for certain occurrence caused by any act or omission while acting within the scope of office or employment under this section.

(g) States that federal, state, and local law enforcement are prohibited from accessing the registry except when acting pursuant to a valid search warrant.

(h) Prohibits the commissioner or any public employee from releasing date about an individual contained in any report, document, or registry or any information obtained about a patient participating in the program, except as provided in this section. Prohibits any information obtained about a patient from being used in a criminal proceeding unless the information was independently obtained or in connected with a proceeding involving a violation of this section.

(i) States any person who violates paragraph (g) or (h) is guilty of a gross misdemeanor.

Subd. 12. Discrimination prohibited. (a) Prohibits a school or landlord from refusing to enroll or lease to a person based on the person's status as a patient in the registry program, unless failing to do so would violate federal law or regulation or cause the school or landlord to lose monetary or licensing-relating benefits under federal law or regulation.

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(b) States that the use of medical cannabis is considered an authorized use of a medication and does not constitute the use of an illicit substance for purposes of medical care, including organ transplants.

(c) Prohibits an employer from discriminating in hiring, termination, or other terms of employment based on a person's status as a patient enrolled in the registry program or a positive drug test, unless the person was impaired by medical cannabis on the premises of employment or during the hours of employment. The prohibition on discrimination exists unless a failure to do so would violate federal law or regulation or cause the employer to lose monetary or licensing-related benefits under federal law or regulation.

(d) Prohibits denial of custody, visitation rights, or parenting time based on a person's status as a patient in the registry program. Prohibits a presumption of neglect or child endangerment unless, as established by clear and convincing evidence, the person's behavior creates an unreasonable danger to a minor's safety.

Subd. 13. Fees; deposit of revenue. (a) Requires the commissioner to collect an annual enrollment fee of $200 from an enrolled patient, or $50 if the patient attests to receiving Social Security disability, Supplemental Security Insurance payments, or is enrolled in medical assistance or MinnesotaCare.

(b) Requires the commissioner to collect a $20,000 application fee from any manufacturer applying for registration and to credit the funds to the state government special revenue fund. Requires a refund of $19,000 to any manufacturer who is not selected for registration.

(c) Requires the commissioner to collect an annual fee from the manufacturer equal to the cost of regulating and inspecting the manufacturer that year. States the funds will be credited to the state government special revenue fund.

(d) Allows the manufacturer to charge patients a reasonable fee for costs associated with the operations of the manufacturer. Allows the manufacturer to charge a fee for delivery services but only to those patients who receive the delivery service. Allows the manufacturer to establish a sliding scale of patient fees based on a patient's household income and allows the manufacturer to accept private donations.

Subd. 14. Nursing facilities. Allows nursing facilities or boarding care homes to adopt reasonable restrictions on the use of medical cannabis by persons receiving inpatient services. States that these facilities are not required to adopt restrictions but may not unreasonably limit a qualifying patient's access to or use of medical cannabis.

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2 Impact Assessment of Medical Cannabis Therapeutic Research. Adds § 152.24.

Subd. 1. Task force on medical cannabis therapeutic research. (a) Establishes a 23 member task force to conduct an impact assessment consisting of listed members.

(b) States that certain task members will be appointed by the governor and that all members serve at the pleasure of the appointing authority.

(c) Requires there to be two co-chairs of the task force with one being selected by the speaker of the house and the other selected by the majority leader of the senate. States that the expense reimbursement for members of the task force is governed by section 15.059.

Subd. 2. Impact assessment. Requires the task force to hold hearings to conduct the impact assessment that must evaluate Minnesota activities and other states' activities involving medical cannabis and offer analysis of topics including, but not limited to, the impacts on the health care providers, the incidence of substance abuse, and law enforcement and prosecution.

Subd. 3. Reports to the legislature. (a) Requires the co-chairs to submit the following reports to the chairs and ranking minority members of certain legislative committees:

- by February 1, 2015, a report on the design and implementation of the registry program; and
- every two years thereafter, a complete report on the impact assessment.

(b) Allows the task force to make recommendations to the legislature on whether to add or remove conditions from the list of qualifying medical conditions.

Subd. 4. Expiration. States the task force does not expire.

3 Financial examinations; pricing reviews. Adds § 152.25.

Subd. 1. Financial records. Requires a manufacturer to maintain detailed financial records in a format approved by the commissioner and keep records updated and accessible to the commissioner when requested.

Subd. 2. Certified annual audit. Requires the manufacturer to submit the results of an annual certified financial audit to the commissioner no later than May 1 of each year and states requirements for the audit.

Subd. 3. Power to examine. (a) Allows the commissioner or a designee to examine the business affairs and conditions of the medical cannabis manufacturer.

(b) States the scope of the examination and requires the commissioner to determine the nature and scope of each examination. Requires the costs of the examination to be paid by the manufacturer.

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(c) Allows the commissioner to retain certain specialists as designees.

(d) Requires the commissioner to make a report on the examination and provide the report to the manufacturer and post a copy on the department's website. States that information other than the official report is not public data.

4 **Drug formulary.** Amends § 256B.0625, subdivision 13d. Adds medical cannabis to the drug formulary.

5 **Rules; adverse incidents.** (a) Requires the commissioner to adopt rules to establish requirements for reporting incidents when individuals who are not authorized under this act are in possession of medical cannabis and states conditions for those rules.

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

(c) Requires rules to include the method by which the commissioner will collect data and tabulate reports.

6 **Intractable pain.** Requires the commissioner to consider the addition of intractable pain to the list of qualifying medical conditions prior to considering any other new qualifying medical conditions. Requires the commissioner to report findings on the need for adding intractable pain to the list by no later than July 1, 2016.

7 **Appropriations; Medical Cannabis Therapeutic Research Study.** Provides the following appropriations:

Subd. 1. Health Department. $2,795,000 in fiscal year 2015 from the general fund to the commissioner of health for the costs of administered section 152.22. States that the base for the appropriation is $829,000 in fiscal year 2016 and $728,000 in fiscal year 2017.

Subd. 2. Legislative Coordinating Commission. $24,000 in fiscal year 2015 from the general fund to the legislative coordinating commission for administration of the task force on medical cannabis therapeutic research and for the task force to conduct the impact assessment.

Subd. 3. Health Department. $24,000 in fiscal year 2015 from the state government special revenue fund to the commissioner of health for the costs of implementing section 152.22. States the base for the appropriation is $734,000 in fiscal year 2016 and $722,000 in fiscal year 2017.

8 **Effective date.** Sections 1 to 7 are effective the day following final enactment.