# HOUSE RESEARCH

## Bill Summary

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## Overview

This amendment creates clinical trials regarding 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 clinical trials.

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**1** **Medical Cannabis Therapeutic Research Act.** Adds § 152.22.

**Subd. 1. Findings and purpose.** States that the legislature finds, among other things, that scientific literature indicates promise for the use of medical cannabis and that strictly controlled experimentation regarding its therapeutic use is necessary and desirable.

**Subd. 2. Definitions.** (a) Defines terms used in the section.

(b) "Clinical investigator" is defined as a doctor, physician assistant, or advanced practice nurse, licensed in Minnesota.

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

(d) "Medical cannabis" is defined as the flowers of any species of the genus cannabis plant with a chemical consistency of cannabidiols and tetrahydrocannabinols determined to be medically beneficial by a principal investigator and only in the form of (1) liquid, including but not limited to, oil; (2) pill; (3) vaporized delivery method,

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not including smoking, with in-person supervision by a clinical investigator; or (4) any other method approved by the commissioner.

(e) "Medical cannabis manufacturer" is defined as an entity under contract with the commissioner to, among other things, cultivate, prepare, and supply medical cannabis, delivery devices, and education materials to patients of the clinical trial.

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

(g) "Principal investigator" is defined as an individual or organization responsible for, among other things, the medical and scientific aspects of the research.

(h) "Program" is defined as the clinical trial research program.

(i) "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. 3. Clinical trials administration.** (a) Requires the commissioner to contract with one or more principal investigators to conduct the clinical trials. As a condition of the contract, the commissioner shall require the principal investigator to, among other things, begin testing patients by July 1, 2015.

(b) Allows the principal investigator to contract with qualified entities for assistance.

(c) Requires the commissioner to provide the parents of patients under age 18 the ability to opt-out of placebo trials for the minor patient.

(d) Requires the commissioner to fulfill the responsibilities of the principal investigator if there is no principal investigator for one or more of the qualifying medical conditions.

(e) Allows the commissioner to approve Minnesota residents' participation in federally approved clinical trials so long as the clinical trials for all other qualifying medical conditions continue to exist.

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**Subd. 4. Principal investigator duties.** Requires the principal investigator to:

(1) give written notice of the program to every health care provider in the state;

(2) allow each clinical investigator with certain qualifications to conduct clinical trials;

(3) provide explanatory information to clinical investigators and inform and counsel patients involved in the program;

(4) supervise the clinical investigators;

(5) obtain medical cannabis from the medical cannabis manufacturer;

(6) determine the medically beneficial chemical consistency of cannabidiols and tetrahydrocannabinols for each qualifying condition;

(7) regulate storage and distribution of medical cannabis products;

(8) distribute medical cannabis products to clinical investigators that are properly labeled for each individual patient;

(9) develop safety criteria for patients to prevent the patient from doing a task which would constitute negligence or professional malpractice;

(10) submit period reports as determined by the commissioner on the number of patients involved and results of the program;

(11) submit reports on intermediate or final research to the commissioner, legislature, and major scientific journals; and

(12) otherwise comply with this section.

**Subd. 5. Clinical investigator duties.** (a) Requires the clinical investigator to:

(1) enroll patients with qualified medical conditions in the trial;

(2) participate in the trials under the supervision of the principal investigator;

(3) provide explanatory information from the principal investigator to the patients;

(4) advise patients and parents of patients under the age of 18 of any nonprofit patient support groups;

(5) determine the proper dosage of medical cannabis for each individual patient, in consultation with the patient and the principal investigator;

(6) obtain all medical cannabis products from the principal investigator;

(7) ensure the medical cannabis products are properly labeled by the principal investigator;

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(8) distribute properly labeled medical cannabis products to patients;

(9) provide in-person supervision if a patient is using a vaporized delivery method;

(10) report findings to the principal investigator; and

(11) otherwise comply with the requirements developed by the supervising principal investigator.

(b) Requires that a patient's enrollment not be denied based on use of medical cannabis in a jurisdiction outside of Minnesota. Also requires that enrollment be denied only if the patient has not been diagnosed with a qualifying medical condition.

**Subd. 6. Manufacturer of medical cannabis.** (a) Requires the commissioner to contract with one manufacturer, located in Minnesota, for the production of all medical cannabis products by December 1, 2014. Allows the commissioner to obtain federally-sourced medical cannabis instead of contracting with a manufacturer if an adequate supply of the federally-sourced medical cannabis is obtained by August 1, 2014. Federally-sourced medical cannabis may also be obtained after December 1, 2014 in addition to medical cannabis from the in-state manufacturer.

(b) Requires the operating documents of the manufacturer to include procedures for oversight and accurate record keeping.

(c) Requires the manufacturer to implement appropriate security measures.

(d) Requires all cultivation, harvesting, manufacturing, and packing of cannabis to be in an enclosed, locked facility at the manufacturer's address as given during the contracting process.

(e) Requires the manufacturer to process the cannabis plant into an allowable form prior to distribution to the principal investigator.

(f) Prohibits the manufacturer from sharing office space with or referring patients to a practitioner.

(g) Prohibits the manufacturer from permitting any person to consume cannabis on the property of the manufacturer.

(h) States that the manufacturer is subject to reasonable inspection by the commissioner after reasonable notice is given.

(i) Prohibits the manufacturer from having an employee or agent under age 21.

(j) Requires all products manufactured to be tested for content, contamination, and consistency by a certified laboratory.

(k) Requires the manufacturer to produce medical cannabis with a chemical consistency of cannabidiols and tetrahydrocannabinols as determined by the principal

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investigator.

(l) States the manufacturer does not need to be licensed under section 151.252 or 151.47 for purposes of this section only.

**Subd. 7. Confidentiality.** (a) Classifies data in patient files with both the clinical investigator and the principal investigator, and data submitted to or by the medical cannabis manufacturer as private or nonpublic as defined in section 13.02.

(b) Precludes the commissioner from using data for any purpose not listed in section 152.22 and precludes data being combined or linked in any manner with other lists or databases.

**Subd. 8. Protections for clinical trial participation; criminal and civil.** (a) States there is a presumption that a patient enrolled in a clinical trial 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.

(c) States the following are not violations under Chapter 152:

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

(2) possession, prescribing the use of, administering, or dispensing medical cannabis by the principal or clinical investigator;

(3) possession or sale of medical cannabis by a pharmacy or the medical cannabis manufacturer; 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 a principal or clinical investigator from being subject to any civil or disciplinary penalties by a business, occupational, or professional licensing board or entity based solely on the investigator's participation in a clinical trial. States nothing prohibits a licensing board from sanctioning the investigator for actions outside of those actions allowed under this section.

(f) States that for purposes of this section, medical cannabis is moved from Schedule I contained in section 152.02, subdivision 2, and inserted in Schedule II contained in section 152.02, subdivision 3.

**Subd. 9. Discrimination prohibited.** (a) Prohibits a school or landlord from

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refusing to enroll or lease to a person based on the person's status as a patient in a clinical trial, 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.

(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 a clinical trial 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 a clinical trial. 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. 10. Fees.** Allows the commissioner to set reasonable application and renewal fees to be paid to the commissioner by the patient that cover the fees incurred in manufacturing medical cannabis by the medical cannabis manufacturer. States fees must be deposited in the state government special revenue fund and are appropriated annually to the commissioner to reimburse the manufacturer for cost. Requires the commissioner to establish a sliding scale based on the qualifying patient's household income and allows the commissioner to accept private donations.

**Subd. 11. Exemption from taxes.** States that fees paid under subdivision 9 are not subject to taxes under section 295.52 (tax on legend drugs). States that sale to or use of medical cannabis products by a principal or clinical investigation are not subject to taxes under chapter 297A (general sales and use taxes). Provides that these exemptions expire June 30, 2019.

**Subd. 12. 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.

**2 Impact Assessment of Medical Cannabis Therapeutic Research.**

**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.

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(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 clinical trial program;
- by February 1, 2016, a final report on the impact assessment; and
- by June 30, 2019, a review and assessment of the clinical trial results

(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 will expire on June 30, 2019 or upon the conclusion of the clinical trial, whichever is later.

**3** **Appropriations; Medical Cannabis Therapeutic Research Act.** Provides for the following appropriations:

(a) $1,100,000 in fiscal year 2016 and $1,100,000 in fiscal year 2017 from the general fund to the commissioner of health for grants to the principal investigators for purposes of conducting the clinical trials.

(b) $450,000 in fiscal year 2015 from the general fund to the commissioner of health for the costs of administering section 152.22. States funds are available until June 30, 2019.

(c) $50,000 in fiscal year 2015 from the general fund to the Legislative Coordinating Commission to administer the task force and for the task force to conduct the impact assessment. States the funds are available until the expiration of the task force.

**4** **Effective date.** Sections 1 and 2 are effective July 1, 2014.