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HOUSE OF REPRESENTATIVES

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Senate Author(s): Tomassoni
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A bill for an act

relating to health; adopting the Medical Cannabis Therapeutic Research Act; requiring clinical trials on the therapeutic use of medical cannabis; setting standards for clinical trials; requiring the commissioner to contract with one manufacturer for medical cannabis products; requiring an impact assessment of medical cannabis therapeutic research; setting fees; requiring reports; appropriating money; amending Minnesota Statutes 2012, section 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. **[152.22] MEDICAL CANNABIS THERAPEUTIC RESEARCH ACT.**

Subdivision 1. **Findings and purpose.** (a) The legislature finds that scientific literature indicates promise for medical cannabis in alleviating certain intractable medical conditions under strictly controlled medical circumstances.

(b) The legislature also finds that further research and strictly controlled experimentation regarding the therapeutic use of medical cannabis is necessary and desirable. The intent of this section is to establish clinical trials to investigate and report on the therapeutic effects of medical cannabis. The intent of the legislature is to allow the greatest possible access to patients with a qualifying medical condition residing in Minnesota who meet protocol requirements for these clinical trials. The establishment of this research program is not intended in any manner whatsoever to condone or promote the illicit recreational use of marijuana.

Subd. 2. **Definitions.** (a) For purposes of this section, the following terms have the meanings given.

(b) "Clinical investigators" means a Minnesota licensed doctor of medicine, a Minnesota licensed physician assistant acting within the scope of authorized practice, or a Minnesota licensed advance practice registered nurse.

(c) "Commissioner" means the commissioner of health.

(d) "Medical cannabis" means the flowers of any species of the genus cannabis plant, or any mixture or preparation of them, including extracts and resins which contain a chemical consistency of cannabidiols and tetrahydrocannabinols determined to be medically beneficial by the principal investigator under subdivision 4 or by the commissioner under subdivision 3, paragraph (d), and that is delivered in the form of:

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

(2) pill; or

(3) vaporized delivery method, which does not include smoking, with in-person supervision by a clinical investigator, as specified under subdivision 5.

(e) "Medical cannabis manufacturer" means an entity under contract with the commissioner to cultivate, acquire, manufacture, possess, prepare, transfer, transport, supply, or dispense medical cannabis, delivery devices, or related supplies and educational materials to patients with a qualifying medical condition who are participating in a clinical trial.

(f) "Medical cannabis product" means medical cannabis as defined in paragraph (d) and any delivery device or related supplies and educational materials used in the administration of a medical cannabis clinical trial for a patient with a qualifying medical condition.

(g) "Principal investigator" means an individual or organization with responsibility for the medical and scientific aspects of the research, development of protocol, and contacting and qualifying the clinical investigators in the state, and duties as provided in subdivision 3, paragraph (d).

(h) "Program" means the clinical trial research program established pursuant to this section.

(i) "Qualifying medical condition" means a diagnosis of the following conditions:

(1) cancer;

(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; or

(9) any other medical condition or its treatment approved by the commissioner.

Subd. 3. **Clinical trials administration.** (a) The commissioner of health shall contract with one or more principal investigators to conduct clinical trials for Minnesota resident patients with a qualifying medical condition regarding the therapeutic use of medical cannabis. As a condition of the contract, the commissioner shall require a principal investigator to:

(1) begin the patient testing phase of a clinical trial by July 1, 2015;

(2) develop guidelines and protocols necessary to establish empirical bases for the evaluation of medical cannabis as a medically recognized therapeutic substance. The guidelines and protocols shall ensure that stringent security and record-keeping requirements for the clinical trial are met and that participants in the program meet research standards;

(3) disclose to all patients the experimental nature of the program and the possible risks and side effects of the proposed treatment and shall provide the program applicants with the Tennessen warning as required by section 13.04, subdivision 2; and

(4) comply with the requirements of subdivision 4.

(b) The principal investigator may contract with additional qualified entities to assist in fulfilling the requirements of this section.

(c) The commissioner shall provide an option to opt out of any placebo trials for patients under age 18 with a qualifying condition. The decision to opt out of placebo trials under this paragraph may only be made by a patient's parent or legal guardian.

(d) If a principal investigator is unavailable to evaluate one or more of the qualifying medical conditions, the commissioner shall fulfill the responsibilities of the principal investigator described in this section for that qualifying medical condition.

(e) The commissioner may approve the participation of Minnesota residents in a federally approved clinical trial testing the effects of medical cannabis on one or more of the qualifying medical conditions listed in subdivision 2, paragraph (i), subject to the continuance of clinical trials for all other qualifying medical conditions.

(f) Nothing in this section requires the medical assistance and MinnesotaCare programs to reimburse an enrollee or a provider for costs associated with the medical use of marijuana.

Subd. 4. **Principal investigator duties.** A principal investigator shall:

(1) give notice of the program to every health care provider in the state who is eligible to serve as a clinical investigator as defined in subdivision 2, paragraph (b), and explain the purposes and requirements of the program;

(2) allow each clinical investigator in the state who meets or agrees to meet the principal investigator's requirements, has adequate institutional support, and who requests to participate, to be included in the research program as a clinical investigator to conduct the clinical trials;

(3) provide explanatory information and assistance to each clinical investigator in understanding the nature of therapeutic use of medical cannabis within program requirements, including the informed consent document contained in the protocol, and inform and counsel patients involved in the program regarding the appropriate use and the effects of therapeutic use of medical cannabis;

(4) supervise the participation of the clinical investigator in conducting the clinical trials;

(5) obtain medical cannabis for this clinical trial from the medical cannabis manufacturer which meets the requirements in subdivision 6;

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

(7) regulate the proper storage and distribution of medical cannabis products to patients with a qualifying condition, including monitoring the chain of custody;

(8) distribute medical cannabis products to clinical investigators for each individual patient after ensuring that the medical cannabis products are properly labeled for each individual patient pursuant to section 151.212 and related rules;

(9) develop safety criteria for patients with a qualifying 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;

(10) submit periodic reports as determined by the commissioner on the numbers of patients involved in the program and the results of the program;

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

(12) otherwise comply with the provisions of this section.

Subd. 5. **Clinical investigator duties.** (a) A clinical investigator shall:

(1) enroll patients with a qualifying medical condition in the clinical trials;

(2) participate in the clinical trials under the guidance and supervision of a principal investigator;

(3) provide explanatory information from the principal investigator to patients with qualifying medical conditions;

(4) advise patients and parents or legal guardians of patients under age 18 of the existence of any nonprofit patient support groups or organizations;

(5) determine, in consultation with the patients, parents or legal guardians of patients under age 18, and the principal investigator, the proper dosage of medical cannabis for each individual patient;

(6) obtain from the principal investigator all medical cannabis products needed for each individual patient;

(7) ensure that medical cannabis products are properly labeled by the principal investigator for each individual patient prior to distribution to the patient;

(8) distribute properly labeled medical cannabis products to patients or provide the patient with information and instructions on obtaining properly labeled medical cannabis from a qualified employee of a principal investigator with responsibility for distributing medical cannabis under subdivision 4, clause (8);

(9) provide in-person supervision for the administration of any vaporized delivery method of medical cannabis;

(10) report findings from the clinical trial to the principal investigator in a manner determined by the principal investigator; and

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

(b) A patient's enrollment in a clinical trial may not be denied based on the use of medical cannabis in a jurisdiction outside of Minnesota. Enrollment shall only be denied if the patient has not been diagnosed with a qualifying medical condition.

Subd. 6. **Manufacturer of medical cannabis.** (a) The commissioner shall contract with one manufacturer for the production of all medical cannabis products within the state by December 1, 2014, unless the commissioner obtains an adequate supply of federally sourced medical cannabis products for the clinical trials no later than August 1, 2014. The commissioner shall continue to accept applications after December 1, 2014, if no manufacturer that meets the qualifications set forth in this subdivision applies prior to December 1, 2014. If a federally approved source of medical cannabis becomes available after December 1, 2014, the commissioner may obtain the federally approved medical cannabis in addition to medical cannabis from the contracted manufacturer within the state of Minnesota.

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

(c) The manufacturer shall implement appropriate security measures to deter and prevent the theft of cannabis and unauthorized entrance into areas containing cannabis.

(d) All cultivation, harvesting, manufacturing, and packing of cannabis must take place in an enclosed, locked facility at a physical address provided to the commissioner during the contracting process.

(e) Prior to distribution of any medical cannabis to the principal investigator, or the commissioner acting as the principal investigator under subdivision 3, paragraph (d), the manufacturer must process and prepare any cannabis plant material into a form allowable under subdivision 2, paragraph (d).

(f) The manufacturer shall not share office space with or refer patients to a practitioner.

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

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

(i) The manufacturer may not employ or otherwise allow any person who is under 21 years of age to be an agent of the manufacturer.

(j) All products manufactured must be tested as to content, contamination, and consistency by a certified laboratory to verify such products meet the requirements of subdivision 2, paragraph (d).

(k) The medical cannabis manufacturer shall produce medical cannabis with a chemical consistency of cannabidiols and tetrahydrocannabinols as determined by the principal investigator.

(l) For the purposes of this section only, the manufacturer of medical cannabis products is not required to be licensed under section 151.252 or 151.47.

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

(b) Data kept or maintained by the commissioner may not be used for any purpose not provided for in this section and may not be combined or linked in any manner with any other list or database.

Subd. 8. **Protections for clinical trial participation; criminal and civil.** (a) There is a presumption that a patient enrolled in a clinical trial under this section 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 pursuant to this section.

(c) For the purposes of this section only, the following are not violations under this chapter:

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

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

(3) possession or sale of medical cannabis by a pharmacy or the medical cannabis manufacturer which produces or stores medical cannabis on behalf of the principal investigator or a clinical investigator; and

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

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

(e) A principal or clinical investigator is not subject to any civil or disciplinary penalties by the Board of Medical Practice or by any business, occupational, or professional licensing board or entity solely for the investigator's participation in a clinical trial under this section. Nothing in this section prohibits a professional licensing board for sanctioning a principal or clinical investigator for an investigator's actions outside of those actions allowed under this section.

(f) For the purposes of this section only, medical cannabis is removed 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) 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 a clinical trial under this section, 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 clinical trial enrollee's use of medical cannabis under this section 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 qualifying 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 a program under this section; 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) A person shall not be denied custody of or visitation rights or parenting time with a minor solely for the person's status as a patient enrolled in a program under this section, and there shall be no presumption of neglect or child endangerment for conduct allowed under this section, 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.

Subd. 10. **Fees.** The commissioner may set reasonable application fees and renewal fees to be paid to the commissioner by a patient with a qualifying medical condition that covers the fees incurred in manufacturing medical cannabis by the medical cannabis manufacturer. Fees collected must be deposited in the special revenue fund and are appropriated annually to the commissioner to reimburse costs incurred by the manufacturer of medical cannabis. The commissioner shall establish a sliding scale of patient fees based upon a qualifying patient's household income. The commissioner may accept private donations to reduce patient fees.

Subd. 11. **Nursing facilities.** Nursing facilities licensed under chapter 144A, or boarding care homes licensed under section 144.50, may adopt reasonable restrictions on the use of medical cannabis by persons receiving inpatient services. 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 qualifying patients, and that cannabis be consumed 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 qualifying patient's access to or use of medical cannabis.

Sec. 2. 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 under section 152.22.

(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. 3. **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 of the state of Minnesota, one selected by the speaker of the house, the other selected by the minority leader;

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

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

(4) four members representing health care providers;

(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. Members shall serve on the task force at the pleasure of the appointing authority.

(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 expense reimbursement for members of the task force is governed by section 15.059.

Subd. 2. **Impact assessment.** The task force shall hold hearings to conduct the impact assessment on medical cannabis therapeutic research that must evaluate Minnesota 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 products;

(6) the impact on law enforcement and prosecutions;

(7) public awareness and perception; and

(8) any unintended consequences.

Subd. 3. **Reports to the legislature.** (a) The cochairs 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, judiciary, and civil law:

(1) by February 1, 2015, a report on the design and implementation of the clinical trial program;

(2) by February 1, 2016, a final report on the impact assessment; and

(3) by June 30, 2019, a review and assessment of the clinical trial results.

(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. 4. **Expiration.** The task force on medical cannabis therapeutic research expires on June 30, 2019, or upon the conclusion of the clinical trial, whichever is later.

Sec. 4. **APPROPRIATIONS; MEDICAL CANNABIS THERAPEUTIC RESEARCH ACT.**

(a) $1,100,000 in fiscal year 2016 and $1,100,000 in fiscal year 2017 are appropriated from the general fund to the commissioner of health for grants to the principal investigators for purposes of conducting the clinical trials under Minnesota Statutes, section 152.22.

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

(c) $50,000 in fiscal year 2015 is appropriated from the general fund to the Legislative Coordinating Commission to administer the task force on medical cannabis therapeutic research and for the task force to conduct the impact assessment on the use of cannabis for medicinal purposes. These funds are available until the expiration of the task force on medical cannabis therapeutic research.

Sec. 5. **EFFECTIVE DATE.**

Sections 1 and 3 are effective July 1, 2014.