

1.1 A bill for an act

1.2 relating to health; providing for medical cannabis therapeutic research study;
1.3 creating account; providing appointments; requiring rulemaking; requiring
1.4 reports; appropriating money; amending Minnesota Statutes 2012, section
1.5 256B.0625, subdivision 13d; proposing coding for new law in Minnesota
1.6 Statutes, chapter 152.

1.7 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.8 Section 1. **[152.22] MEDICAL CANNABIS THERAPEUTIC RESEARCH**
1.9 **STUDY.**

1.10 Subdivision 1. Definitions. (a) For purposes of this section, the following terms
1.11 have the meanings given.

1.12 (b) "Commissioner" means the commissioner of health.

1.13 (c) "Health care practitioner" means a Minnesota licensed doctor of medicine, a
1.14 Minnesota licensed physician assistant acting within the scope of authorized practice, or a
1.15 Minnesota licensed advanced practice registered nurse, who has the primary responsibility
1.16 for the care and treatment of the qualifying medical condition of a person diagnosed with
1.17 a qualifying medical condition under this section.

1.18 (d) "Health records" means health record as defined in section 144.291.

1.19 (e) "Medical cannabis" means the flowers of any species of the genus cannabis plant,
1.20 or any mixture or preparation of them, including extracts and resins which contain a
1.21 chemical composition determined to likely be medically beneficial by the commissioner,
1.22 and that is delivered in the form of:

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

1.24 (2) pill;

2.1 (3) vaporized delivery method with use of liquid or oil but which does not require
2.2 the use of dried leaves or plant form; or

2.3 (4) any other method approved by the commissioner but which shall not include
2.4 smoking.

2.5 (f) "Medical cannabis manufacturer" or "manufacturer" means an entity registered
2.6 by the commissioner to cultivate, acquire, manufacture, possess, prepare, transfer,
2.7 transport, supply, or dispense medical cannabis, delivery devices, or related supplies and
2.8 educational materials to patients with a qualifying medical condition who are enrolled
2.9 in the registry program.

2.10 (g) "Medical cannabis product" means medical cannabis as defined in paragraph
2.11 (e) and any delivery device or related supplies and educational materials used in the
2.12 administration of medical cannabis for a patient with a qualifying medical condition
2.13 enrolled in the registry program.

2.14 (h) "Patient" means a Minnesota resident who has been diagnosed by a health care
2.15 practitioner with a qualifying medical condition and who has otherwise met any other
2.16 requirements of patients under this section to participate in the registry program.

2.17 (i) "Patient registry number" means a unique identification number assigned to a
2.18 patient by the commissioner after the commissioner has enrolled the patient in the registry
2.19 program.

2.20 (j) "Registered designated caregiver" means a person who is at least 21 years old and
2.21 who has been approved by the commissioner to assist a patient who has been identified
2.22 by a health care provider as developmentally or physically disabled and therefore unable
2.23 to self-administer medication, and who is authorized by the commissioner to administer
2.24 medical cannabis to the patient only within the patient's primary place of residence;

2.25 (k) "Registry program" means the patient registry established under this section.

2.26 (l) "Registry verification" means the verification provided by the commissioner that
2.27 a patient is enrolled in the registry program and that includes the patient's name, patient
2.28 registry number, qualifying medical condition, and, if applicable, the name of the patient's
2.29 registered designated caregiver or parent or legal guardian.

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

2.31 (1) cancer;

2.32 (2) glaucoma;

2.33 (3) human immunodeficiency virus or acquired immune deficiency syndrome;

2.34 (4) Tourette's syndrome;

2.35 (5) amyotrophic lateral sclerosis;

2.36 (6) seizures, including those characteristic of epilepsy;

3.1 (7) severe and persistent muscle spasms, including those characteristic of multiple
3.2 sclerosis;

3.3 (8) Crohn's disease; or

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

3.5 Subd. 2. **Limitations.** This section does not permit any person to engage in and
3.6 does not prevent the imposition of any civil, criminal, or other penalties for:

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

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

3.10 (i) a school bus or van, which will be punishable in the same manner in which
3.11 possession of a controlled substance in a school zone is punishable under this chapter;

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

3.13 (iii) in any correctional facility; or

3.14 (iv) the grounds of any child care facility or home daycare, which will be punishable
3.15 in the same manner in which possession of a controlled substance in a school zone
3.16 is punishable under this chapter;

3.17 (3) vaporizing medical cannabis pursuant to subdivision 1, paragraph (e):

3.18 (i) on any form of public transportation;

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

3.20 (iii) in any public place; and

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

3.24 Subd. 3. **Federally approved clinical trials.** The commissioner may prohibit
3.25 enrollment of a patient in the registry program if the patient is simultaneously enrolled in a
3.26 federally approved clinical trial for the treatment of a qualifying medical condition with
3.27 medical cannabis. The commissioner shall provide information to all patients enrolled in
3.28 the registry program on the existence of federally approved clinical trials for the treatment
3.29 of the patient's qualifying medical condition with medical cannabis, as an alternative to
3.30 enrollment in the patient registry program.

3.31 Subd. 4. **Commissioner duties.** (a) The commissioner shall register one in-state
3.32 manufacturer for the production of all medical cannabis products within the state by
3.33 December 1, 2014, unless the commissioner obtains an adequate supply of federally
3.34 sourced medical cannabis products by August 1, 2014. The commissioner shall register
3.35 a new manufacturer or reregister the existing manufacturer by December 1 of each
3.36 year, thereafter using the factors described in paragraph (b). The commissioner shall

4.1 continue to accept applications after December 1, 2014, if no manufacturer that meets
4.2 the qualifications set forth in this subdivision applies prior to December 1, 2014. The
4.3 commissioner's determination that no manufacturer exists to fulfill the duties under this
4.4 section is subject to judicial review in Ramsey County District Court. Data obtained
4.5 during the application process is governed by section 13.591. As a condition for
4.6 registration, the commissioner shall require the manufacturer to:

4.7 (1) supply medical cannabis products to patients by July 1, 2015; and

4.8 (2) comply with all requirements under subdivision 8.

4.9 (b) The commissioner shall consider the following factors when determining which
4.10 manufacturer to register:

4.11 (1) the technical expertise of the manufacturer in cultivating medical cannabis and
4.12 converting the medical cannabis into an acceptable delivery method under subdivision 1,
4.13 paragraph (e);

4.14 (2) the qualifications of the manufacturer's employees;

4.15 (3) the long-term financial stability of the manufacturer;

4.16 (4) the ability to provide appropriate security measures on the premises of the
4.17 manufacturer;

4.18 (5) whether the manufacturer has demonstrated an ability to meet the medical
4.19 cannabis production needs required by this section; and

4.20 (6) the manufacturer's projection and ongoing assessment of fee levels on patients
4.21 with a qualifying condition.

4.22 (c) The commissioner shall require the medical cannabis manufacturer to contract
4.23 with an independent laboratory to test medical cannabis produced by the manufacturer.

4.24 The commissioner shall approve the laboratory chosen by the manufacturer and require
4.25 that the laboratory report testing results to the manufacturer in a manner determined by
4.26 the commissioner.

4.27 (d) The commissioner shall review and publicly report the existing medical and
4.28 scientific literature regarding the range of recommended dosages for each qualifying
4.29 condition and the range of chemical compositions of any plant of the genus cannabis that
4.30 will likely be medically beneficial for each of the qualifying medical conditions. The
4.31 commissioner shall make this information available to patients with qualifying conditions
4.32 beginning December 1, 2014. The commissioner may consult with the independent
4.33 laboratory under contract with the manufacturer or other experts in reporting the range of
4.34 recommended dosage for each qualifying condition, the range of chemical compositions
4.35 that will likely be medically beneficial, and any risks of noncannabis drug interactions.
4.36 The commissioner shall consult with the manufacturer on an annual basis on medical

5.1 cannabis products offered by the manufacturer. The list of medical cannabis products shall
5.2 be published on the Health Department Web site.

5.3 (e) The commissioner shall adopt rules necessary for the manufacturer to begin
5.4 distribution of medical cannabis products to patients under the registry program by July 1,
5.5 2015, and have notice of proposed rules published in the State Register prior to January
5.6 1, 2015.

5.7 (f) The commissioner shall, within 30 days of a deadline listed in this section, advise
5.8 the public and the co-chairs of the task force on medical cannabis therapeutic research if
5.9 the commissioner is unable to complete any requirements under this section by the deadline
5.10 listed in this section. The commissioner shall provide a written statement as to the reason or
5.11 reasons the deadline will not be met. Upon request of the commissioner, the task force shall
5.12 extend any deadline by six months, but may not extend any deadline more than three times.

5.13 (g) The commissioner shall provide regular updates to the task force on medical
5.14 cannabis therapeutic research regarding any changes in federal law or regulatory
5.15 restrictions regarding the use of medical cannabis.

5.16 (h) The commissioner may submit medical research based on the data collected
5.17 under this section to any federal agency with regulatory or enforcement authority over
5.18 medical cannabis to demonstrate the efficacy of medical cannabis for treating a qualifying
5.19 medical condition.

5.20 Subd. 5. **Rulemaking.** The commissioner may adopt rules to implement this
5.21 section. Rules for which notice is published in the State Register before January 1, 2015
5.22 may be adopted using the process in section 14.389.

5.23 Subd. 6. **Patient registry program established.** (a) The commissioner of health
5.24 shall establish a patient registry program to evaluate data on patient demographics,
5.25 effective treatment options, clinical outcomes, and quality-of-life outcomes for the purpose
5.26 of reporting on the benefits, risks, and outcomes regarding patients with a qualifying
5.27 medical condition engaged in the therapeutic use of medical cannabis.

5.28 (b) The commissioner shall:

5.29 (1) give notice of the program to health care practitioners in the state who are
5.30 eligible to serve as a health care practitioner as defined in subdivision 1, paragraph (c),
5.31 and explain the purposes and requirements of the program;

5.32 (2) allow each health care practitioner in the state who meets or agrees to meet the
5.33 program's requirements and who requests to participate, to be included in the registry
5.34 program to collect data for the patient registry;

6.1 (3) provide explanatory information and assistance to each health care practitioner
6.2 in understanding the nature of therapeutic use of medical cannabis within program
6.3 requirements;

6.4 (4) create and provide a certification to be used by a health practitioner for the
6.5 practitioner to certify whether a patient has been diagnosed with a qualifying medical
6.6 condition and include in the certification an option for the practitioner to certify whether the
6.7 patient, in the health care practitioner's medical opinion, is developmentally or physically
6.8 disabled and, as a result of that disability, the patient is unable to self-administer medication;

6.9 (5) supervise the participation of the health care practitioner in conducting patient
6.10 treatment and health records reporting in a manner that ensures stringent security and
6.11 record-keeping requirements and that prevents the unauthorized release of private data on
6.12 individuals as defined by section 13.02;

6.13 (6) develop safety criteria for patients with a qualifying condition as a requirement of
6.14 the patient's participation in the program, to prevent the patient from undertaking any task
6.15 under the influence of medical cannabis that would constitute negligence or professional
6.16 malpractice on the part of the patient; and

6.17 (7) conduct research and studies based on data from health records submitted to
6.18 the registry program and submit reports on intermediate or final research results to the
6.19 legislature and major scientific journals. The commissioner may contract with a third
6.20 party to complete the requirements of this clause.

6.21 (c) The commissioner shall develop a patient application for enrollment into the
6.22 registry program. The application shall be available to the patient and given to health care
6.23 practitioners in the state who are eligible to serve as a health care practitioner as defined
6.24 under subdivision 1, paragraph (c). The application must include:

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

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

6.28 (3) the name, mailing address, and date of birth of the patient's designated caregiver,
6.29 if any, or, if the patient is under age 18, the patient's parent or legal guardian;

6.30 (4) a copy of the certification from the patient's health care practitioner that is dated
6.31 within 90 days prior to submitting the application which certifies that the patient has been
6.32 diagnosed with a qualifying medical condition and, if applicable, that, in the health care
6.33 practitioner's medical opinion, the patient is developmentally or physically disabled and,
6.34 as a result of that disability, the patient is unable to self-administer medication; and

6.35 (5) all other signed affidavits and enrollment forms required by the commissioner
6.36 under this section, including, but not limited to, the disclosure under paragraph (e).

7.1 (d) The commissioner shall register a single designated caregiver for a patient if the
7.2 patient's health care provider certified that the patient, in the health care practitioner's
7.3 medical opinion, is developmentally or physically disabled and, as a result of that
7.4 disability, the patient is unable to self-administer medication and the caregiver has agreed,
7.5 in writing, to be a patient's designated caregiver. As a condition of registration as a
7.6 designated caregiver, the commissioner shall require the person:

7.7 (1) to be at least 21 years of age;

7.8 (2) to not already be registered as a caregiver for another patient enrolled in the
7.9 registry program;

7.10 (3) to agree to only possess any medical cannabis product for purposes of
7.11 administration of the medical cannabis to the patient within the patient's primary place of
7.12 residence; and

7.13 (4) to agree that if the application is approved, the patient's designated caregiver will
7.14 not be a registered designated caregiver for more than one patient.

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

7.17 (1) a statement that notwithstanding any law to the contrary, the commissioner of
7.18 health, or an employee of any state agency, may not be held civilly or criminally liable for
7.19 any injury, loss of property, personal injury, or death caused by any act or omission while
7.20 acting within the scope of office or employment under this section; and

7.21 (2) the patient's acknowledgement that enrollment in the patient registry program is
7.22 conditional on the patient's agreement to meet all of the requirements of subdivision 9;

7.23 (f) After receipt of a patient's application and signed disclosure, the commissioner
7.24 shall enroll the patient in the registry program and assign the patient a patient registry
7.25 number. A patient's enrollment in the registry program shall only be denied if the patient:

7.26 (1) does not have certification from a health care provider that the patient has been
7.27 diagnosed with a qualifying medical condition;

7.28 (2) has not signed and returned the disclosure form required under paragraph (d) to
7.29 the commissioner;

7.30 (3) does not provide the information required;

7.31 (4) has previously been removed from the registry program for violations of
7.32 subdivision 9; or

7.33 (5) provides false information.

7.34 (g) The commissioner shall give written notice to a patient of the reason for denying
7.35 enrollment in the registry program.

8.1 (h) Denial of enrollment into the registry program is considered a final decision of
8.2 the commissioner and is subject to judicial review under the Administrative Procedure
8.3 Act pursuant to chapter 14.

8.4 (i) A patient's enrollment in the registry program may only be revoked if a patient
8.5 violates a requirement in subdivision 9.

8.6 (j) The commissioner shall develop a registry verification to provide to the health
8.7 care practitioner identified in the patient's application and to the manufacturer. The
8.8 registry verification shall include:

8.9 (1) the patient's name and date of birth;

8.10 (2) the patient registry number assigned to the patient;

8.11 (3) the patient's qualifying medical condition as provided by the patient's health care
8.12 provider in the certification; and

8.13 (4) the name and date of birth of the patient's registered designated caregiver, if any,
8.14 or, if the patient is under age 18, the name of the patient's parent or legal guardian.

8.15 (k) If the commissioner adds a delivery form under subdivision 1, paragraph (e), or a
8.16 qualifying medical condition under subdivision 1, paragraph (m), the commissioner shall
8.17 notify the legislature by January 15 of any year in which the commissioner wishes to make
8.18 the change. The change shall be effective on August 1 of that year, unless the legislature
8.19 by law provides otherwise. As part of the January submission, the commissioner shall
8.20 notify the chairs and ranking minority members of the legislative policy committees
8.21 having jurisdiction over health and public safety of the addition and the reasons for its
8.22 addition, including any written comments received by the commissioner from the public
8.23 and any guidance received from the task force on medical cannabis research.

8.24 (l) Nothing in this section requires the medical assistance and MinnesotaCare
8.25 programs to reimburse an enrollee or a provider for costs associated with the medical use
8.26 of cannabis. Medical assistance and MinnesotaCare shall continue to reimburse providers
8.27 for covered services related to treatment of a recipient's qualifying medical condition.

8.28 (m) The establishment of the registry program is not intended in any manner
8.29 whatsoever to condone or promote the illicit recreational use of marijuana.

8.30 Subd. 7. **Health care practitioner duties.** (a) Prior to a patient's enrollment in the
8.31 registry program, a health care practitioner shall:

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

9.1 (2) determine whether a patient is developmentally or physically disabled and, as
9.2 a result of that disability, the patient is unable to self-administer medication, and, if so
9.3 determined, include that determination on the patient's certification of diagnosis;

9.4 (3) advise patients, registered designated caregivers, and parents or legal guardians
9.5 of patients under age 18 of the existence of any nonprofit patient support groups or
9.6 organizations;

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

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

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

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

9.18 (2) report health records of the patient throughout the ongoing treatment of the
9.19 patient to the commissioner in a manner determined by the commissioner of health and in
9.20 accordance with paragraph (c); and

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

9.22 (c) Data collected on patients by a health care practitioner and reported to the patient
9.23 registry are health records under section 144.291 and are private data on individuals under
9.24 section 13.02 but may be used or reported in an aggregated, nonidentifiable form as part of
9.25 a scientific, peer-reviewed publication of research conducted under this section or in the
9.26 creation of summary data, as defined in section 13.02, subdivision 19.

9.27 (d) Nothing in this section requires a health care practitioner to enroll patients in the
9.28 registry created by this section.

9.29 **Subd. 8. Manufacturer of medical cannabis duties.** (a) The manufacturer of
9.30 medical cannabis shall provide a reliable and ongoing supply of all medical cannabis
9.31 products needed for the registry program.

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

9.35 (c) The manufacturer may operate up to two satellite distribution centers, located
9.36 throughout the state to improve patient access, where the manufacturer may distribute

10.1 medical cannabis products in addition to the manufacturer's primary location. The
10.2 manufacturer shall disclose the proposed locations for the distribution centers to the
10.3 commissioner during the registration process. The distribution centers may not contain
10.4 any medical cannabis products in a form other than those forms allowed under subdivision
10.5 1, paragraph (e), and the manufacturer shall not conduct any cultivation, harvesting,
10.6 manufacturing, packaging, or processing at the distribution center site. Any distribution
10.7 center operated by the manufacturer is subject to all of the requirements applying to the
10.8 manufacturer under this subdivision, including, but not limited to, security and distribution
10.9 requirements.

10.10 (d) The medical cannabis manufacturer shall produce medical cannabis with
10.11 chemical compositions as determined by the commissioner.

10.12 (e) The medical cannabis manufacturer shall contract with a laboratory, subject to
10.13 the commissioner's approval of the laboratory and any additional requirements set by the
10.14 commissioner, for purposes of testing medical cannabis manufactured by the medical
10.15 cannabis manufacturer as to content, contamination, and consistency to verify the medical
10.16 cannabis meets the requirements of subdivision 1, paragraph (e). The cost of lab testing
10.17 shall be paid by the manufacturer.

10.18 (f) The manufacturer must process and prepare any cannabis plant material into a form
10.19 allowable under subdivision 1, paragraph (e), prior to distribution of any medical cannabis.

10.20 (g) The manufacturer shall require that any employee licensed as a pharmacist
10.21 pursuant to chapter 151 and the rules promulgated pursuant to that chapter be the only
10.22 employees to distribute the medical cannabis to a patient.

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

10.25 (i) Prior to distribution of any medical cannabis products to any patient or, if the
10.26 patient is under age 18, the patient's parent or legal guardian, the manufacturer shall:

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

10.29 (2) verify that the person requesting the distribution of medical cannabis is the
10.30 patient, or, if the patient is under age 18, the patient's parent or legal guardian, listed in the
10.31 registry verification, in accordance with section 152.11, subdivision 2d;

10.32 (3) assign a tracking number to each individual medical cannabis product;

10.33 (4) ensure that any employee of the manufacturer licensed as a pharmacist pursuant
10.34 to chapter 151 and the rules promulgated pursuant to that chapter has consulted with the
10.35 patient to determine the proper dosage for the individual patient based on the ranges of

11.1 chemical compositions of the medical cannabis and the ranges of proper dosages reported
11.2 by the commissioner;

11.3 (5) properly label each medical cannabis product with individually identifying
11.4 information, including:

11.5 (i) the patient's name and date of birth;

11.6 (ii) the name and date of birth of the patient's registered designated caregiver, or,
11.7 if the patient is under age 18, the name of the patient's parent or legal guardian, if either
11.8 were included on the registry verification;

11.9 (iii) the patient's registry number;

11.10 (iv) the chemical composition of the medical cannabis; and

11.11 (v) the dosage; and

11.12 (6) ensure that the medical cannabis distributed to a patient contains a maximum of a
11.13 30-day supply of the dosage determined for that patient.

11.14 (j) If the patient has a registered designated caregiver, the manufacturer shall deliver
11.15 properly labeled medical cannabis products to the patient or the patient's registered
11.16 designated caregiver but only at the patient's primary residence. The manufacturer shall
11.17 verify that the person to whom the medical cannabis product is being delivered is either
11.18 the patient or the patient's registered designated caregiver, in accordance with section
11.19 152.11, subdivision 2d. The manufacturer shall not distribute medical cannabis products
11.20 to a registered designated caregiver at the premises of the manufacturer.

11.21 (k) The manufacturer shall report to the commissioner, on a monthly basis, the
11.22 following information on each individual patient from the month prior to the report:

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

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

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

11.26 (l) The operating documents of the manufacturer must include:

11.27 (1) procedures for the oversight of the manufacturer and procedures to ensure
11.28 accurate record keeping; and

11.29 (2) procedures for the implementation of appropriate security measures to deter and
11.30 prevent the theft of cannabis and unauthorized entrance into areas containing cannabis.

11.31 (m) The manufacturer shall not share office space with, refer patients to a health care
11.32 practitioner, or have any financial relationship with a health care practitioner.

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

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

12.1 (p) For purposes of this section only, the medical cannabis manufacturer is not
12.2 subject to the Board of Pharmacy licensure or regulatory requirements under chapter 151.

12.3 (q) A medical cannabis manufacturer may not employ or otherwise allow any person
12.4 who is under 21 years of age or who has been convicted of a disqualifying felony offense
12.5 to be an employee of the medical cannabis organization. For purposes of this paragraph, a
12.6 disqualifying felony offense means a violation of a state or federal controlled substance law
12.7 that is classified as a felony under Minnesota law, or would be classified as a felony under
12.8 Minnesota law if committed in Minnesota, regardless of the sentence imposed, unless the
12.9 person's conviction was for the medical use of cannabis or assisting with the medical use
12.10 of cannabis in accordance with any other state's law. An employee of a medical cannabis
12.11 manufacturer must submit a completed criminal history records check consent form, a
12.12 full set of fingerprints and the required fees for submission to the Bureau of Criminal
12.13 Apprehension before an employee may begin working with the manufacturer. The bureau
12.14 must conduct a Minnesota criminal history records check and the superintendent is
12.15 authorized to exchange the fingerprints with the Federal Bureau of Investigation to obtain
12.16 the applicant's national criminal history record information. The bureau will return the
12.17 results of the Minnesota and federal criminal history records checks to the commissioner.

12.18 Subd. 9. **Patient duties.** (a) A patient shall apply to the commissioner for enrollment
12.19 in the registry program by submitting an application, as defined in subdivision 6, paragraph
12.20 (c), and an annual registration fee as determined under subdivision 13, paragraph (a).

12.21 (b) As a condition of continued enrollment, a patient shall agree to:

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

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

12.26 Subd. 10. **Data practices.** (a) Government data in patient files maintained by the
12.27 commissioner and the health care practitioner, and data submitted to or by the medical
12.28 cannabis manufacturer, are private data on individuals, as defined in section 13.02,
12.29 subdivision 12, or nonpublic data, as defined in section 13.02, subdivision 9, and may be
12.30 used for purposes of complying with chapter 13 and complying with a request from the
12.31 legislative auditor in the performance of official duties. The provisions of section 13.05,
12.32 subdivision 11, apply to a registration agreement entered between the commissioner and a
12.33 medical cannabis manufacturer under this section.

12.34 (b) Not public data maintained by the commissioner may not be used for any
12.35 purpose not provided for in this section, and may not be combined or linked in any manner
12.36 with any other list, dataset, or database.

13.1 Subd. 11. **Protections for registry program participation; criminal and civil.** (a)

13.2 There is a presumption that a patient enrolled in the registry program under this section is
13.3 engaged in the authorized use of medical cannabis.

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

13.8 (c) For the purposes of this section only, subject to subdivision 2, the following are
13.9 not violations under this chapter:

13.10 (1) use or possession of medical cannabis products by a patient enrolled in the
13.11 registry program, or possession by the parent or guardian of a patient under age 18;

13.12 (2) possession of medical cannabis products by a registered designated caregiver,
13.13 only if the registered designated caregiver is in possession of the medical cannabis
13.14 products within the primary residence of the individual patient in which the caregiver has
13.15 been registered to assist;

13.16 (3) possession, dosage determination, or sale of medical cannabis products by the
13.17 medical cannabis manufacturer, employees of the manufacturer, the laboratory conducting
13.18 testing on medical marijuana products, or employees of the laboratory; and

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

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

13.23 (e) The commissioner, the commissioner's staff, the commissioner's agents or
13.24 contractors and any health care practitioner are not subject to any civil or disciplinary
13.25 penalties by the Board of Medical Practice or by any business, occupational, or
13.26 professional licensing board or entity, solely for the participation in the registry program
13.27 under this section. Nothing in this section prohibits a professional licensing board for
13.28 sanctioning actions outside of those actions allowed under this section.

13.29 (f) Notwithstanding any law to the contrary, the commissioner of health, the
13.30 governor of Minnesota, or an employee of any state agency, may not be held civilly or
13.31 criminally liable for any injury, loss of property, personal injury, or death caused by any
13.32 act or omission while acting within the scope of office or employment under this section.

13.33 (g) Federal, state, and local law enforcement authorities are prohibited from accessing
13.34 the patient registry under this section except when acting pursuant to a valid search warrant.

13.35 (h) Notwithstanding any law to the contrary, neither the commissioner nor a public
13.36 employee may release data or information about an individual contained in any report,

14.1 document, or registry created under this section or any information obtained about a
14.2 patient participating in the program, except as provided in this section. No information
14.3 contained in a report, document, registry, or obtained from a patient under this section
14.4 may be used against a patient in a criminal proceeding unless independently obtained or in
14.5 connection with a proceeding involving a violation of this section.

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

14.7 Subd. 12. **Discrimination prohibited.** (a) No school or landlord may refuse to
14.8 enroll or lease to and may not otherwise penalize a person solely for the person's status as
14.9 a patient enrolled in the registry program under this section, unless failing to do so would
14.10 violate federal law or regulations or cause the school or landlord to lose a monetary or
14.11 licensing-related benefit under federal law or regulations.

14.12 (b) For the purposes of medical care, including organ transplants, a registry program
14.13 enrollee's use of medical cannabis under this section is considered the equivalent of the
14.14 authorized use of any other medication used at the discretion of a physician and does
14.15 not constitute the use of an illicit substance or otherwise disqualify a qualifying patient
14.16 from needed medical care.

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

14.22 (1) the person's status as a patient enrolled in the registry program under this section;
14.23 or

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

14.27 (d) A person shall not be denied custody of or visitation rights or parenting time
14.28 with a minor solely for the person's status as a patient enrolled in the registry program
14.29 under this section, and there shall be no presumption of neglect or child endangerment
14.30 for conduct allowed under this section, unless the person's behavior is such that it creates
14.31 an unreasonable danger to the safety of the minor as established by clear and convincing
14.32 evidence.

14.33 Subd. 13. **Fees; deposit of revenue.** (a) The commissioner shall collect an
14.34 enrollment fee of \$200 from qualified patients enrolled under this section. If the patient
14.35 attests to receiving Social Security disability, Supplemental Security Insurance payments,
14.36 or being enrolled in medical assistance or MinnesotaCare then the fee shall be \$50.

15.1 The fees shall be payable annually and are due on the anniversary date of the patient's
15.2 enrollment. The fee amount shall be deposited in the state treasury and credited to the
15.3 state government special revenue fund.

15.4 (b) The commissioner shall collect an application fee of \$20,000 from each entity
15.5 submitting an application for registration as a medical cannabis manufacturer. Revenue
15.6 from the fee shall be deposited in the state treasury and credited to the state government
15.7 special revenue fund. If an entity is not selected to be registered as a medical cannabis
15.8 manufacturer, the commissioner shall refund \$19,000 to the entity.

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

15.13 (d) The medical cannabis manufacturer may charge patients enrolled in the registry
15.14 program a reasonable fee for costs associated with the operations of the manufacturer.
15.15 The manufacturer may charge fees associated with the delivery of medical cannabis
15.16 pursuant to subdivision 8, paragraph (i), but shall only charge the fee to those patients
15.17 who received the delivery service. The manufacturer may establish a sliding scale of
15.18 patient fees based upon a qualifying patient's household income and may accept private
15.19 donations to reduce patient fees.

15.20 Subd. 14. **Nursing facilities.** Nursing facilities licensed under chapter 144A, or
15.21 boarding care homes licensed under section 144.50, may adopt reasonable restrictions on
15.22 the use of medical cannabis by persons receiving services. The restrictions may include a
15.23 provision that the facility will not store or maintain the patient's supply of medical cannabis,
15.24 that the facility is not responsible for providing the medical cannabis for qualifying patients,
15.25 and that medical cannabis be consumed only in a place specified by the facility. Nothing
15.26 contained in this section shall require the facilities to adopt such restrictions, and no
15.27 facility shall unreasonably limit a qualifying patient's access to or use of medical cannabis.

15.28 Sec. 2. **[152.24] IMPACT ASSESSMENT OF MEDICAL CANNABIS**
15.29 **THERAPEUTIC RESEARCH.**

15.30 Subdivision 1. **Task force on medical cannabis therapeutic research.** (a) A
15.31 23-member task force on medical cannabis therapeutic research is created to conduct an
15.32 impact assessment of medical cannabis therapeutic research. The task force shall consist
15.33 of the following members:

15.34 (1) two members of the house of representatives, one selected by the speaker of the
15.35 house, the other selected by the minority leader;

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

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

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

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

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

16.12 (7) the commissioners of health, human services, and public safety.

16.13 (b) Task force members listed under paragraph (a), clauses (3), (4), (5), and (6), shall
16.14 be appointed by the governor. Members shall serve on the task force at the pleasure of
16.15 the appointing authority.

16.16 (c) There shall be two cochair of the task force chosen from the members listed
16.17 under paragraph (a). One cochair shall be selected by the speaker of the house and
16.18 the other cochair shall be selected by the majority leader of the senate. The expense
16.19 reimbursement for members of the task force is governed by section 15.059.

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

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

16.26 (1) program design and implementation;

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

16.28 (3) patient experiences;

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

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

16.31 (6) the impact on law enforcement and prosecutions;

16.32 (7) public awareness and perception; and

16.33 (8) any unintended consequences.

16.34 Subd. 3. **Reports to the legislature.** (a) The cochair shall submit the following
16.35 reports to the chairs and ranking minority members of the legislative committees and

17.1 divisions with jurisdiction over health and human services, public safety, judiciary, and
17.2 civil law:

17.3 (1) by February 1, 2015, a report on the design and implementation of the registry
17.4 program; and

17.5 (2) every two years thereafter, a complete report on the impact assessment.

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

17.8 Subd. 4. **Expiration.** The task force on medical cannabis therapeutic research
17.9 does not expire.

17.10 Sec. 3. **[152.25] FINANCIAL EXAMINATIONS; PRICING REVIEWS.**

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

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

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

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

17.32 (c) When making an examination under this section, the commissioner may retain
17.33 attorneys, appraisers, independent economists, independent certified public accountants,
17.34 or other professionals and specialists as designees. A certified public accountant retained

18.1 by the commissioner may not be the same certified public accountant providing the
18.2 certified annual audit in subdivision 2.

18.3 (d) The commissioner shall make a report of an examination conducted pursuant to
18.4 this chapter and shall provide a copy of the report to the medical cannabis manufacturer.
18.5 The commissioner shall then post a copy of the report on the department's Website. All
18.6 working papers, recorded information, documents, and copies thereof produced by,
18.7 obtained by, or disclosed to the commissioner or any other person in the course of an
18.8 examination, other than the information contained in any commissioner official report,
18.9 made under this subdivision is not public data.

18.10 Sec. 4. Minnesota Statutes 2012, section 256B.0625, subdivision 13d, is amended to
18.11 read:

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

18.16 (b) The formulary shall not include:

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

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

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

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

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

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

18.29 (7) medical cannabis as defined under section 152.22.

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

19.1 Sec. 5. **RULES; ADVERSE INCIDENTS.**

19.2 (a) The commissioner of health shall adopt rules to establish requirements for
19.3 reporting incidents when individuals who are not authorized to possess medical cannabis
19.4 under Minnesota Statutes, section 152.22, subdivision 11, are found in possession of
19.5 medical cannabis. The rules must identify professionals required to report, the information
19.6 they are required to report, and actions the reporter must take to secure the medical cannabis.

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

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

19.12 Sec. 6. **INTRACTABLE PAIN.**

19.13 The commissioner of health shall consider the addition of intractable pain, as defined
19.14 in Minnesota Statutes, section 152.125, subdivision 1, to the list of qualifying medical
19.15 conditions under Minnesota Statutes, section 152.22, subdivision 1, paragraph (m), prior
19.16 to the consideration of any other new qualifying medical conditions. The commissioner
19.17 shall report findings on the need for adding intractable pain to the list of qualifying
19.18 medical conditions to the task force established under Minnesota Statutes, section 152.24,
19.19 no later than July 1, 2016.

19.20 Sec. 7. **APPROPRIATIONS, MEDICAL CANNABIS RESEARCH.**

19.21 Subdivision 1. **Health Department.** \$2,795,000 is appropriated in fiscal year
19.22 2015 from the general fund to the commissioner of health for the costs of administering
19.23 Minnesota Statutes, section 152.22. The base for this appropriation is \$829,000 in fiscal
19.24 year 2016 and \$728,000 in fiscal year 2017.

19.25 Subd. 2. **Legislative Coordinating Commission.** \$24,000 is appropriated in
19.26 fiscal year 2015 from the general fund to the Legislative Coordinating Commission to
19.27 administer the task force on medical cannabis therapeutic research and for the task force to
19.28 conduct the impact assessment on the use of cannabis for medicinal purposes.

19.29 Subd. 3. **Health Department.** \$24,000 in fiscal year 2015 is appropriated from the
19.30 state government special revenue fund to the commissioner of health for the costs of
19.31 implementing Minnesota Statutes, section 152.22. The base for this appropriation is
19.32 \$734,000 in fiscal year 2016 and \$722,000 in fiscal year 2017.

20.1 Sec. 8. **EFFECTIVE DATE.**

20.2 Sections 1 to 7 are effective the day following final enactment.