04/05/22 **REVISOR** BD/LN 22-07476 as introduced

SENATE STATE OF MINNESOTA NINETY-SECOND SESSION

S.F. No. 4500

(SENATE AUTHORS: BIGHAM, Koran, López Franzen, Dziedzic and McEwen) OFFICIAL STATUS

D-PG 6954 **DATE** 04/19/2022

1.1

1.26

Introduction and first reading Referred to State Government Finance and Policy and Elections

A bill for an act

relating to state government; establishing the Office of Cannabis Derivatives; 1 2 transferring the regulation and implementation of the medical cannabis program 1.3 to the Office of Cannabis Derivatives; transferring the regulation of industrial 1.4 hemp to the Office of Cannabis Derivatives; requiring the Office of Cannabis 1.5 Derivatives to regulate all hemp and hemp-derivative products; proposing coding 1.6 for new law as Minnesota Statutes, chapter 342; repealing Minnesota Statutes 1.7 2020, sections 18K.01; 18K.02; 18K.03; 18K.04; 18K.05; 18K.06; 18K.07; 18K.08; 1.8 18K.09; 151.72, subdivisions 1, 2, 3, 4, 6; 152.21; 152.22, subdivisions 1, 2, 3, 4, 1.9 5, 5a, 5b, 7, 8, 9, 10, 12, 13, 14; 152.24; 152.25; 152.27, subdivisions 1, 5, 6, 7; 1.10 152.28, subdivisions 2, 3; 152.29, subdivisions 2, 3a, 4; 152.30; 152.32; 152.33; 1.11 152.34; 152.35; 152.36; 152.37; Minnesota Statutes 2021 Supplement, sections 1.12 151.72, subdivision 5; 152.22, subdivisions 5c, 6, 11; 152.23; 152.26; 152.27, 1.13 subdivisions 2, 3, 4; 152.28, subdivision 1; 152.29, subdivisions 1, 3, 3b, 3c; 1.14 1.15 152.31. BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA: 1.16 Section 1. [342.01] DEFINITIONS. 1.17 Subdivision 1. **Terms.** For purposes of this chapter, the following terms have the 1.18 1.19 meanings given. Subd. 2. Applicant. "Applicant" means an individual who submits an application for a 1.20 1.21 license as required under this chapter. If the applicant is an entity, applicant means the owner or most responsible individual in charge of the entity. 1.22 Subd. 3. Commissioner. "Commissioner" means the commissioner of the Office of 1.23 Cannabis Derivatives. 1.24 Subd. 4. Consumer. "Consumer" means an individual who purchases a hemp-derived 1.25

consumable or topical product for personal consumption and not for resale.

Section 1. 1

partnership, limited liability partnership, limited liability company, irrevocable trust, estate,
charitable organization, or other similar organization, including any such organization
participating in hemp production as a partner in a general partnership, a participant in a joint
venture, or a participant in a similar organization.
Subd. 6. Hemp. "Hemp" means the plant Cannabis sativa L. and any part of the plant,
whether growing or not, including the plant's seeds, and all the plant's derivatives, extracts,
cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a
tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.
Hemp does not include marijuana. Hemp does not include industrial hemp products.
Subd. 7. Hemp-derived consumable or topical product. "Hemp-derived consumable
or topical product" or "hemp product" means a finished product that is derived from hemp
and that contains cannabidiol or another cannabinoid, derivative, or extract of hemp and
the finished product:
(1) is a cosmetic, food, food additive, or herb;
(2) is intended for human or animal use or consumption, including consumption through
a vaporized delivery method using a liquid or oil;
(3) contains any part of the hemp plant, including naturally occurring cannabinoids,
compounds, concentrates, extracts, isolates, resins, or derivatives; and
(4) contains a tetrahydrocannabinol concentration of no more than three-tenths of one
percent on a dry weight basis.
Subd. 8. Hemp grower. "Hemp grower" means a person licensed by the commissioner
under this chapter to plant or grow raw hemp for commercial or research purposes.
Subd. 9. Hemp processor. "Hemp processor" means a person licensed by the
commissioner under this chapter to process raw hemp into hemp products for commercial
purposes.
Subd. 10. Hemp retailer. "Hemp retailer" means a person licensed by the commissioner
under this chapter to sell at the retail level hemp-derived consumable or topical products to
consumers.
Subd. 11. Industrial hemp product. "Industrial hemp product" means the intermediate
or finished product made from fibrous waste that is not intended for human or animal use
or consumption and is not usable or recognizable as medical cannabis or a hemp-derived
consumable or topical product.

Section 1. 2

Subd. 12. Label. "Label" has the meaning given in section 151.01, subdivision 18. 3.1 Subd. 13. Marijuana. "Marijuana" has the meaning given in section 152.01, subdivision 3.2 9. Marijuana does not include hemp, industrial hemp products, or hemp-derived consumable 3.3 or topical products. 3.4 3.5 Subd. 14. **Medical cannabis program.** "Medical cannabis program" means the program administered in accordance with sections 342.15 to 342.29. 3.6 3.7 Subd. 15. **Office.** "Office" means the Office of Cannabis Derivatives. Subd. 16. **Processing.** "Processing" means rendering by refinement hemp plants or hemp 3.8 plant parts from their natural or original state after harvest. Processing includes but is not 3.9 limited to decortication, devitalization, chopping, crushing, extraction, and packaging. 3.10 Processing does not include typical farm operations such as sorting, grading, baling, and 3.11 harvesting. 3.12 Subd. 17. Processing location. "Processing location" means any area, building, plant, 3.13 or facility registered with and approved by the commissioner in which a licensee converts 3.14 raw hemp into a marketable product. 3.15 Subd. 18. Raw hemp. "Raw hemp" means the whole hemp plant, whether growing or 3.16 not, or the stalk, viable seeds, unaltered flowers or leaves, or any unprocessed plant pieces 3.17 or parts of the hemp plant. 3.18 Sec. 2. [342.02] OFFICE OF CANNABIS DERIVATIVES. 3.19 Subdivision 1. Scope. (a) The office is created to establish and implement policy and 3.20 regulations for growing, cultivating, and processing hemp for the production of hemp 3.21 products, the commercial retail sale of these products in this state, and the implementation 3.22 of the medical cannabis program under sections 342.15 to 342.29. 3.23 3.24 (b) Nothing in this chapter shall be construed to regulate the sale of industrial hemp products or any other product with a tetrahydrocannabinol concentration of more than 0.3 3.25 percent on a dry weight basis. This paragraph does not include medical cannabis as defined 3.26 under section 342.15, subdivision 5. 3.27 (c) Nothing in this chapter shall be construed to authorize or regulate the recreational 3.28 use of marijuana unless the state or federal government enacts legislation legalizing the 3.29 adult use of recreational marijuana. 3.30

Sec. 2. 3

1.1	Subd. 2. Creation. The Office of Cannabis Derivatives is created with a commissioner
1.2	appointed by the governor with the advice and consent of the senate and serving at the
1.3	pleasure of the governor.
1.4	Subd. 3. Responsibilities. The office has the following powers and duties:
1.5	(1) develop, maintain, and enforce an organized system of regulation for hemp and
1.6	hemp-derived consumable or topical products;
1.7	(2) establish standards for product testing, packaging, and labeling of hemp products;
1.8	(3) issue and reissue licenses for growing and processing raw hemp for commercial
1.9	purposes;
1.10	(4) issue and reissue licenses for the retail sales of hemp-derived consumable or topical
1.11	products to consumers;
1.12	(5) inspect the premises, records, books, and other documents of license holders to ensure
1.13	compliance with all applicable laws and rules;
1.14	(6) enforce the laws and rules adopted under this chapter;
1.15	(7) authorize research and studies of the use of hemp products and medical cannabis as
1.16	defined under section 342.15, subdivision 5;
1.17	(8) establish limits on the potency of hemp-derived consumable or topical products that
1.18	can be grown and sold;
1.19	(9) implement the medical cannabis patient registry program under sections 342.15 to
1.20	342.29; and
1.21	(10) exercise other powers and authority as required by law.
1.22	Subd. 4. Rulemaking. The office may adopt rules to implement any provision in this
1.23	chapter.
1.24	Sec. 3. [342.03] EXECUTIVE OFFICERS; EMPLOYEES.
	· · · · · · · · · · · · · · · · · · ·
1.25	The office shall be under the administrative control of the commissioner. The
1.26	commissioner shall serve in the unclassified service of the state civil service. On behalf of
1.27	the office, the commissioner or the commissioner's designated representative is authorized
1.28	to sign contracts and execute all instruments necessary or appropriate to carry out the
1.29	purposes of this chapter. The salary of the commissioner shall be established according to
1.30	section 15A.0815. The commissioner may appoint other professional employees who shall

Sec. 3. 4

se	rve in the unclassified service of the state civil service. All other employees shall be in
th	e classified civil service.
;	Sec. 4. [342.04] CANNABIS ADVISORY COUNCIL.
	Subdivision 1. Establishment; membership. A cannabis advisory council to the office
is	established. The members of the advisory council shall include the following members:
	(1) the commissioner of health or a designee;
	(2) the commissioner of public safety or a designee;
	(3) the commissioner of agriculture or a designee;
	(4) the executive director of the board pharmacy or a designee;
	(5) a representative from the League of Minnesota Cities, appointed by the league;
	(6) a representative from the Association of Minnesota Counties, appointed by the
as	sociation;
	(7) two patient advocates who are patients enrolled in the medical cannabis program;
an	<u>d</u>
	(8) three representatives of the hemp market, appointed by the commissioner, with one
m	ember representing hemp growers, one member representing hemp processors, and one
m	ember representing retailers selling hemp products in this state.
	Subd. 2. Organization. The advisory council shall be organized and administered as
pr	ovided in section 15.059. The advisory council shall select one of its members to serve
as	chair.
	Subd. 3. Duties. The advisory council shall determine its meeting times as necessary
bι	t must meet at least quarterly to advise the commissioner and make recommendations to
th	e commissioner as it finds appropriate regarding the state's hemp industry. The advisory
co	uncil shall also meet at the call of the commissioner.
	Subd. 4. Expiration. Notwithstanding section 15.059, the advisory council does not
ex	pire.
,	Sec. 5. [342.05] APPROVAL OF HEMP PRODUCTS.
	(a) Notwithstanding any law to the contrary, a hemp product containing cannabinoids
<u>m</u>	ay be sold in Minnesota through a licensed hemp retailer if the product does not contain
a	concentration of more than 0.3 percent of tetrahydrocannabinol.

Sec. 5. 5

(b) A licensed hemp retailer located in Minnesota may only sell hemp products that are 6.1 approved for retail sale by the office and that comply with this chapter and any rules adopted 6.2 6.3 pursuant to this chapter. (c) The office may adopt rules to limit or prohibit toxic ingredients in or additives to 6.4 6.5 hemp-derived consumable or topical products. (d) Any hemp product that has been approved for sale by the office and meets the 6.6 requirements of this chapter is not a controlled substance under section 152.02. 6.7 Sec. 6. [342.06] LICENSING. 6.8 Subdivision 1. Requirement; issuance; presumption. (a) A person must obtain a license 6.9 6.10 from the commissioner before: (1) planting or growing hemp for commercial or research purposes; 6.11 6.12 (2) obtaining raw hemp materials for processing hemp to make hemp products for commercial purposes; and 6.13 6.14 (3) selling hemp-derived consumable and topical products at the retail level to consumers 6.15 for personal consumption. (b) To obtain a license under paragraph (a), a person must apply to the commissioner 6.16 6.17 in the form prescribed by the commissioner and must pay the annual registration and inspection fee established by the commissioner pursuant to section 16A.1285, subdivision 6.18 2. 6.19 (c) For a license to grow hemp for commercial or research purposes, the license 6.20 application must include the name and address of the applicant and the legal description of 6.21 the land area or areas where hemp will be grown by the applicant and any other information 6.22 required under Code of Federal Regulations, title 7, part 990. 6.23 (d) For a license to process raw hemp for commercial purposes, the license application 6.24 must include the name and address of the applicant, the legal description of the processing 6.25 6.26 location, and any other information required by the commissioner. (e) For a license to sell hemp products at the retail level, the license application must 6.27 include the name and address of the applicant, the address of the retail business, if applicable, 6.28 and any other information required by the commissioner. 6.29 (f) When an applicant has paid the fee and completed the application process to the 6.30 satisfaction of the commissioner, the commissioner shall issue a license that is valid until 6.31 December 31 of the year of application. 6.32

Sec. 6. 6

7.1	(g) A person licensed under this section to grow or process hemp is presumed to be
7.2	growing or processing hemp for commercial or research purposes.
7.3	Subd. 2. Background check; data classification. The commissioner must require each
7.4	first-time applicant for a license to submit to a background investigation conducted by the
7.5	Bureau of Criminal Apprehension as a condition of licensure. As part of the background
7.6	investigation, the Bureau of Criminal Apprehension must conduct criminal history checks
7.7	of Minnesota records and is authorized to exchange fingerprints with the United States
7.8	Department of Justice, Federal Bureau of Investigation for the purpose of a criminal
7.9	background check of the national files. The cost of the investigation must be paid by the
7.10	applicant. Criminal history records provided to the commissioner under this section must
7.11	be treated as private data on individuals, as defined in section 13.02, subdivision 12.
7.12	Subd. 3. Federal requirements. The applicant must demonstrate to the satisfaction of
7.13	the commissioner that the applicant has complied with all applicable federal requirements
7.14	pertaining to the processing, production, distribution, and sale of hemp.
7.15	Subd. 4. Hemp licensing data classification. (a) In addition to data classified pursuant
7.16	to section 13.41, the following data collected, created, or maintained by the commissioner
7.17	under this chapter are classified as private data, as defined in section 13.02, subdivision 12,
7.18	or nonpublic data, as defined in section 13.02, subdivision 9:
7.19	(1) nondesignated addresses provided by licensees and applicants; and
7.20	(2) data that identify the specific locations where licensees and applicants grow or
7.21	process, or will grow or process, hemp, including but not limited to legal descriptions, street
7.22	addresses, geospatial locations, maps, and property boundaries and dimensions.
7.23	(b) The commissioner may disclose data classified as private data or nonpublic data
7.24	under this subdivision if the commissioner determines that there is a substantive threat to
7.25	human health or safety or to the environment, or to aid in the law enforcement process.
7.26	Subd. 5. Hemp licensing data security and auditing. (a) The commissioner must
7.27	establish written procedures to ensure that only individuals authorized by law may access
7.28	the private data and nonpublic data identified in subdivision 4. An authorized individual's
7.29	ability to enter, update, or access data must correspond to the official duties or training level
7.30	of the individual and to the statutory authorization granting access for that purpose. All

queries and responses, including the specific purpose for which data are requested and, if

applicable, disclosed, and all actions in which data are entered, updated, accessed, shared,

or disseminated must be recorded in the data audit trail. Data contained in the audit trail are

Sec. 6. 7

public to the extent the data are not otherwise classified by law.

7.31

7.32

7.33

7.34

(b) The commissioner must immediately and permanently revoke the authorization of any individual who willfully entered, updated, accessed, shared, or disseminated data in violation of state or federal law. If an individual willfully gained access to data without authorization by law, the commissioner must forward the matter to the appropriate prosecuting authority for prosecution.

(c) By January 15 of each odd-numbered year, the commissioner must provide a copy of the data audit trail required under paragraph (a) to the commissioner of administration, the chairs and ranking members of the legislative committees and divisions with jurisdiction over public safety and data practices, and the Legislative Commission on Data Practices and Personal Data Privacy or its successor commission.

Sec. 7. [342.07] TESTING REQUIREMENTS.

8.1

8.2

8.3

8.4

8.5

8.6

8.7

8.8

8.9

8.10

8.11

8.12

8.13

8.14

8.15

8.16

8.17

8.18

8.19

8.20

8.21

8.22

8.26

8.27

- (a) A manufacturer of a hemp product regulated under this chapter must submit representative samples of the product to an independent, accredited laboratory in order to certify that the product complies with the standards adopted by the office. Testing must be consistent with generally accepted industry standards for herbal and botanical substances and, at a minimum, the testing must confirm that the product:
- (1) contains the amount or percentage of cannabinoids that is stated on the label of the product within a variation of plus or minus ten percent;
- (2) does not contain more than trace amounts of any pesticides, fertilizers, or heavy metals or residual solvents; and
 - (3) does not contain a concentration of tetrahydrocannabinol that exceeds the concentration permitted for hemp.
- 8.23 (b) Upon the request of the office, the manufacturer of the product must provide the office with the results of the testing required in this section.

8.25 Sec. 8. [342.08] LABELING.

- Subdivision 1. General. All hemp-derived consumable or topical products sold in this state must be labeled as required by this section and rules adopted under this chapter.
- 8.28 Subd. 2. Content of label; hemp-derived consumable or topical products. (a) All
 8.29 hemp-derived consumable or topical products sold in this state must have affixed to the
 8.30 packaging or container of the product a label that contains at least the following information:

Sec. 8. 8

9.1	(1) the name, location, contact phone number, and website of the manufacturer of the
9.2	product;
9.3	(2) the name and address of the independent, accredited laboratory used by the
9.4	manufacturer to test the product; and
9.5	(3) an accurate statement of the amount or percentage of cannabinoids found in each
9.6	unit of the product meant to be consumed.
9.7	(b) The information in paragraph (a) may be provided:
9.8	(1) on an outer package if the immediate container that holds the product is too small
9.9	to contain the information; and
9.10	(2) through the use of a scannable barcode or matrix barcode that links to a page on the
9.11	manufacturer's website if that page contains all the information required by this section.
9.12	(c) The information required by this subdivision must be prominently and conspicuously
9.13	placed on the label or displayed on the website in terms that can be easily read and understood
9.14	by the consumer.
9.15	(d) The labeling must not contain any claim that the product may be used or is effective
9.16	for the diagnosis, prevention, treatment, or cure of a disease or that it may be used to alter
9.17	the structure or function of human or animal bodies, unless the claim has been approved by
9.18	the United States Food and Drug Administration.
9.19	Sec. 9. [342.09] PACKAGING.
9.20	Subdivision 1. General. Any hemp-derived consumable or topical product sold in this
9.21	state must be packaged as required by this section and rules adopted under this chapter.
9.22	Subd. 2. Packaging requirements. (a) Any hemp-derived consumable or topical product
9.23	sold in this state must be:
9.24	(1) prepackaged in packaging or a container that is plain, child-resistant, tamper-evident
9.25	and opaque; or
9.26	(2) placed in packaging or a container that is plain, child-resistant, tamper-evident, and
9.27	opaque at the final point of sale to a customer.
9.28	(b) If a hemp-derived consumable or topical product is packaged in a manner that
9.29	indicates serving sizes, the product must be packaged in one or more easily identifiable
9.30	single-serving portions.

Sec. 9. 9

<u>(c</u>	c) If a hemp-derived consumable or topical product is an edible product for human
cons	umption intended for more than a single use or containing multiple servings, the product
must	be prepackaged or placed at the final point of sale in packaging or a container that is
resea	<u>llable.</u>
<u>s</u>	ubd. 3. Packaging prohibitions. (a) Hemp-derived consumable or topical products
sold	in this state must not be packaged in a manner that:
<u>(</u>	1) bears a reasonable resemblance to any commercially available product; or
<u>(2</u>	2) is designed to appeal to persons under age 21.
<u>(l</u>	b) Packaging for hemp-derived consumables or topical products must not contain or
be co	pated with any perfluoroalkyl substance.
Car	10 1240 101 ADMEDITICEMENT
Sec	e. 10. [342.10] ADVERTISEMENT.
N	To business shall publish or cause to be published an advertisement for a hemp-derived
cons	umable or topical product in a manner that:
<u>(</u>	1) contains false or misleading statements; or
<u>(2</u>	2) contains unverified claims about the health or therapeutic benefits or effects of
cons	uming the product.
C	11 12 40 111 ENEOD CEMENT
Sec	c. 11. [342.11] ENFORCEMENT.
<u>(</u> a	a) A hemp product sold under this chapter shall be considered an adulterated drug if
the h	emp product:
<u>(</u>	1) consists, in whole or in part, of any filthy, putrid, or decomposed substance;
<u>(2</u>	2) has been produced, prepared, packed, or held under unsanitary conditions where it
may	have been rendered injurious to health or where it may have been contaminated with
filth;	
<u>(3</u>	3) has a container that is composed, in whole or in part, of any poisonous or deleterious
subst	tance that may render the contents injurious to health;
(4	4) contains any color additives or excipients that have been found by the FDA to be
	fe for human or animal consumption; or
<u>(:</u>	5) contains an amount or percentage of cannabinoids that is different than the amount
or pe	ercentage stated on the label.

Sec. 11. 10

(b) A product sold under this section shall be considered a misbranded drug if the 11.1 product's labeling is false or misleading in any manner or in violation of the requirements 11.2 11.3 of this section. (c) The office has the authority to issue cease and desist orders and to seek injunctive 11.4 11.5 relief for a violation of this section. Sec. 12. [342.12] FEES. 11.6 Fees collected under this chapter must be credited to the hemp account, which is hereby 11.7 established in the state treasury. Interest earned in the account accrues to the account. Funds 11.8 in the hemp account are annually appropriated to the commissioner to implement and enforce 11.9 11.10 this chapter. Sec. 13. [342.15] DEFINITIONS. 11.11 Subdivision 1. Terms. For purposes of sections 342.15 to 342.29, the following terms 11.12 have the meanings given. 11.13 Subd. 2. **Disqualifying felony offense.** "Disqualifying felony offense" means a violation 11.14 of a state or federal controlled substance law that is a felony under Minnesota law or would 11.15 be a felony if committed in Minnesota, regardless of the sentence imposed, unless the 11.16 commissioner determines that the person's conviction was for the medical use of cannabis 11.17 or assisting with the medical use of cannabis. 11.18 Subd. 3. Health care practitioner. "Health care practitioner" means a Minnesota-licensed 11.19 doctor of medicine, a Minnesota-licensed physician assistant acting within the scope of 11.20 authorized practice, or a Minnesota-licensed advanced practice registered nurse who has 11.21 the primary responsibility for the care and treatment of the qualifying medical condition of 11.22 a person diagnosed with a qualifying medical condition. 11.23 11.24 Subd. 4. Health records. "Health records" means health records as defined in section 144.291, subdivision 2, paragraph (c). 11.25 11.26 Subd. 5. Medical cannabis. (a) "Medical cannabis" means any species of the genus cannabis plant or any mixture or preparation of them, including whole plant extracts and 11.27 11.28 resins, and is delivered in the form of: (1) liquid, including but not limited to oil; 11.29 (2) pill; 11.30 (3) vaporized delivery method with use of liquid or oil; 11.31

Sec. 13.

(4) combustion with use of dried raw cannabis; or	
(5) any other method approved by the commissioner.	
(b) This definition includes any part of the genus cannabis plant before being processed	d
into a form allowed under paragraph (a) that is possessed by a person while that person is	<u>s</u>
engaged in employment duties necessary to carry out a requirement under sections 342.13	5
to 342.29 for a registered manufacturer or a laboratory under contract with a registered	
manufacturer. This definition also includes any hemp acquired by a manufacturer by a hem	p
grower as permitted under section 342.17.	
(c) Medical cannabis does not include industrial hemp products or hemp-derived	
consumable or topical products.	
Subd. 6. Medical cannabis manufacturer. "Medical cannabis manufacturer" or	
"manufacturer" means an entity registered by the commissioner to cultivate, acquire,	
manufacture, possess, prepare, transfer, transport, supply, or dispense medical cannabis,	
delivery devices, or related supplies and educational materials.	
Subd. 7. Medical cannabis product. "Medical cannabis product" means any delivery	<u>/</u>
device or related supplies and educational materials used in the administration of medical	1
cannabis for a patient with a qualifying medical condition enrolled in the registry program	<u>1.</u>
Subd. 8. Patient. "Patient" means a Minnesota resident who has been diagnosed with	a
qualifying medical condition by a health care practitioner and who has otherwise met any	<u>y</u>
other requirements for patients under sections 342.15 to 342.29 to participate in the registry	<u>y</u>
program under sections 342.15 to 342.29.	
Subd. 9. Patient registry number. "Patient registry number" means a unique	
identification number assigned by the commissioner to a patient enrolled in the registry	
program.	
Subd. 10. Registered designated caregiver. "Registered designated caregiver" means	<u>S</u>
a person who:	
(1) is at least 18 years old;	
(2) does not have a conviction for a disqualifying felony offense;	
(3) has been approved by the commissioner to assist a patient who requires assistance	<u>;</u>
in administering medical cannabis or obtaining medical cannabis from a distribution facility	y ;
<u>and</u>	

Sec. 13. 12

13.1	(4) is authorized by the commissioner to assist the patient with the use of medical
13.2	<u>cannabis.</u>
13.3	Subd. 11. Registry program. "Registry program" means the patient registry established
13.4	in sections 342.15 to 342.29.
13.5	Subd. 12. Registry verification. "Registry verification" means the verification provided
13.6	by the commissioner that a patient is enrolled in the registry program and that includes the
13.7	patient's name, registry number, and, if applicable, the name of the patient's registered
13.8	designated caregiver or parent, legal guardian, or spouse.
13.9	Subd. 13. Qualifying medical condition. "Qualifying medical condition" means a
13.10	diagnosis of any of the following conditions:
13.11	(1) cancer, if the underlying condition or treatment produces one or more of the following:
13.12	(i) severe or chronic pain;
13.13	(ii) nausea or severe vomiting; or
13.14	(iii) cachexia or severe wasting;
13.15	(2) glaucoma;
13.16	(3) human immunodeficiency virus or acquired immune deficiency syndrome;
13.17	(4) Tourette syndrome;
13.18	(5) amyotrophic lateral sclerosis;
13.19	(6) seizures, including those characteristic of epilepsy;
13.20	(7) severe and persistent muscle spasms, including those characteristic of multiple
13.21	sclerosis;
13.22	(8) inflammatory bowel disease, including Crohn's disease;
13.23	(9) terminal illness, with a probable life expectancy of under one year, if the illness or
13.24	its treatment produces one or more of the following:
13.25	(i) severe or chronic pain;
13.26	(ii) nausea or severe vomiting; or
13.27	(iii) cachexia or severe wasting; or
13.28	(10) any other medical condition or its treatment approved by the commissioner.

Sec. 13. 13

14.2

14.3

14.4

14.5

14.6

14.7

14.8

14.9

14.10

14.11

14.12

14.13

14.14

14.15

14.16

14.17

14.18

14.19

14.20

14.21

14.22

14.23

14.24

14.25

14.26

14.27

14.28

14.29

14.30

14.31

14.32

14.33

Sec. 14. [342.16] PATIENT REGISTRY PROGRAM ESTABLISHED.

Subdivision 1. Patient registry program; establishment. (a) The commissioner shall establish a patient registry program to evaluate data on patient demographics, effective treatment options, clinical outcomes, and quality-of-life outcomes for the purpose of reporting on the benefits, risks, and outcomes regarding patients with a qualifying medical condition engaged in the therapeutic use of medical cannabis.

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

Subd. 2. Commissioner duties. (a) The commissioner shall:

- (1) give notice of the program to health care practitioners in the state who are eligible to serve as health care practitioners and explain the purposes and requirements of the program;
- (2) allow each health care practitioner who meets or agrees to meet the program's requirements and who requests to participate to be included in the registry program to collect data for the patient registry;
- (3) provide explanatory information and assistance to each health care practitioner in understanding the nature of therapeutic use of medical cannabis within program requirements;
- (4) create and provide a certification to be used by a health care practitioner for the practitioner to certify whether a patient has been diagnosed with a qualifying medical condition and include in the certification an option for the practitioner to certify whether the patient, in the health care practitioner's medical opinion, is developmentally or physically disabled and, as a result of that disability, the patient requires assistance in administering medical cannabis or obtaining medical cannabis from a distribution facility;
- (5) supervise the participation of the health care practitioner in conducting patient treatment and health records reporting in a manner that ensures stringent security and record-keeping requirements and that prevents the unauthorized release of private data on individuals as defined by section 13.02;
- (6) develop safety criteria for patients with a qualifying medical condition as a requirement of the patient's participation in the program to prevent the patient from undertaking any task under the influence of medical cannabis that would constitute negligence or professional malpractice on the part of the patient; and
- (7) conduct research and studies based on data from health records submitted to the registry program and submit reports on intermediate or final research results to the legislature

15.2

15.3

15.4

15.5

15.6

15.7

15.8

15.9

and major scientific journals. The commissioner may contract with a third party to complete the requirements of this clause. Any reports submitted must comply with section 342.18, subdivision 2. (b) The commissioner may add a delivery method under section 342.15, subdivision 5, or add, remove, or modify a qualifying medical condition under section 342.15, subdivision 13, upon a petition from a member of the public or the task force on medical cannabis therapeutic research or as directed by law. The commissioner shall evaluate all petitions to add a qualifying medical condition or to remove or modify an existing qualifying medical condition submitted by the task force on medical cannabis therapeutic research or as directed by law and may make the addition, removal, or modification if the commissioner determines 15.10 the addition, removal, or modification is warranted based on the best available evidence 15.11 and research. If the commissioner wishes to add a delivery method under section 342.15, 15.12 subdivision 5, or add or remove a qualifying medical condition under section 342.15, 15.13 subdivision 13, the commissioner must notify the chairs and ranking minority members of 15.14 the legislative committees with jurisdiction over health and public safety policy of the 15.15 addition or removal and the reasons for its addition or removal, including any written 15.16 comments received by the commissioner from the public and any guidance received from 15.17 the task force on medical cannabis research, by January 15 of the year in which the 15.18 commissioner wishes to make the change. The change is effective on August 1 of that year 15.19 unless the legislature by law provides otherwise. 15.20 Subd. 3. Patient application. (a) The commissioner shall develop a patient application 15.21 for enrollment into the registry program. The application shall be available to the patient 15.22 and given to health care practitioners in the state who are eligible to serve as health care 15.23 15.24 practitioners. The application must include: (1) the name, mailing address, and date of birth of the patient; 15.25 15.26 (2) the name, mailing address, and telephone number of the patient's health care practitioner; 15.27 15.28 (3) the name, mailing address, and date of birth of the patient's designated caregiver, if any, or the patient's parent, legal guardian, or spouse if the parent, legal guardian, or spouse 15.29 is acting as a caregiver; 15.30 (4) a copy of the certification from the patient's health care practitioner that is dated 15.31 within 90 days prior to submitting the application that certifies that the patient has been 15.32 15.33 diagnosed with a qualifying medical condition; and

16.1	(5) all other signed affidavits and enrollment forms required by the commissioner under
16.2	sections 342.15 to 342.29, including but not limited to the disclosure form required under
16.3	paragraph (c).
16.4	(b) The commissioner shall require a patient to resubmit a copy of the certification from
16.5	the patient's health care practitioner on a yearly basis and shall require that the recertification
16.6	be dated within 90 days of submission.
16.7	(c) The commissioner shall develop a disclosure form and require, as a condition of
16.8	enrollment, all patients to sign a copy of the disclosure. The disclosure must include:
16.9	(1) a statement that, notwithstanding any law to the contrary, the commissioner, or an
16.10	employee of any state agency, may not be held civilly or criminally liable for an injury, loss
16.11	of property, personal injury, or death caused by any act or omission while acting within the
16.12	scope of office or employment under sections 342.15 to 342.29; and
16.13	(2) the patient's acknowledgment that enrollment in the patient registry program is
16.14	conditional on the patient's agreement to meet the requirements of sections 342.15 to 342.29.
16.15	Subd. 4. Registered designated caregiver. (a) The commissioner shall register a
16.16	designated caregiver for a patient if the patient requires assistance in administering medical
16.17	cannabis or obtaining medical cannabis from a distribution facility and the caregiver has
16.18	agreed, in writing, to be the patient's designated caregiver. As a condition of registration as
16.19	a designated caregiver, the commissioner shall require the person to:
16.20	(1) be at least 18 years of age;
16.21	(2) agree to only possess the patient's medical cannabis for purposes of assisting the
16.22	patient; and
16.23	(3) agree that if the application is approved, the person will not be a registered designated
16.24	caregiver for more than six registered patients at one time. Patients who reside in the same
16.25	residence shall count as one patient.
16.26	(b) The commissioner shall conduct a criminal background check on the designated
16.27	caregiver prior to registration to ensure that the person does not have a conviction for a
16.28	disqualifying felony offense. Any cost of the background check shall be paid by the person
16.29	seeking registration as a designated caregiver. A designated caregiver must have the criminal
16.30	background check renewed every two years.
16.31	(c) Nothing in sections 342.15 to 342.29 shall be construed to prevent a person registered
16.32	as a designated caregiver from also being enrolled in the registry program as a patient and
16.33	possessing and using medical cannabis as a patient.

17.1	Subd. 5. Parent, legal guardian, or spouse. A parent, legal guardian, or spouse of a
17.2	patient may act as the caregiver to the patient without having to register as a designated
17.3	caregiver. The parent, legal guardian, or spouse shall follow the requirements in sections
17.4	342.15 to 342.29. Nothing in sections 342.15 to 342.29 limits any legal authority of a parent,
17.5	legal guardian, or spouse for the patient under any other law.
17.6	Subd. 6. Patient enrollment. (a) After receipt of a patient's application, application fees,
17.7	and signed disclosure, the commissioner shall enroll the patient in the registry program and
17.8	issue a registry verification to the patient and patient's registered designated caregiver or
17.9	parent, legal guardian, or spouse, if applicable. The commissioner shall approve or deny a
17.10	patient's application for participation in the registry program within 30 days after the
17.11	commissioner receives the patient's application and application fee. A patient's enrollment
17.12	in the registry program shall only be denied if the patient:
17.13	(1) does not have certification from a health care practitioner that the patient has been
17.14	diagnosed with a qualifying medical condition;
17.15	(2) has not signed and returned to the commissioner the disclosure form required under
17.16	subdivision 3, paragraph (c);
17.17	(3) does not provide the information required;
17.18	(4) has previously been removed from the registry program for violations of section
17.19	<u>342.20 or 342.24; or</u>
17.20	(5) provides false information.
17.21	(b) The commissioner shall give written notice to a patient of the reason for denying
17.22	enrollment in the registry program.
17.23	(c) Denial of enrollment into the registry program is considered a final decision of the
17.24	commissioner and is subject to judicial review under the Administrative Procedure Act
17.25	pursuant to chapter 14.
17.26	(d) A patient's enrollment in the registry program may only be revoked upon the death
17.27	of the patient or if a patient violates a requirement under section 342.20 or 342.24.
17.28	(e) The commissioner shall develop a registry verification to provide to the patient, the
17.29	health care practitioner identified in the patient's application, and the manufacturer. The
17.30	registry verification shall include:
17.31	(1) the patient's name and date of birth;
17.32	(2) the patient registry number assigned to the patient; and

(3) the name and date of birth of the patient's registered designated caregiver, if any, or 18.1 the name of the patient's parent, legal guardian, or spouse if the parent, legal guardian, or 18.2 18.3 spouse is acting as a caregiver. Subd. 7. Notice requirements. Patients and registered designated caregivers shall notify 18.4 the commissioner of any address or name change within 30 days of the change. A patient 18.5 or registered designated caregiver is subject to a \$100 fine for failure to notify the 18.6 commissioner of the change. 18.7 Sec. 15. [342.17] COMMISSIONER DUTIES. 18.8 Subdivision 1. Medical cannabis manufacturer registration. (a) The commissioner 18.9 shall register two in-state manufacturers for the production of all medical cannabis within 18.10 the state. A registration agreement between the commissioner and a manufacturer is 18.11 nontransferable. The commissioner shall register new manufacturers or reregister the existing 18.12 18.13 manufacturers by December 1 every two years using the factors described in this subdivision. The commissioner shall accept applications after December 1, 2014, if one of the 18.14 manufacturers registered before December 1, 2014, ceases to be registered as a manufacturer. 18.15 18.16 The commissioner's determination that no manufacturer exists to fulfill the duties under sections 342.15 to 342.29 is subject to judicial review in Ramsey County District Court. 18.17 Data submitted during the application process are private data on individuals or nonpublic 18.18 18.19 data as defined in section 13.02 until the manufacturer is registered under this section. Data on a manufacturer that is registered are public data unless the data are trade secret or security 18.20 18.21 information under section 13.37. (b) As a condition for registration, a manufacturer must: 18.22 (1) supply medical cannabis to patients; and 18.23 (2) comply with sections 342.15 to 342.29. 18.24 (c) The commissioner shall consider the following factors when determining which 18.25 manufacturer to register: 18.26 (1) the technical expertise of the manufacturer in cultivating medical cannabis and 18.27 converting the medical cannabis into an acceptable delivery method under section 342.15, 18.28 18.29 subdivision 5; (2) the qualifications of the manufacturer's employees; 18.30 18.31 (3) the long-term financial stability of the manufacturer;

Sec. 15.

(4) the ability to provide appropriate security measures on the premises of the 19.1 19.2 manufacturer; 19.3 (5) whether the manufacturer has demonstrated an ability to meet the medical cannabis production needs required by sections 342.15 to 342.29; and 19.4 19.5 (6) the manufacturer's projection and ongoing assessment of fees on patients with a qualifying medical condition. 19.6 19.7 (d) If an officer, director, or controlling person of the manufacturer pleads or is found guilty of intentionally diverting medical cannabis to a person other than allowed by law 19.8 under section 342.24, subdivision 1, the commissioner may decide not to renew the 19.9 registration of the manufacturer, provided the violation occurred while the person was an 19.10 officer, director, or controlling person of the manufacturer. 19.11 19.12 (e) The commissioner shall require each medical cannabis manufacturer to contract with an independent laboratory to test medical cannabis produced by the manufacturer. The 19.13 commissioner shall approve the laboratory chosen by each manufacturer and require that 19.14 the laboratory report testing results to the manufacturer in a manner determined by the 19.15 19.16 commissioner. Subd. 2. Revocation or nonrenewal of a medical cannabis manufacturer 19.17 registration. If the commissioner intends to revoke or not renew a registration issued under 19.18 this section, the commissioner must first notify in writing the manufacturer against whom 19.19 the action is to be taken and provide the manufacturer with an opportunity to request a 19.20 hearing under the contested case provisions of chapter 14. If the manufacturer does not 19.21 request a hearing by notifying the commissioner in writing within 20 days after receipt of 19.22 the notice of proposed action, the commissioner may proceed with the action without a 19.23 hearing. For revocations, the registration of a manufacturer is considered revoked on the 19.24 date specified in the commissioner's written notice of revocation. 19.25 Subd. 3. Temporary suspension proceedings. The commissioner may institute 19.26 proceedings to temporarily suspend the registration of a medical cannabis manufacturer for 19.27 up to 90 days by notifying the manufacturer in writing if any action by an employee, agent, 19.28 officer, director, or controlling person of the manufacturer: 19.29 19.30 (1) violates sections 342.15 to 342.29 or the rules adopted under those sections; (2) permits, aids, or abets the commission of any violation of state law at the 19.31 manufacturer's location for cultivation, harvesting, manufacturing, packaging, and processing 19.32 or at any site for distribution of medical cannabis; 19.33

Sec. 15. 19

(3) performs an act contrary to the welfare of a registered patient or registered designated 20.1 20.2 caregiver; or (4) obtains or attempts to obtain a registration by fraudulent means or misrepresentation. 20.3 Subd. 4. **Notice to patients.** Upon the revocation or nonrenewal of a manufacturer's 20.4 20.5 registration under subdivision 2 or implementation of an enforcement action under section 342.24, subdivision 1, that may affect the ability of a registered patient, a registered 20.6 designated caregiver, or a registered patient's parent, legal guardian, or spouse to obtain 20.7 medical cannabis from the manufacturer subject to the enforcement action, the commissioner 20.8 shall notify in writing each registered patient and the patient's registered designated caregiver 20.9 20.10 or registered patient's parent, legal guardian, or spouse about the outcome of the proceeding and information regarding alternative registered manufacturers. The notice must be provided 20.11 two or more business days prior to the effective date of the revocation, nonrenewal, or other 20.12 enforcement action. 20.13 Subd. 5. Range of compounds and dosages; report. The commissioner shall review 20.14 and publicly report the existing medical and scientific literature regarding the range of 20.15 recommended dosages for each qualifying condition and the range of chemical compositions 20.16 of any plant of the genus cannabis that will likely be medically beneficial for each of the 20.17 qualifying medical conditions. The commissioner shall make the information available to 20.18 patients with qualifying medical conditions and update the information annually. The 20.19 commissioner may consult with the independent laboratory under contract with the 20.20 manufacturer or other experts in reporting the range of recommended dosages for each 20.21 qualifying medical condition, the range of chemical compositions that will likely be medically 20.22 beneficial, and any risks of noncannabis drug interactions. The commissioner shall consult 20.23 with each manufacturer on an annual basis on medical cannabis offered by the manufacturer. 20.24 The list of medical cannabis offered by a manufacturer shall be published on the Department 20.25 of Health website. 20.26 Subd. 6. Reports. (a) The commissioner shall provide regular updates to the Task Force 20.27 on Medical Cannabis Therapeutic Research and to the chairs and ranking minority members 20.28 of the legislative committees with jurisdiction over health and human services, public safety, 20.29 judiciary, and civil law regarding: (1) any changes in federal law or regulatory restrictions 20.30 regarding the use of medical cannabis or hemp; and (2) the market demand and supply in 20.31 this state for products made from hemp that can be used for medicinal purposes. 20.32 (b) The commissioner may submit medical research based on the data collected under 20.33 sections 342.15 to 342.29 to any federal agency with regulatory or enforcement authority 20.34

Sec. 15. 20

over medical cannabis to demonstrate the effectiveness of medical cannabis for treating a 21.1 qualifying medical condition. 21.2 Sec. 16. [342.18] HEALTH CARE PRACTITIONER DUTIES. 21.3 Subdivision 1. Health care practitioner duties. (a) Prior to a patient's enrollment in 21.4 the registry program, a health care practitioner shall: 21.5 (1) determine, in the health care practitioner's medical judgment, whether a patient suffers 21.6 from a qualifying medical condition and, if so determined, provide the patient with a 21.7 certification of that diagnosis; 21.8 21.9 (2) advise patients, registered designated caregivers, and parents, legal guardians, or spouses who are acting as caregivers of the existence of any nonprofit patient support groups 21.10 or organizations; 21.11 21.12 (3) provide explanatory information from the commissioner to patients with qualifying 21.13 medical conditions, including disclosure to all patients about the experimental nature of therapeutic use of medical cannabis; the possible risks, benefits, and side effects of the 21.14 proposed treatment; and the application and other materials from the commissioner; and 21.15 provide patients with the Tennessen warning as required by section 13.04, subdivision 2; 21.16 21.17 and 21.18 (4) agree to continue treatment of the patient's qualifying medical condition and report medical findings to the commissioner. 21.19 21.20 (b) Upon notification from the commissioner of the patient's enrollment in the registry program, the health care practitioner shall: 21.21 (1) participate in the patient registry reporting system under the guidance and supervision 21.22 of the commissioner; 21.23 21.24 (2) report health records of the patient to the commissioner throughout the ongoing treatment of the patient in a manner determined by the commissioner and in accordance 21.25 with subdivision 2; 21.26 (3) determine, on a yearly basis, if the patient continues to suffer from a qualifying 21.27 medical condition and, if so, issue the patient a new certification of that diagnosis; and 21.28 21.29 (4) otherwise comply with all requirements developed by the commissioner. (c) A health care practitioner may conduct a patient assessment to issue a recertification 21.30 as required under paragraph (b), clause (3), via telehealth, as defined in section 62A.673, 21.31 subdivision 2.

Sec. 16. 21

21.32

22.1	(d) Nothing in this section requires a health care practitioner to participate in the registry
22.2	program.
22.3	Subd. 2. Data collected on patients by a health care practitioner and reported to
22.4	the patient registry are health records under section 144.291 and are private data on
22.5	individuals under section 13.02, but may be used or reported in an aggregated, nonidentifiable
22.6	form as part of a scientific, peer-reviewed publication of research conducted under section
22.7	342.17 or in the creation of summary data, as defined in section 13.02, subdivision 19.
22.8	Subd. 3. Advertising restrictions. (a) A health care practitioner shall not publish or
22.9	cause to be published any advertisement that:
22.10	(1) contains false or misleading statements about medical cannabis or the medical
22.11	cannabis registry program;
22.12	(2) uses colloquial terms to refer to medical cannabis, such as pot, weed, or grass;
22.13	(3) states or implies the health care practitioner is endorsed by the Department of Health,
22.14	the Office of Cannabis Derivatives, or the medical cannabis registry program;
22.15	(4) includes images of cannabis in its plant or leaf form or of cannabis-smoking
22.16	paraphernalia; or
22.17	(5) contains medical symbols that could reasonably be confused with symbols of
22.18	established medical associations or groups.
22.19	(b) A health care practitioner found by the commissioner to have violated this subdivision
22.20	is prohibited from certifying that patients have a qualifying medical condition for purposes
22.21	of patient participation in the registry program. The commissioner's decision that a health
22.22	care practitioner has violated this subdivision is a final decision of the commissioner and
22.23	is not subject to the contested case procedures in chapter 14.
22.24	Sec. 17. [342.19] MANUFACTURER OF MEDICAL CANNABIS DUTIES.
22.25	Subdivision 1. Manufacturer; requirements. (a) A manufacturer may operate eight
22.26	distribution facilities, which may include the manufacturer's single location for cultivation,
22.27	harvesting, manufacturing, packaging, and processing but is not required to include that
22.28	location. The commissioner shall designate the geographical service areas to be served by
22.29	each manufacturer based on geographical need throughout the state to improve patient
22.30	access. A manufacturer shall not have more than two distribution facilities in each
22.31	geographical service area assigned to the manufacturer by the commissioner. A manufacturer
22.32	shall operate only one location where all cultivation, harvesting, manufacturing, packaging,

23.2

23.3

23.4

23.5

23.6

23.7

23.8

23.9

23.10

23.11

23.21

23.22

23.23

23.24

23.25

23.26

23.27

23.31

and processing of medical cannabis shall be conducted. This location may be one of the manufacturer's distribution facility sites. The additional distribution facilities may dispense medical cannabis and medical cannabis products but may not contain any medical cannabis in a form other than those forms allowed under section 342.15, subdivision 5, and the manufacturer shall not conduct any cultivation, harvesting, manufacturing, packaging, or processing at the other distribution facility sites. Any distribution facility operated by the manufacturer is subject to the requirements applying to the manufacturer under sections 342.15 to 342.29, including but not limited to security and distribution requirements. (b) A manufacturer may acquire hemp grown in this state from a hemp grower and may acquire hemp products produced by a hemp processor. A manufacturer may manufacture or process hemp and hemp products into an allowable form of medical cannabis under section 342.15, subdivision 5. Hemp and hemp products acquired by a manufacturer under 23.12 this paragraph are subject to the same quality control program, security and testing 23.13 requirements, and other requirements that apply to medical cannabis under sections 342.15 23.14 to 342.29 and Minnesota Rules, chapter 4770. 23.15 (c) A medical cannabis manufacturer shall contract with a laboratory approved by the 23.16 commissioner, subject to any additional requirements set by the commissioner, for purposes 23.17 of testing medical cannabis manufactured or hemp or hemp products acquired by the medical 23.18 cannabis manufacturer as to content, contamination, and consistency to verify the medical 23.19 cannabis meets the requirements of section 342.15, subdivision 5. The cost of laboratory 23.20 testing shall be paid by the manufacturer. (d) The operating documents of a manufacturer must include procedures for: (1) the oversight of the manufacturer and procedures to ensure accurate record keeping; (2) the implementation of appropriate security measures to deter and prevent the theft of medical cannabis and unauthorized entrance into areas containing medical cannabis; and (3) the delivery and transportation of hemp between hemp growers and manufacturers and for the delivery and transportation of hemp products between hemp processors and manufacturers. 23.28 (e) A manufacturer shall implement security requirements, including requirements for 23.29 the delivery and transportation of hemp and hemp products, protection of each location by 23.30 a fully operational security alarm system, facility access controls, perimeter intrusion 23.32 detection systems, and a personnel identification system.

(f) A manufacturer shall not share office space with, refer patients to, or have any financial 24.1 relationship with a health care practitioner. 24.2 24.3 (g) A manufacturer shall not permit any person to consume medical cannabis on the property of the manufacturer. 24.4 24.5 (h) A manufacturer is subject to reasonable inspection by the commissioner. (i) For purposes of sections 342.15 to 342.29, a medical cannabis manufacturer is not 24.6 24.7 subject to the Board of Pharmacy licensure or regulatory requirements under chapter 151. (j) A medical cannabis manufacturer may not employ any person who is under 21 years 24.8 of age or who has been convicted of a disqualifying felony offense. An employee of a 24.9 medical cannabis manufacturer must submit a completed criminal history records check 24.10 consent form, a full set of classifiable fingerprints, and the required fees for submission to 24.11 the Bureau of Criminal Apprehension before an employee may begin working with the 24.12 manufacturer. The bureau must conduct a Minnesota criminal history records check and 24.13 the superintendent is authorized to exchange the fingerprints with the Federal Bureau of 24.14 Investigation to obtain the applicant's national criminal history record information. The 24.15 bureau shall return the results of the Minnesota and federal criminal history records checks 24.16 to the commissioner. 24.17 (k) A manufacturer may not operate in any location, whether for distribution or 24.18 cultivation, harvesting, manufacturing, packaging, or processing, within 1,000 feet of a 24.19 public or private school existing before the date of the manufacturer's registration with the 24.20 commissioner. 24.21 (l) A manufacturer shall comply with reasonable restrictions set by the commissioner 24.22 relating to signage, marketing, display, and advertising of medical cannabis. 24.23 24.24 (m) Before a manufacturer acquires hemp from a hemp grower or hemp products from 24.25 a hemp processor, the manufacturer must verify that the hemp grower or hemp processor has a valid license issued by the commissioner under this chapter. 24.26 24.27 (n) Until a state-centralized, seed-to-sale system is implemented that can track a specific medical cannabis plant from cultivation through testing and point of sale, the commissioner 24.28 shall conduct at least one unannounced inspection per year of each manufacturer that includes 24.29 inspection of: 24.30 24.31 (1) business operations; (2) physical locations of the manufacturer's manufacturing facility and distribution 24.32 facilities; 24.33

(3) financial information and inventory documentation, including laboratory testing 25.1 25.2 results; and (4) physical and electronic security alarm systems. 25.3 Subd. 2. Manufacturer; production. (a) A manufacturer of medical cannabis shall 25.4 25.5 provide a reliable and ongoing supply of all medical cannabis needed for the registry program through cultivation by the manufacturer and through the purchase of hemp from hemp 25.6 25.7 growers. (b) All cultivation, harvesting, manufacturing, packaging, and processing of medical 25.8 cannabis must take place in an enclosed, locked facility at a physical address provided to 25.9 the commissioner during the registration process. 25.10 (c) A manufacturer must process and prepare any medical cannabis plant material or 25.11 hemp plant material into a form allowable under section 342.15, subdivision 5, before 25.12 distribution of any medical cannabis. 25.13 Subd. 3. Manufacturer; distribution. (a) A manufacturer shall require that employees 25.14 licensed as pharmacists pursuant to chapter 151 be the only employees to give final approval 25.15 for the distribution of medical cannabis to a patient. A manufacturer may transport medical 25.16 cannabis or medical cannabis products that have been cultivated, harvested, manufactured, 25.17 packaged, and processed by that manufacturer to another registered manufacturer for the 25.18 other manufacturer to distribute. 25.19 25.20 (b) A manufacturer may distribute medical cannabis products whether or not the products have been manufactured by that manufacturer. 25.21 (c) Prior to distribution of any medical cannabis, the manufacturer shall: 25.22 (1) verify that the manufacturer has received the registry verification from the 25.23 commissioner for that individual patient; 25.24 (2) verify that the person requesting the distribution of medical cannabis is the patient, 25.25 the patient's registered designated caregiver, or the patient's parent, legal guardian, or spouse 25.26 25.27 listed in the registry verification using the procedures described in section 152.11, subdivision 2d; 25.28 25.29 (3) assign a tracking number to any medical cannabis distributed from the manufacturer; (4) ensure that any employee of the manufacturer licensed as a pharmacist pursuant to 25.30 chapter 151 has consulted with the patient to determine the proper dosage for the individual 25.31 patient after reviewing the ranges of chemical compositions of the medical cannabis and 25.32

26.2

26.3

26.4

26.5

26.6

26.7

26.8

26.9

26.10

26.11

26.12

26.13

26.14

26.15

26.16

26.17

26.18

26.19

26.20

26.21

26.22

26.23

26.24

26.25

26.26

26.27

26.28

26.29

26.30

26.31

26.32

26.33

the ranges of proper dosages reported by the commissioner. For purposes of this clause, a consultation may be conducted remotely by secure videoconference, telephone, or other remote means if the employee providing the consultation is able to confirm the identity of the patient and the consultation adheres to patient privacy requirements that apply to health care services delivered through telehealth. A pharmacist consultation under this clause is not required if a manufacturer is distributing medical cannabis to a patient according to a patient-specific dosage plan established with that manufacturer and is not modifying the dosage or product being distributed under that plan and the medical cannabis is distributed by a pharmacy technician; (5) properly package medical cannabis in compliance with the United States Poison Prevention Packing Act regarding child-resistant packaging and exemptions for packaging for elderly patients, and label distributed medical cannabis with a list of all active ingredients and individually identifying information, including: (i) the patient's name and date of birth; (ii) the name and date of birth of the patient's registered designated caregiver or, if listed on the registry verification, the name of the patient's parent or legal guardian, if applicable; (iii) the patient's registry identification number; (iv) the chemical composition of the medical cannabis; and (v) the dosage; and (6) ensure that the medical cannabis distributed contains a maximum of a 90-day supply of the dosage determined for that patient. (d) A manufacturer shall require an employee of the manufacturer who is transporting medical cannabis or medical cannabis products to a distribution facility or to another registered manufacturer to carry identification showing that the person is an employee of the manufacturer. (e) A manufacturer shall distribute medical cannabis in dried raw cannabis form only to a patient age 21 or older or to the registered designated caregiver, parent, legal guardian, or spouse of a patient age 21 or older. Subd. 4. Transportation of medical cannabis; staffing. (a) A medical cannabis manufacturer may staff a transport motor vehicle with only one employee if the medical cannabis manufacturer is transporting medical cannabis to either a certified laboratory for the purpose of testing or a facility for the purpose of disposal. If the medical cannabis manufacturer is transporting medical cannabis for any other purpose or destination, the

transport motor vehicle must be staffed with a minimum of two employees as required by 27.1 27.2 rules adopted by the commissioner. 27.3 (b) Notwithstanding paragraph (a), a medical cannabis manufacturer that is only transporting hemp for any purpose may staff the transport motor vehicle with only one 27.4 27.5 employee. Subd. 5. Distribution to recipient in a motor vehicle. A manufacturer may distribute 27.6 medical cannabis to a patient, registered designated caregiver, or parent, legal guardian, or 27.7 spouse of a patient who is at the distribution facility but remains in a motor vehicle if: 27.8 (1) distribution facility staff receive payment and distribute medical cannabis in a 27.9 designated zone that is as close as possible to the front door of the distribution facility; 27.10 (2) the manufacturer ensures that the receipt of payment and distribution of medical 27.11 cannabis are visually recorded by a closed-circuit television surveillance camera at the 27.12 distribution facility and provides any other necessary security safeguards; 27.13 (3) the manufacturer does not store medical cannabis outside a restricted access area at 27.14 the distribution facility, and distribution facility staff transport medical cannabis from a 27.15 restricted access area at the distribution facility to the designated zone for distribution only 27.16 after confirming that the patient, designated caregiver, or parent, guardian, or spouse has 27.17 arrived in the designated zone; 27.18 (4) the payment and distribution of medical cannabis take place only after a pharmacist 27.19 27.20 consultation takes place, if required under subdivision 3, paragraph (c), clause (4); (5) immediately following distribution of medical cannabis, distribution facility staff 27.21 enter the transaction in the state medical cannabis registry information technology database; 27.22 27.23 and (6) immediately following distribution of medical cannabis, distribution facility staff 27.24 take the payment received into the distribution facility. 27.25 Subd. 6. Disposal of medical cannabis plant root balls. Notwithstanding Minnesota 27.26 27.27 Rules, part 4770.1200, subpart 2, item C, a manufacturer is not required to grind root balls of medical cannabis plants or incorporate them with a greater quantity of nonconsumable 27.28 27.29 solid waste before transporting root balls to another location for disposal. For purposes of this subdivision, "root ball" means a compact mass of roots formed by a plant and any 27.30 attached growing medium. 27.31 Subd. 7. Report. Each manufacturer shall report to the commissioner on a monthly basis 27.32 the following information on each individual patient for the month prior to the report: 27.33

28.1	(1) the amount and dosages of medical cannabis distributed;
28.2	(2) the chemical composition of the medical cannabis; and
28.3	(3) the tracking number assigned to any medical cannabis distributed.
28.4	Sec. 18. [342.20] PATIENT DUTIES.
28.5	(a) A patient shall apply to the commissioner for enrollment in the registry program by
28.6	submitting an application as required in section 342.16 and an annual registration fee as
28.7	determined under section 342.26.
28.8	(b) As a condition of continued enrollment, a patient shall agree to:
28.9	(1) continue to receive regularly scheduled treatment for a qualifying medical condition
28.10	from the patient's health care practitioner; and
28.11	(2) report changes in the patient's qualifying medical condition to the patient's health
28.12	care practitioner.
28.13	(c) A patient shall only receive medical cannabis from a registered manufacturer but is
28.14	not required to receive medical cannabis products from only a registered manufacturer.
28.15	Sec. 19. [342.21] LIMITATIONS.
28.16	(a) Nothing in sections 342.15 to 342.29 permits any person to engage in and does not
28.17	prevent the imposition of any civil, criminal, or other penalties for:
28.18	(1) undertaking any task under the influence of medical cannabis that would constitute
28.19	negligence or professional malpractice;
28.20	(2) possessing or engaging in the use of medical cannabis:
28.21	(i) on a school bus or van;
28.22	(ii) on the grounds of any preschool or primary or secondary school;
28.23	(iii) in any correctional facility; or
28.24	(iv) on the grounds of any child care facility or home day care;
28.25	(3) vaporizing or combusting medical cannabis pursuant to section 342.15, subdivision
28.26	<u>5:</u>
28.27	(i) on any form of public transportation;
28.28	(ii) where the vapor would be inhaled by a nonpatient minor child or where the smoke
28.29	would be inhaled by a minor child; or

04/05/22

REVISOR

BD/LN

22-07476

as introduced

Sec. 19. 28

(iii) in any public place, including any indoor or outdoor area used by or open to the 29.1 general public or a place of employment as defined under section 144.413, subdivision 1b; 29.2 29.3 and (4) operating, navigating, or being in actual physical control of any motor vehicle, 29.4 29.5 aircraft, train, or motorboat or working on transportation property, equipment, or facilities while under the influence of medical cannabis. 29.6 (b) Nothing in sections 342.15 to 342.29 requires the medical assistance and 29.7 MinnesotaCare programs to reimburse an enrollee or a provider for costs associated with 29.8 the medical use of cannabis. Medical assistance and MinnesotaCare shall continue to provide 29.9 29.10 coverage for all services related to treatment of an enrollee's qualifying medical condition if the service or services are covered under chapter 256B or 256L. 29.11 Sec. 20. [342.22] DATA PRACTICES. 29.12 (a) Government data in patient files maintained by the commissioner and the health care 29.13 practitioner, and data submitted to or by a medical cannabis manufacturer, are private data 29.14 on individuals, as defined in section 13.02, subdivision 12, or nonpublic data, as defined in 29.15 29.16 section 13.02, subdivision 9, but may be used for purposes of complying with chapter 13 and complying with a request from the legislative auditor or the state auditor in the 29.17 performance of official duties. The provisions of section 13.05, subdivision 11, apply to a 29.18 registration agreement entered between the commissioner and a medical cannabis 29.19 29.20 manufacturer under section 342.17. (b) Not public data maintained by the commissioner may not be used for any purpose 29.21 not provided for in sections 342.15 to 342.29 and may not be combined or linked in any 29.22 manner with any other list, dataset, or database. 29.23 (c) The commissioner may execute data-sharing arrangements with the commissioner 29.24 29.25 of agriculture to verify licensing, inspection, and compliance information related to hemp growers and hemp processors under this chapter. 29.26 Sec. 21. [342.23] PROTECTIONS FOR REGISTRY PROGRAM PARTICIPATION. 29.27 Subdivision 1. Presumption. (a) There is a presumption that a patient enrolled in the 29.28 registry program under sections 342.15 to 342.29 is engaged in the authorized use of medical 29.29 cannabis. 29.30

Sec. 21. 29

(b) The presumption may be rebutted by evidence that conduct related to use of medical 30.1 cannabis was not for the purpose of treating or alleviating the patient's qualifying medical 30.2 30.3 condition or symptoms associated with the patient's qualifying medical condition. Subd. 2. Criminal and civil protections. (a) Subject to section 342.21, the following 30.4 30.5 are not violations under this chapter: (1) use or possession of medical cannabis or medical cannabis products by a patient 30.6 enrolled in the registry program or possession by a registered designated caregiver or the 30.7 parent, legal guardian, or spouse of a patient if the parent, legal guardian, or spouse is listed 30.8 on the registry verification; 30.9 (2) possession, dosage determination, or sale of medical cannabis or medical cannabis 30.10 products by a medical cannabis manufacturer, employees of a manufacturer, a laboratory 30.11 30.12 conducting testing on medical cannabis, or employees of the laboratory; and (3) possession of medical cannabis or medical cannabis products by any person while 30.13 carrying out the duties required under sections 342.15 to 342.29. 30.14 (b) Medical cannabis obtained and distributed pursuant to sections 342.15 to 342.29 and 30.15 associated property is not subject to forfeiture under sections 609.531 to 609.5316. 30.16 (c) The commissioner, the commissioner's staff, the commissioner's agents or contractors, 30.17 and any health care practitioner are not subject to any civil or disciplinary penalties by the 30.18 Board of Medical Practice, the Board of Nursing, or any business, occupational, or 30.19 professional licensing board or entity solely for participation in the registry program under 30.20 sections 342.15 to 342.29. A pharmacist licensed under chapter 151 is not subject to any 30.21 civil or disciplinary penalties by the Board of Pharmacy when acting in accordance with 30.22 sections 342.15 to 342.29. Nothing in this section affects a professional licensing board 30.23 from taking action in response to violations of any other section of law. 30.24 30.25 (d) Notwithstanding any law to the contrary, the commissioner, the governor of Minnesota, or an employee of any state agency may not be held civilly or criminally liable 30.26 for any injury, loss of property, personal injury, or death caused by any act or omission 30.27 while acting within the scope of office or employment under sections 342.15 to 342.29. 30.28 (e) Federal, state, and local law enforcement authorities are prohibited from accessing 30.29 the patient registry under sections 342.15 to 342.29, except when acting pursuant to a valid 30.30 search warrant. 30.31 (f) Notwithstanding any law to the contrary, neither the commissioner nor a public 30.32 employee may release data or information about an individual contained in any report, 30.33

Sec. 21. 30

31.2

31.3

31.4

31.5

31.6

31.7

31.8

31.9

31.10

31.11

31.12

31.13

31.14

31.15

31.16

31.17

31.18

31.19

31.20

31.21

31.22

31.23

31.24

31.25

31.26

31.27

31.28

31.29

31.30

31.31

31.32

following:

REVISOR

document, or registry created under sections 342.15 to 342.29 or any information obtained about a patient participating in the program, except as provided in sections 342.15 to 342.29. (g) No information contained in a report, document, or registry or obtained from a patient under sections 342.15 to 342.29 may be admitted as evidence in a criminal proceeding unless independently obtained or in connection with a proceeding involving a violation of sections 342.15 to 342.29. (h) Notwithstanding section 13.09, any person who violates paragraph (e) or (f) is guilty of a gross misdemeanor. (i) An attorney may not be subject to disciplinary action by the Minnesota Supreme Court or the Lawyers Professional Responsibility Board for providing legal assistance to prospective or registered manufacturers or others related to activity that is no longer subject to criminal penalties under state law pursuant to sections 342.15 to 342.29. (j) Possession of a registry verification or application for enrollment in the program by a person entitled to possess or apply for enrollment in the registry program does not constitute probable cause or reasonable suspicion, nor shall it be used to support a search of the person or property of the person possessing or applying for the registry verification or otherwise subject the person or property of the person to inspection by any governmental agency. Subd. 3. **Discrimination prohibited.** (a) No school or landlord may refuse to enroll or lease to and may not otherwise penalize a person solely for the person's status as a patient enrolled in the registry program under sections 342.15 to 342.29 unless failing to do so would violate federal law or regulations or cause the school or landlord to lose a monetary or licensing-related benefit under federal law or regulations. (b) For the purposes of medical care, including organ transplants, a registry program enrollee's use of medical cannabis under sections 342.15 to 342.29 is considered the equivalent of the authorized use of any other medication used at the discretion of a physician or advanced practice registered nurse and does not constitute the use of an illicit substance or otherwise disqualify a patient from needed medical care. (c) Unless a failure to do so would violate federal law or regulations or cause an employer to lose a monetary or licensing-related benefit under federal law or regulations, an employer

may not discriminate against a person in hiring, termination, or any term or condition of

employment or otherwise penalize a person if the discrimination is based upon either of the

Sec. 21. 31

(1) the person's status as a patient enrolled in the registry program under sections 342.15 32.1 32.2 to 342.29; or 32.3 (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 32.4 32.5 of employment or during the hours of employment. (d) An employee who is required to undergo employer drug testing pursuant to section 32.6 181.953 may present verification of enrollment in the patient registry as part of the employee's 32.7 explanation under section 181.953, subdivision 6. 32.8 (e) A person shall not be denied custody of a minor child or visitation rights or parenting 32.9 time with a minor child solely based on the person's status as a patient enrolled in the registry 32.10 program under sections 342.15 to 342.29. There shall be no presumption of neglect or child 32.11 32.12 endangerment for conduct allowed under sections 342.15 to 342.29 unless the person's behavior is such that it creates an unreasonable danger to the safety of the minor as 32.13 established by clear and convincing evidence. 32.14 32.15 Sec. 22. [342.24] VIOLATIONS. Subdivision 1. Intentional diversion; criminal penalty. In addition to any other 32.16 applicable penalty in law, a manufacturer or an agent of a manufacturer who intentionally 32.17 32.18 transfers medical cannabis to a person other than another registered manufacturer, a patient, a registered designated caregiver, or, if listed on the registry verification, a parent, legal 32.19 guardian, or spouse of a patient is guilty of a felony punishable by imprisonment for not 32.20 more than two years or by payment of a fine of not more than \$3,000, or both. A person 32.21 convicted under this subdivision may not continue to be affiliated with the manufacturer 32.22 and is disqualified from further participation under sections 342.15 to 342.29. 32.23 Subd. 2. **Intentional diversion outside the state**; **penalties.** (a) In addition to any other 32.24 applicable penalty in law, the commissioner may levy a fine of \$250,000 against a 32.25 manufacturer and may immediately initiate proceedings to revoke the manufacturer's 32.26 registration using the procedure in section 342.17 if: 32.27 (1) an officer, director, or controlling person of the manufacturer pleads or is found 32.28 guilty under subdivision 1 of intentionally transferring medical cannabis, while the person 32.29 was an officer, director, or controlling person of the manufacturer, to a person other than 32.30 allowed by law; and 32.31

Sec. 22. 32

(2) in intentionally transferring medical cannabis to a person other than allowed by law, 33.1 the officer, director, or controlling person transported or directed the transport of medical 33.2 33.3 cannabis outside of Minnesota. (b) All fines collected under this subdivision shall be deposited in the state government 33.4 33.5 special revenue fund. Subd. 3. Diversion by patient, registered designated caregiver, parent, legal guardian, 33.6 or patient's spouse; criminal penalty. In addition to any other applicable penalty in law, 33.7 a patient, a registered designated caregiver, or, if listed on the registry verification, a parent, 33.8 legal guardian, or spouse of a patient who intentionally sells or otherwise transfers medical 33.9 33.10 cannabis to a person other than a patient, a designated registered caregiver, or, if listed on the registry verification, a parent, legal guardian, or spouse of a patient is guilty of a felony 33.11 punishable by imprisonment for not more than two years or payment of a fine of not more 33.12 than \$3,000, or both. 33.13 Subd. 4. False statement; criminal penalty. A person who intentionally makes a false 33.14 statement to a law enforcement official about any fact or circumstance relating to the medical 33.15 use of cannabis to avoid arrest or prosecution is guilty of a misdemeanor punishable by 33.16 imprisonment for not more than 90 days or by payment of a fine of not more than \$1,000, 33.17 or both. The penalty is in addition to any other penalties that may apply for making a false 33.18 statement or for the possession, cultivation, or sale of cannabis not protected by sections 33.19 342.15 to 342.29. If a person convicted of violating this subdivision is a patient or a registered 33.20 designated caregiver, the person is disqualified from further participation under sections 33.21 33.22 342.15 to 342.29. Subd. 5. Submission of false records; criminal penalty. A person who knowingly 33.23 submits false records or documentation required by the commissioner to register as a 33.24 33.25 manufacturer of medical cannabis under sections 342.15 to 342.29 is guilty of a felony and 33.26 may be sentenced to imprisonment for not more than two years or payment of a fine of not more than \$3,000, or both. 33.27 33.28 Subd. 6. Violation by health care practitioner; criminal penalty. A health care practitioner who knowingly refers patients to a manufacturer or to a designated caregiver, 33.29 who advertises as a manufacturer, or who issues certifications while holding a financial 33.30 interest in a manufacturer is guilty of a misdemeanor and may be sentenced to imprisonment 33.31 for not more than 90 days or payment of a fine of not more than \$1,000, or both. 33.32

Sec. 22. 33

34.2

34.3

34.4

34.5

34.6

34.7

34.8

34.9

34.10

34.11

34.12

34.13

34.14

34.15

34.16

34.17

34.18

34.19

34.20

34.21

34.22

34.23

34.24

34.25

34.26

34.27

34.28

34.29

34.30

34.31

34.32

34.33

Subd. 7. Other violations; civil penalty. If no penalty has been specified, a manufacturer must be fined up to \$1,000 for any violation of sections 342.15 to 342.29 or the regulations issued pursuant to them. This penalty is in addition to any other applicable penalties in law.

Sec. 23. [342.25] HEALTH CARE FACILITIES.

- (a) Health care facilities licensed under chapter 144A; hospice providers licensed under chapter 144A; boarding care homes or supervised living facilities licensed under section 144.50; assisted living facilities; facilities owned, controlled, managed, or under common control with hospitals licensed under chapter 144; and other health facilities licensed by the commissioner of health may adopt reasonable restrictions on the use of medical cannabis by a patient enrolled in the registry program who resides at or is actively receiving treatment or care at the facility. The restrictions may include a provision that the facility will not store or maintain the patient's supply of medical cannabis, that the facility is not responsible for providing the medical cannabis for patients, and that medical cannabis is used only in a place specified by the facility.
- (b) Any employee or agent of a facility listed in this section or a person licensed under chapter 144E is not subject to violations under this chapter for possession of medical cannabis while carrying out employment duties, including providing or supervising care to a registered patient, or distribution of medical cannabis to a registered patient who resides at or is actively receiving treatment or care at the facility with which the employee or agent is affiliated.

 Nothing in this section requires the facilities to adopt such restrictions and no facility shall unreasonably limit a patient's access to or use of medical cannabis to the extent that use is authorized by the patient under sections 342.15 to 342.29.

Sec. 24. [342.26] FEES; DEPOSIT OF REVENUE.

- (a) The commissioner shall collect an enrollment fee of \$40 from patients enrolled in the registry program. The fees shall be payable annually and are due on the anniversary date of the patient's enrollment. The fee amount shall be deposited in the state treasury and credited to the state government special revenue fund.
 - (b) The commissioner shall collect an application fee of \$20,000 from each entity submitting an application for registration as a medical cannabis manufacturer. Revenue from the fee shall be deposited in the state treasury and credited to the state government special revenue fund.
 - (c) The commissioner shall establish and collect an annual fee from a medical cannabis manufacturer equal to the cost of regulating and inspecting the manufacturer in that year.

Sec. 24. 34

Sec. 25. 35

35.31

senate. The authority to convene meetings shall alternate between the cochairs.

36.1	(d) Members of the task force other than those in paragraph (a), clauses (1), (2), and (7),
36.2	shall receive expenses as provided in section 15.059, subdivision 6.
36.3	Subd. 2. Administration. The commissioner of health shall provide administrative and
36.4	technical support to the task force.
36.5	Subd. 3. Impact assessment. The task force shall hold hearings to evaluate the impact
36.6	of the use of medical cannabis and Minnesota's activities involving medical cannabis,
36.7	including but not limited to:
36.8	(1) program design and implementation;
36.9	(2) the impact on the health care provider community;
36.10	(3) patient experiences;
36.11	(4) the impact on the incidence of substance abuse;
36.12	(5) access to and quality of medical cannabis and medical cannabis products;
36.13	(6) the impact on law enforcement and prosecutions;
36.14	(7) public awareness and perception; and
36.15	(8) any unintended consequences.
36.16	Subd. 4. No expiration. The Task Force on Medical Cannabis Therapeutic Research
36.17	does not expire.
36.18	Sec. 26. [342.28] FEDERALLY APPROVED CLINICAL TRIALS.
36.19	The commissioner may prohibit enrollment of a patient in the registry program if the
36.20	patient is simultaneously enrolled in a federally approved clinical trial for the treatment of
36.21	a qualifying medical condition with medical cannabis. The commissioner shall provide
36.22	information to all patients enrolled in the registry program on the existence of federally
36.23	approved clinical trials for the treatment of the patient's qualifying medical condition with
36.24	medical cannabis as an alternative to enrollment in the patient registry program.
36.25	Sec. 27. [342.29] FINANCIAL EXAMINATIONS; PRICING REVIEWS.
36.26	Subdivision 1. Financial records. A medical cannabis manufacturer shall maintain
36.27	detailed financial records in a manner and format approved by the commissioner and shall
36.28	keep all records updated and accessible to the commissioner when requested.
36.29	Subd. 2. Certified annual audit. A medical cannabis manufacturer shall submit the
36.30	results of an annual certified financial audit to the commissioner no later than May 1 of

Sec. 27. 36

37.1

37.2

37.3

37.4

37.5

37.6

37.7

37.8

37.9

37.10

37.11

37.12

37.13

37.14

37.15

37.16

37.17

37.18

37.19

37.20

37.21

37.22

37.23

37.24

37.25

37.26

37.27

37.28

37.29

37.30

37.31

37.32

37.33

each year for the previous calendar year. The annual audit shall be conducted by an independent certified public accountant and the costs of the audit are the responsibility of the medical cannabis manufacturer. Results of the audit shall be provided to the medical cannabis manufacturer and the commissioner. The commissioner may also require another audit of the medical cannabis manufacturer by a certified public accountant chosen by the commissioner with the costs of the audit paid by the medical cannabis manufacturer. Subd. 3. Power to examine. (a) The commissioner or a designee may examine the business affairs and conditions of any medical cannabis manufacturer, including but not limited to a review of the financing, budgets, revenues, sales, and pricing. (b) The commissioner shall determine the nature and scope of each examination and in doing so shall take into account all available relevant factors concerning the financial and business affairs, practices, and conditions of the examinee. The costs incurred by the department in conducting an examination shall be paid for by the medical cannabis manufacturer. (c) When making an examination under this section, the commissioner may retain attorneys, appraisers, independent economists, independent certified public accountants, or other professionals and specialists as designees. A certified public accountant retained by the commissioner may not be the same certified public accountant providing the certified annual audit in subdivision 2. (d) The commissioner shall make a report of an examination conducted under this section and provide a copy to the medical cannabis manufacturer. The commissioner shall then post a copy of the report on the department's website. All working papers, recorded information, documents, and copies produced by, obtained by, or disclosed to the commissioner or any other person in the course of an examination made under this section, other than the information contained in the commissioner's official report, are private data on individuals or nonpublic data, as defined in section 13.02. Sec. 28. TRANSFER.

- (a) Any responsibilities to regulate the commercial production and processing of hemp as provided in Minnesota Statutes, chapter 18K, and the rules adopted under that chapter are transferred from the Department of Agriculture to the Office of Cannabis Derivatives in accordance with Minnesota Statutes, section 15.039.
- (b) Any responsibilities to regulate the medical cannabis program under Minnesota Statutes, sections 151.22 to 151.37, and the rules adopted under those sections are transferred

Sec. 28. 37

BD/LN

22-07476

as introduced

38.17 Sec. 30. EFFECTIVE DATE.

04/05/22

REVISOR

Sections 1 to 29 are effective July 1, 2023.

Sec. 30. 38

Repealed Minnesota Statutes: 22-07476

18K.01 SHORT TITLE.

This chapter may be referred to as the "Industrial Hemp Development Act."

18K.02 DEFINITIONS.

Subdivision 1. **Scope.** The definitions in this section apply to this chapter.

- Subd. 1a. **Applicant.** "Applicant" means an individual who submits an application for a license as required under this chapter. If the applicant is an entity, applicant means the owner or most responsible individual in charge of the entity.
- Subd. 1b. **Authorized representative.** "Authorized representative" means any individual authorized by the licensee to make changes to the license and share data on behalf of the licensee.
 - Subd. 2. Commissioner. "Commissioner" means the commissioner of agriculture.
- Subd. 2a. **Entity.** "Entity" means a corporation, joint stock company, association, limited partnership, limited liability partnership, limited liability company, irrevocable trust, estate, charitable organization, or other similar organization, including any such organization participating in hemp production as a partner in a general partnership, a participant in a joint venture, or a participant in a similar organization.
- Subd. 3. **Industrial hemp.** "Industrial hemp" means the plant Cannabis sativa L. and any part of the plant, whether growing or not, including the plant's seeds, and all the plant's derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Industrial hemp is not marijuana as defined in section 152.01, subdivision 9.
 - Subd. 4. Marijuana. "Marijuana" has the meaning given in section 152.01, subdivision 9.
- Subd. 5. **Processing.** "Processing" means rendering by refinement hemp plants or hemp plant parts from their natural or original state after harvest. Processing includes but is not limited to decortication, devitalization, chopping, crushing, extraction, and packaging. Processing does not include typical farm operations such as sorting, grading, baling, and harvesting.
- Subd. 6. **Processing location.** "Processing location" means any area, building, plant, or facility registered with and approved by the commissioner in which a licensee converts raw hemp into a marketable product.
- Subd. 7. **Processor.** "Processor" means a person or business that converts raw hemp into a product.

18K.03 AGRICULTURAL CROP; POSSESSION AUTHORIZED.

Subdivision 1. **Industrial hemp.** Industrial hemp is an agricultural crop in this state. A person may possess, transport, process, sell, or buy industrial hemp that is grown pursuant to this chapter or lawfully grown in another state.

Subd. 2. **Sale to medical cannabis manufacturers.** A licensee under this chapter may sell hemp products derived from industrial hemp grown in this state to medical cannabis manufacturers as authorized under sections 152.22 to 152.37.

18K.04 LICENSING.

- Subdivision 1. **Requirement; issuance; presumption.** (a) A person must obtain a license from the commissioner before (1) growing industrial hemp for commercial or research purposes, and (2) before processing industrial hemp for commercial purposes.
- (b) To obtain a license under paragraph (a), a person must apply to the commissioner in the form prescribed by the commissioner and must pay the annual registration and inspection fee established by the commissioner in accordance with section 16A.1285, subdivision 2.
- (c) For a license to grow industrial hemp for commercial or research purposes, the license application must include the name and address of the applicant and the legal description of the land area or areas where industrial hemp will be grown by the applicant and any other information required under Code of Federal Regulations, title 7, part 990.
- (d) For a license to process industrial hemp for commercial purposes, the license application must include the name and address of the applicant, the legal description of the processing location, and any other information required by the commissioner.

Repealed Minnesota Statutes: 22-07476

- (e) A licensee is responsible for compliance with the license requirements irrespective of the acts or omissions of an authorized representative acting on behalf of the licensee.
- (f) When an applicant has paid the fee and completed the application process to the satisfaction of the commissioner, the commissioner must issue a license which is valid until December 31 of the year of application.
- (g) A person licensed under paragraph (a) to grow industrial hemp is presumed to be growing industrial hemp for commercial or research purposes.
- Subd. 2. **Background check; data classification.** The commissioner must require each first-time applicant for a license to submit to a background investigation conducted by the Bureau of Criminal Apprehension as a condition of licensure. As part of the background investigation, the Bureau of Criminal Apprehension must conduct criminal history checks of Minnesota records and is authorized to exchange fingerprints with the United States Department of Justice, Federal Bureau of Investigation for the purpose of a criminal background check of the national files. The cost of the investigation must be paid by the applicant. Criminal history records provided to the commissioner under this section must be treated as private data on individuals, as defined in section 13.02, subdivision 12.
- Subd. 3. **Federal requirements.** The applicant must demonstrate to the satisfaction of the commissioner that the applicant has complied with all applicable federal requirements pertaining to the processing, production, distribution, and sale of industrial hemp.
- Subd. 4. **Industrial hemp licensing data classification.** (a) In addition to data classified pursuant to section 13.41, the following data collected, created, or maintained by the commissioner under this chapter is classified as private data, as defined in section 13.02, subdivision 12, or nonpublic data, as defined in section 13.02, subdivision 9:
 - (1) nondesignated addresses provided by licensees and applicants; and
- (2) data that identify the specific locations where licensees and applicants grow or process, or will grow or process, industrial hemp, including but not limited to legal descriptions, street addresses, geospatial locations, maps, and property boundaries and dimensions.
- (b) The commissioner may disclose data classified as private data or nonpublic data under this subdivision if the commissioner determines that there is a substantive threat to human health or safety or to the environment, or to aid in the law enforcement process.
- Subd. 5. Industrial hemp licensing data security and auditing. (a) The commissioner must establish written procedures to ensure that only individuals authorized by law may access the private data and nonpublic data identified in subdivision 4. An authorized individual's ability to enter, update, or access data must correspond to the official duties or training level of the individual and to the statutory authorization granting access for that purpose. All queries and responses, including the specific purpose for which data is requested and, if applicable, disclosed, and all actions in which data are entered, updated, accessed, shared, or disseminated, must be recorded in the data audit trail. Data contained in the audit trail are public to the extent the data are not otherwise classified by law.
- (b) The commissioner must immediately and permanently revoke the authorization of any individual who willfully entered, updated, accessed, shared, or disseminated data in violation of state or federal law. If an individual willfully gained access to data without authorization by law, the commissioner must forward the matter to the appropriate prosecuting authority for prosecution.
- (c) By January 15 of each odd-numbered year, the commissioner must provide a copy of the data audit trail required under paragraph (a) to the commissioner of administration; the chairs and ranking members of the legislative committees and divisions with jurisdiction over agriculture policy and finance, public safety, and data practices; and the Legislative Commission on Data Practices and Personal Data Privacy or its successor commission.

18K.05 ANNUAL REPORT; SALES NOTIFICATION.

- (a) Annually, a licensee must file with the commissioner:
- (1) documentation demonstrating to the commissioner's satisfaction that the seeds planted by the licensee are of a type and variety that contain no more than three-tenths of one percent delta-9 tetrahydrocannabinol; and
 - (2) a copy of any contract to grow industrial hemp.

Repealed Minnesota Statutes: 22-07476

(b) Within 30 days, a licensee must notify the commissioner of each sale or distribution of industrial hemp grown by the licensee including, but not limited to, the name and address of the person receiving the industrial hemp and the amount of industrial hemp sold or distributed.

18K.06 RULEMAKING.

- (a) The commissioner shall adopt rules governing the production, testing, processing, and licensing of industrial hemp. Notwithstanding section 14.125, the commissioner's authority to adopt these rules expires June 30, 2022.
 - (b) Rules adopted under paragraph (a) must include, but not be limited to, provisions governing:
 - (1) the supervision and inspection of industrial hemp during its growth and harvest;
 - (2) the testing of industrial hemp to determine delta-9 tetrahydrocannabinol levels;
- (3) the use of background check results required under section 18K.04 to approve or deny a license application; and
 - (4) any other provision or procedure necessary to carry out the purposes of this chapter.
- (c) Rules issued under this section must be consistent with federal law regarding the production, distribution, and sale of industrial hemp.

18K.07 FEES.

Fees collected under this chapter must be credited to the industrial hemp account, which is hereby established in the agricultural fund in the state treasury. Interest earned in the account accrues to the account. Funds in the industrial hemp account are annually appropriated to the commissioner to implement and enforce this chapter.

18K.08 DEFENSE FOR POSSESSION OF MARIJUANA.

It is an affirmative defense to a prosecution for the possession of marijuana under chapter 152 if:

- (1) the defendant possesses industrial hemp grown pursuant to this chapter; or
- (2) the defendant has a valid controlled substance registration from the United States Department of Justice, Drug Enforcement Administration, if required under federal law.

18K.09 PILOT PROGRAM; OTHER RESEARCH AUTHORIZED.

Subdivision 1. **Authorized activity.** The commissioner may grow or cultivate industrial hemp pursuant to a pilot program administered by the commissioner to study the growth, cultivation, or marketing of industrial hemp. The commissioner may: (1) authorize institutions of higher education to grow or cultivate industrial hemp as part of the commissioner's pilot program or as is necessary to perform other agricultural, renewable energy, or academic research; and (2) contract with public or private entities for testing or other activities authorized under this subdivision. Authorized activity under this section may include collecting seed from wild hemp sources.

- Subd. 2. **Site registration.** Before growing or cultivating industrial hemp pursuant to this section, each site must be registered with and certified by the commissioner. A person must register each site annually in the form prescribed by the commissioner and must pay the annual registration and certification fee established by the commissioner in accordance with section 16A.1285, subdivision 2.
- Subd. 3. **Rulemaking.** The commissioner may adopt rules that govern the pilot program pursuant to this section and Public Law 113-79.

151.72 SALE OF CERTAIN CANNABINOID PRODUCTS.

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

- (b) "Hemp" has the meaning given to "industrial hemp" in section 18K.02, subdivision 3.
- (c) "Labeling" means all labels and other written, printed, or graphic matter that are:
- (1) affixed to the immediate container in which a product regulated under this section is sold; or

Repealed Minnesota Statutes: 22-07476

- (2) provided, in any manner, with the immediate container, including but not limited to outer containers, wrappers, package inserts, brochures, or pamphlets.
- Subd. 2. **Scope.** (a) This section applies to the sale of any product that contains nonintoxicating cannabinoids extracted from hemp other than food that is intended for human or animal consumption by any route of administration.
- (b) This section does not apply to any product dispensed by a registered medical cannabis manufacturer pursuant to sections 152.22 to 152.37.
- Subd. 3. **Sale of cannabinoids derived from hemp.** Notwithstanding any other section of this chapter, a product containing nonintoxicating cannabinoids may be sold for human or animal consumption if all of the requirements of this section are met.
- Subd. 4. **Testing requirements.** (a) A manufacturer of a product regulated under this section must submit representative samples of the product to an independent, accredited laboratory in order to certify that the product complies with the standards adopted by the board. Testing must be consistent with generally accepted industry standards for herbal and botanical substances, and, at a minimum, the testing must confirm that the product:
 - (1) contains the amount or percentage of cannabinoids that is stated on the label of the product;
 - (2) does not contain more than trace amounts of any pesticides, fertilizers, or heavy metals; and
- (3) does not contain a delta-9 tetrahydrocannabinol concentration that exceeds the concentration permitted for industrial hemp as defined in section 18K.02, subdivision 3.
- (b) Upon the request of the board, the manufacturer of the product must provide the board with the results of the testing required in this section.
- Subd. 5. **Labeling requirements.** (a) A product regulated under this section must bear a label that contains, at a minimum:
 - (1) the name, location, contact phone number, and website of the manufacturer of the product;
- (2) the name and address of the independent, accredited laboratory used by the manufacturer to test the product; and
- (3) an accurate statement of the amount or percentage of cannabinoids found in each unit of the product meant to be consumed; or
- (4) instead of the information required in clauses (1) to (3), a scannable bar code or QR code that links to the manufacturer's website.

The label must also include a statement stating that this product does not claim to diagnose, treat, cure, or prevent any disease and has not been evaluated or approved by the United States Food and Drug Administration (FDA) unless the product has been so approved.

- (b) The information required to be on the label must be prominently and conspicuously placed and in terms that can be easily read and understood by the consumer.
- (c) The label must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the FDA.
- Subd. 6. **Enforcement.** (a) A product sold under this section shall be considered an adulterated drug if:
 - (1) it consists, in whole or in part, of any filthy, putrid, or decomposed substance;
- (2) it has been produced, prepared, packed, or held under unsanitary conditions where it may have been rendered injurious to health, or where it may have been contaminated with filth;
- (3) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;
- (4) it contains any color additives or excipients that have been found by the FDA to be unsafe for human or animal consumption; or
- (5) it contains an amount or percentage of cannabinoids that is different than the amount or percentage stated on the label.

Repealed Minnesota Statutes: 22-07476

- (b) A product sold under this section shall be considered a misbranded drug if the product's labeling is false or misleading in any manner or in violation of the requirements of this section.
- (c) The board's authority to issue cease and desist orders under section 151.06; to embargo adulterated and misbranded drugs under section 151.38; and to seek injunctive relief under section 214.11, extends to any violation of this section.

152.21 THC THERAPEUTIC RESEARCH ACT.

Subdivision 1. **Findings and purpose.** The legislature finds that scientific literature indicates promise for delta-9-tetrahydro-cannabinol (THC), the active component of marijuana, in alleviating certain side effects of cancer chemotherapy under strictly controlled medical circumstances.

The legislature also finds that further research and strictly controlled experimentation regarding the therapeutic use of THC is necessary and desirable. The intent of this section is to establish an extensive research program to investigate and report on the therapeutic effects of THC under strictly controlled circumstances in compliance with all federal laws and regulations promulgated by the federal Food and Drug Administration, the National Institute on Drug Abuse and the Drug Enforcement Administration. The intent of the legislature is to allow this research program the greatest possible access to qualified cancer patients residing in Minnesota who meet protocol requirements. 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.** For purposes of this section, the following terms shall have the meanings given.
 - (a) "Commissioner" means the commissioner of health.
- (b) "Marijuana" means marijuana as defined in section 152.01, subdivision 9, and delta-9-tetrahydro-cannabinol (THC), tetrahydrocannabinols or a chemical derivative of tetrahydrocannabinols, and all species of the genus Cannabis.
- (c) "Principal investigator" means the individual responsible for the medical and scientific aspects of the research, development of protocol, and contacting and qualifying the clinical investigators in the state.
 - (d) "Clinical investigators" means those individuals who conduct the clinical trials.
- (e) "Sponsor" means that individual or organization who, acting on behalf of the state, has the total responsibility for the state program.
- Subd. 3. **Research grant.** The commissioner of health shall grant funds to the principal investigator selected by the commissioner pursuant to subdivision 4 for the purpose of conducting a research program under a protocol approved by the FDA regarding the therapeutic use of oral THC and other dosage forms, if available, according to the guidelines and requirements of the federal Food and Drug Administration, the Drug Enforcement Administration and the National Institute on Drug Abuse. The commissioner shall ensure that the research principal investigator complies with the requirements of subdivision 5. The commissioner may designate the principal investigator as the sponsor.
- Subd. 4. **Principal investigator.** Within three months of April 25, 1980, the commissioner shall, in consultation with a representative chosen by the state Board of Pharmacy and a representative chosen by the state Board of Medical Examiners, select a person or research organization to be the principal investigator of the research program.
 - Subd. 5. **Duties.** The principal investigator shall:
- (1) apply to the Food and Drug Administration for a notice of "Claimed Investigational Exemption for a New Drug (IND)" pursuant to the Federal Food, Drug and Cosmetic Act, United States Code, title 21, section 301, et seq., and shall comply with all applicable laws and regulations of the federal Food and Drug Administration, the Drug Enforcement Administration, and the National Institute on Drug Abuse in establishing the program;
- (2) notify every oncologist in the state of the program, explain the purposes and requirements of the program to them, provide on request each of them with a copy of the approved protocol which shall include summaries of current papers in medical journals reporting on research concerning the safety, efficacy and appropriate use of THC in alleviating the nausea and emetic effects of cancer chemotherapy, and provide on request each of them with a bibliography of other articles published in medical journals;

Repealed Minnesota Statutes: 22-07476

- (3) allow each oncologist (clinical investigator) in the state who meets or agrees to meet all applicable federal requirements for investigational new drug research and who so requests to be included in the research program as a clinical investigator to conduct the clinical trials;
- (4) provide explanatory information and assistance to each clinical investigator in understanding the nature of therapeutic use of THC within program requirements, including the informed consent document contained in the protocol, informing and counseling patients involved in the program regarding the appropriate use and the effects of therapeutic use of THC;
- (5) apply to contract with the National Institute on Drug Abuse for receipt of dosage forms of THC, fully characterized as to contents and delivery to the human system, pursuant to regulations promulgated by the National Institute on Drug Abuse, and the federal Food and Drug Administration. The principal investigator shall ensure delivery of the THC dosages to clinical investigators as needed for participation in the program;
- (6) conduct the research program in compliance with federal laws and regulations promulgated by the federal Food and Drug Administration, the Drug Enforcement Administration, the National Institute on Drug Abuse, and the purposes and provisions of this section;
- (7) submit periodic reports as determined by the commissioner on the numbers of oncologists and patients involved in the program and the results of the program;
- (8) submit reports on intermediate or final research results, as appropriate, to the major scientific journals in the United States; and
 - (9) otherwise comply with the provisions of this section.
- Subd. 6. **Exemption from criminal sanctions.** For the purposes of this section, the following are not violations under this chapter:
 - (1) use or possession of THC, or both, by a patient in the research program;
- (2) possession, prescribing use of, administering, or dispensing THC, or any combination of these actions, by the principal investigator or by any clinical investigator; and
- (3) possession or distribution of THC, or both, by a pharmacy registered to handle Schedule I substances which stores THC on behalf of the principal investigator or a clinical investigator.

THC obtained and distributed pursuant to this section is not subject to forfeiture under sections 609.531 to 609.5316.

For the purposes of this section, THC 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. 7. Citation. This section may be cited as the "THC Therapeutic Research Act."

152.22 DEFINITIONS.

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

- Subd. 2. Commissioner. "Commissioner" means the commissioner of health.
- Subd. 3. **Disqualifying felony offense.** "Disqualifying felony offense" means a violation of a state or federal controlled substance law that is a felony under Minnesota law, or would be a felony if committed in Minnesota, regardless of the sentence imposed, unless the commissioner determines that the person's conviction was for the medical use of cannabis or assisting with the medical use of cannabis.
- Subd. 4. **Health care practitioner.** "Health care practitioner" means a Minnesota licensed doctor of medicine, a Minnesota licensed physician assistant acting within the scope of authorized practice, or a Minnesota licensed advanced practice registered nurse who has the primary responsibility for the care and treatment of the qualifying medical condition of a person diagnosed with a qualifying medical condition.
- Subd. 5. **Health records.** "Health records" means health records as defined in section 144.291, subdivision 2, paragraph (c).
- Subd. 5a. **Hemp.** "Hemp" has the meaning given to industrial hemp in section 18K.02, subdivision 3.

- Subd. 5b. **Hemp grower.** "Hemp grower" means a person licensed by the commissioner of agriculture under chapter 18K to grow hemp for commercial purposes.
- Subd. 5c. **Hemp processor.** "Hemp processor" means a person or business licensed by the commissioner of agriculture under chapter 18K to convert raw hemp into a product.
- Subd. 6. **Medical cannabis.** (a) "Medical cannabis" means any species of the genus cannabis plant, or any mixture or preparation of them, including whole plant extracts and resins, and is delivered in the form of:
 - (1) liquid, including, but not limited to, oil;
 - (2) pill
 - (3) vaporized delivery method with use of liquid or oil;
 - (4) combustion with use of dried raw cannabis; or
 - (5) any other method approved by the commissioner.
- (b) This definition includes any part of the genus cannabis plant prior to being processed into a form allowed under paragraph (a), that is possessed by a person while that person is engaged in employment duties necessary to carry out a requirement under sections 152.22 to 152.37 for a registered manufacturer or a laboratory under contract with a registered manufacturer. This definition also includes any hemp acquired by a manufacturer by a hemp grower as permitted under section 152.29, subdivision 1, paragraph (b).
- Subd. 7. **Medical cannabis manufacturer.** "Medical cannabis manufacturer" or "manufacturer" means an entity registered by the commissioner to cultivate, acquire, manufacture, possess, prepare, transfer, transport, supply, or dispense medical cannabis, delivery devices, or related supplies and educational materials.
- Subd. 8. **Medical cannabis product.** "Medical cannabis product" means any delivery device or related supplies and educational materials used in the administration of medical cannabis for a patient with a qualifying medical condition enrolled in the registry program.
- Subd. 9. **Patient.** "Patient" means a Minnesota resident who has been diagnosed with a qualifying medical condition by a health care practitioner and who has otherwise met any other requirements for patients under sections 152.22 to 152.37 to participate in the registry program under sections 152.22 to 152.37.
- Subd. 10. **Patient registry number.** "Patient registry number" means a unique identification number assigned by the commissioner to a patient enrolled in the registry program.
- Subd. 11. **Registered designated caregiver.** "Registered designated caregiver" means a person who:
 - (1) is at least 18 years old;
 - (2) does not have a conviction for a disqualifying felony offense;
- (3) has been approved by the commissioner to assist a patient who requires assistance in administering medical cannabis or obtaining medical cannabis from a distribution facility; and
 - (4) is authorized by the commissioner to assist the patient with the use of medical cannabis.
- Subd. 12. **Registry program.** "Registry program" means the patient registry established in sections 152.22 to 152.37.
- Subd. 13. **Registry verification.** "Registry verification" means the verification provided by the commissioner that a patient is enrolled in the registry program and that includes the patient's name, registry number, and, if applicable, the name of the patient's registered designated caregiver or parent, legal guardian, or spouse.
- Subd. 14. **Qualifying medical condition.** "Qualifying medical condition" means a diagnosis of any of the following conditions:
 - (1) cancer, if the underlying condition or treatment produces one or more of the following:
 - (i) severe or chronic pain;
 - (ii) nausea or severe vomiting; or

Repealed Minnesota Statutes: 22-07476

- (iii) cachexia or severe wasting;
- (2) glaucoma;
- (3) human immunodeficiency virus or acquired immune deficiency syndrome;
- (4) Tourette's syndrome;
- (5) amyotrophic lateral sclerosis;
- (6) seizures, including those characteristic of epilepsy;
- (7) severe and persistent muscle spasms, including those characteristic of multiple sclerosis;
- (8) inflammatory bowel disease, including Crohn's disease;
- (9) terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:
 - (i) severe or chronic pain;
 - (ii) nausea or severe vomiting; or
 - (iii) cachexia or severe wasting; or
 - (10) any other medical condition or its treatment approved by the commissioner.

152.23 LIMITATIONS.

- (a) Nothing in sections 152.22 to 152.37 permits any person to engage in and does not prevent the imposition of any civil, criminal, or other penalties for:
- (1) undertaking any task under the influence of medical cannabis that would constitute negligence or professional malpractice;
 - (2) possessing or engaging in the use of medical cannabis:
 - (i) on a school bus or van;
 - (ii) on the grounds of any preschool or primary or secondary school;
 - (iii) in any correctional facility; or
 - (iv) on the grounds of any child care facility or home day care;
 - (3) vaporizing or combusting medical cannabis pursuant to section 152.22, subdivision 6:
 - (i) on any form of public transportation;
- (ii) where the vapor would be inhaled by a nonpatient minor child or where the smoke would be inhaled by a minor child; or
- (iii) in any public place, including any indoor or outdoor area used by or open to the general public or a place of employment as defined under section 144.413, subdivision 1b; and
- (4) operating, navigating, or being in actual physical control of any motor vehicle, aircraft, train, or motorboat, or working on transportation property, equipment, or facilities while under the influence of medical cannabis.
- (b) Nothing in sections 152.22 to 152.37 require the medical assistance and MinnesotaCare programs to reimburse an enrollee or a provider for costs associated with the medical use of cannabis. Medical assistance and MinnesotaCare shall continue to provide coverage for all services related to treatment of an enrollee's qualifying medical condition if the service is covered under chapter 256B or 256L.

152.24 FEDERALLY APPROVED CLINICAL TRIALS.

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

Repealed Minnesota Statutes: 22-07476

152.25 COMMISSIONER DUTIES.

Subdivision 1. **Medical cannabis manufacturer registration.** (a) The commissioner shall register two in-state manufacturers for the production of all medical cannabis within the state. A registration agreement between the commissioner and a manufacturer is nontransferable. The commissioner shall register new manufacturers or reregister the existing manufacturers by December 1 every two years, using the factors described in this subdivision. The commissioner shall accept applications after December 1, 2014, if one of the manufacturers registered before December 1, 2014, ceases to be registered as a manufacturer. The commissioner's determination that no manufacturer exists to fulfill the duties under sections 152.22 to 152.37 is subject to judicial review in Ramsey County District Court. Data submitted during the application process are private data on individuals or nonpublic data as defined in section 13.02 until the manufacturer is registered under this section. Data on a manufacturer that is registered are public data, unless the data are trade secret or security information under section 13.37.

- (b) As a condition for registration, a manufacturer must agree to:
- (1) begin supplying medical cannabis to patients by July 1, 2015; and
- (2) comply with all requirements under sections 152.22 to 152.37.
- (c) The commissioner shall consider the following factors when determining which manufacturer to register:
- (1) the technical expertise of the manufacturer in cultivating medical cannabis and converting the medical cannabis into an acceptable delivery method under section 152.22, subdivision 6;
 - (2) the qualifications of the manufacturer's employees;
 - (3) the long-term financial stability of the manufacturer;
 - (4) the ability to provide appropriate security measures on the premises of the manufacturer;
- (5) whether the manufacturer has demonstrated an ability to meet the medical cannabis production needs required by sections 152.22 to 152.37; and
- (6) the manufacturer's projection and ongoing assessment of fees on patients with a qualifying medical condition.
- (d) If an officer, director, or controlling person of the manufacturer pleads or is found guilty of intentionally diverting medical cannabis to a person other than allowed by law under section 152.33, subdivision 1, the commissioner may decide not to renew the registration of the manufacturer, provided the violation occurred while the person was an officer, director, or controlling person of the manufacturer.
- (e) The commissioner shall require each medical cannabis manufacturer to contract with an independent laboratory to test medical cannabis produced by the manufacturer. The commissioner shall approve the laboratory chosen by each manufacturer and require that the laboratory report testing results to the manufacturer in a manner determined by the commissioner.
- Subd. 1a. Revocation or nonrenewal of a medical cannabis manufacturer registration. If the commissioner intends to revoke or not renew a registration issued under this section, the commissioner must first notify in writing the manufacturer against whom the action is to be taken and provide the manufacturer with an opportunity to request a hearing under the contested case provisions of chapter 14. If the manufacturer does not request a hearing by notifying the commissioner in writing within 20 days after receipt of the notice of proposed action, the commissioner may proceed with the action without a hearing. For revocations, the registration of a manufacturer is considered revoked on the date specified in the commissioner's written notice of revocation.
- Subd. 1b. **Temporary suspension proceedings.** The commissioner may institute proceedings to temporarily suspend the registration of a medical cannabis manufacturer for a period of up to 90 days by notifying the manufacturer in writing if any action by an employee, agent, officer, director, or controlling person of the manufacturer:
 - (1) violates any of the requirements of sections 152.21 to 152.37 or the rules adopted thereunder;
- (2) permits, aids, or abets the commission of any violation of state law at the manufacturer's location for cultivation, harvesting, manufacturing, packaging, and processing or at any site for distribution of medical cannabis;

Repealed Minnesota Statutes: 22-07476

- (3) performs any act contrary to the welfare of a registered patient or registered designated caregiver; or
 - (4) obtains, or attempts to obtain, a registration by fraudulent means or misrepresentation.
- Subd. 1c. **Notice to patients.** Upon the revocation or nonrenewal of a manufacturer's registration under subdivision 1a or implementation of an enforcement action under subdivision 1b that may affect the ability of a registered patient, registered designated caregiver, or a registered patient's parent, legal guardian, or spouse to obtain medical cannabis from the manufacturer subject to the enforcement action, the commissioner shall notify in writing each registered patient and the patient's registered designated caregiver or registered patient's parent, legal guardian, or spouse about the outcome of the proceeding and information regarding alternative registered manufacturers. This notice must be provided two or more business days prior to the effective date of the revocation, nonrenewal, or other enforcement action.
- Subd. 2. Range of compounds and dosages; report. The commissioner shall review and publicly report the existing medical and scientific literature regarding the range of recommended dosages for each qualifying condition and the range of chemical compositions of any plant of the genus cannabis that will likely be medically beneficial for each of the qualifying medical conditions. The commissioner shall make this information available to patients with qualifying medical conditions beginning December 1, 2014, and update the information annually. The commissioner may consult with the independent laboratory under contract with the manufacturer or other experts in reporting the range of recommended dosages for each qualifying medical condition, the range of chemical compositions that will likely be medically beneficial, and any risks of noncannabis drug interactions. The commissioner shall consult with each manufacturer on an annual basis on medical cannabis offered by the manufacturer. The list of medical cannabis offered by a manufacturer shall be published on the Department of Health website.
- Subd. 3. **Deadlines.** The commissioner shall adopt rules necessary for the manufacturer to begin distribution of medical cannabis to patients under the registry program by July 1, 2015, and have notice of proposed rules published in the State Register prior to January 1, 2015.
- Subd. 4. **Reports.** (a) The commissioner shall provide regular updates to the task force on medical cannabis therapeutic research and to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services, public safety, judiciary, and civil law regarding: (1) any changes in federal law or regulatory restrictions regarding the use of medical cannabis or hemp; and (2) the market demand and supply in this state for products made from hemp that can be used for medicinal purposes.
- (b) The commissioner may submit medical research based on the data collected under sections 152.22 to 152.37 to any federal agency with regulatory or enforcement authority over medical cannabis to demonstrate the effectiveness of medical cannabis for treating a qualifying medical condition.

152.26 RULEMAKING.

- (a) The commissioner may adopt rules to implement sections 152.22 to 152.37. Rules for which notice is published in the State Register before January 1, 2015, may be adopted using the process in section 14.389.
- (b) The commissioner may adopt or amend rules, using the procedure in section 14.386, paragraph (a), to implement the addition of dried raw cannabis as an allowable form of medical cannabis under section 152.22, subdivision 6, paragraph (a), clause (4). Section 14.386, paragraph (b), does not apply to these rules.

152.27 PATIENT REGISTRY PROGRAM ESTABLISHED.

Subdivision 1. **Patient registry program; establishment.** (a) The commissioner shall establish a patient registry program to evaluate data on patient demographics, effective treatment options, clinical outcomes, and quality-of-life outcomes for the purpose of reporting on the benefits, risks, and outcomes regarding patients with a qualifying medical condition engaged in the therapeutic use of medical cannabis.

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

Subd. 2. Commissioner duties. (a) The commissioner shall:

- (1) give notice of the program to health care practitioners in the state who are eligible to serve as health care practitioners and explain the purposes and requirements of the program;
- (2) allow each health care practitioner who meets or agrees to meet the program's requirements and who requests to participate, to be included in the registry program to collect data for the patient registry;
- (3) provide explanatory information and assistance to each health care practitioner in understanding the nature of therapeutic use of medical cannabis within program requirements;
- (4) create and provide a certification to be used by a health care practitioner for the practitioner to certify whether a patient has been diagnosed with a qualifying medical condition and include in the certification an option for the practitioner to certify whether the patient, in the health care practitioner's medical opinion, is developmentally or physically disabled and, as a result of that disability, the patient requires assistance in administering medical cannabis or obtaining medical cannabis from a distribution facility;
- (5) supervise the participation of the health care practitioner in conducting patient treatment and health records reporting in a manner that ensures stringent security and record-keeping requirements and that prevents the unauthorized release of private data on individuals as defined by section 13.02;
- (6) develop safety criteria for patients with a qualifying medical condition as a requirement of the patient's participation in the program, to prevent the patient from undertaking any task under the influence of medical cannabis that would constitute negligence or professional malpractice on the part of the patient; and
- (7) conduct research and studies based on data from health records submitted to the registry program and submit reports on intermediate or final research results to the legislature and major scientific journals. The commissioner may contract with a third party to complete the requirements of this clause. Any reports submitted must comply with section 152.28, subdivision 2.
- (b) The commissioner may add a delivery method under section 152.22, subdivision 6, or add, remove, or modify a qualifying medical condition under section 152.22, subdivision 14, upon a petition from a member of the public or the task force on medical cannabis therapeutic research or as directed by law. The commissioner shall evaluate all petitions to add a qualifying medical condition or to remove or modify an existing qualifying medical condition submitted by the task force on medical cannabis therapeutic research or as directed by law and may make the addition, removal, or modification if the commissioner determines the addition, removal, or modification is warranted based on the best available evidence and research. If the commissioner wishes to add a delivery method under section 152.22, subdivision 6, or add or remove a qualifying medical condition under section 152.22, subdivision 14, the commissioner must notify the chairs and ranking minority members of the legislative policy committees having jurisdiction over health and public safety of the addition or removal and the reasons for its addition or removal, including any written comments received by the commissioner from the public and any guidance received from the task force on medical cannabis research, by January 15 of the year in which the commissioner wishes to make the change. The change shall be effective on August 1 of that year, unless the legislature by law provides otherwise.
- Subd. 3. **Patient application.** (a) The commissioner shall develop a patient application for enrollment into the registry program. The application shall be available to the patient and given to health care practitioners in the state who are eligible to serve as health care practitioners. The application must include:
 - (1) the name, mailing address, and date of birth of the patient;
 - (2) the name, mailing address, and telephone number of the patient's health care practitioner;
- (3) the name, mailing address, and date of birth of the patient's designated caregiver, if any, or the patient's parent, legal guardian, or spouse if the parent, legal guardian, or spouse will be acting as a caregiver;
- (4) a copy of the certification from the patient's health care practitioner that is dated within 90 days prior to submitting the application that certifies that the patient has been diagnosed with a qualifying medical condition; and
- (5) all other signed affidavits and enrollment forms required by the commissioner under sections 152.22 to 152.37, including, but not limited to, the disclosure form required under paragraph (c).

- (b) The commissioner shall require a patient to resubmit a copy of the certification from the patient's health care practitioner on a yearly basis and shall require that the recertification be dated within 90 days of submission.
- (c) The commissioner shall develop a disclosure form and require, as a condition of enrollment, all patients to sign a copy of the disclosure. The disclosure must include:
- (1) a statement that, notwithstanding any law to the contrary, the commissioner, or an employee of any state agency, may not be held civilly or criminally liable for any injury, loss of property, personal injury, or death caused by any act or omission while acting within the scope of office or employment under sections 152.22 to 152.37; and
- (2) the patient's acknowledgment that enrollment in the patient registry program is conditional on the patient's agreement to meet all of the requirements of sections 152.22 to 152.37.
- Subd. 4. **Registered designated caregiver.** (a) The commissioner shall register a designated caregiver for a patient if the patient requires assistance in administering medical cannabis or obtaining medical cannabis from a distribution facility and the caregiver has agreed, in writing, to be the patient's designated caregiver. As a condition of registration as a designated caregiver, the commissioner shall require the person to:
 - (1) be at least 18 years of age;
- (2) agree to only possess the patient's medical cannabis for purposes of assisting the patient; and
- (3) agree that if the application is approved, the person will not be a registered designated caregiver for more than six registered patients at one time. Patients who reside in the same residence shall count as one patient.
- (b) The commissioner shall conduct a criminal background check on the designated caregiver prior to registration to ensure that the person does not have a conviction for a disqualifying felony offense. Any cost of the background check shall be paid by the person seeking registration as a designated caregiver. A designated caregiver must have the criminal background check renewed every two years.
- (c) Nothing in sections 152.22 to 152.37 shall be construed to prevent a person registered as a designated caregiver from also being enrolled in the registry program as a patient and possessing and using medical cannabis as a patient.
- Subd. 5. **Parents, legal guardians, and spouses.** A parent, legal guardian, or spouse of a patient may act as the caregiver to the patient without having to register as a designated caregiver. The parent, legal guardian, or spouse shall follow all of the requirements of parents, legal guardians, and spouses listed in sections 152.22 to 152.37. Nothing in sections 152.22 to 152.37 limits any legal authority a parent, legal guardian, or spouse may have for the patient under any other law.
- Subd. 6. **Patient enrollment.** (a) After receipt of a patient's application, application fees, and signed disclosure, the commissioner shall enroll the patient in the registry program and issue the patient and patient's registered designated caregiver or parent, legal guardian, or spouse, if applicable, a registry verification. The commissioner shall approve or deny a patient's application for participation in the registry program within 30 days after the commissioner receives the patient's application and application fee. The commissioner may approve applications up to 60 days after the receipt of a patient's application and application fees until January 1, 2016. A patient's enrollment in the registry program shall only be denied if the patient:
- (1) does not have certification from a health care practitioner that the patient has been diagnosed with a qualifying medical condition;
- (2) has not signed and returned the disclosure form required under subdivision 3, paragraph (c), to the commissioner;
 - (3) does not provide the information required;
- (4) has previously been removed from the registry program for violations of section 152.30 or 152.33; or
 - (5) provides false information.
- (b) The commissioner shall give written notice to a patient of the reason for denying enrollment in the registry program.

Repealed Minnesota Statutes: 22-07476

- (c) Denial of enrollment into the registry program is considered a final decision of the commissioner and is subject to judicial review under the Administrative Procedure Act pursuant to chapter 14.
- (d) A patient's enrollment in the registry program may only be revoked upon the death of the patient or if a patient violates a requirement under section 152.30 or 152.33.
- (e) The commissioner shall develop a registry verification to provide to the patient, the health care practitioner identified in the patient's application, and to the manufacturer. The registry verification shall include:
 - (1) the patient's name and date of birth;
 - (2) the patient registry number assigned to the patient; and
- (3) the name and date of birth of the patient's registered designated caregiver, if any, or the name of the patient's parent, legal guardian, or spouse if the parent, legal guardian, or spouse will be acting as a caregiver.
- Subd. 7. **Notice requirements.** Patients and registered designated caregivers shall notify the commissioner of any address or name change within 30 days of the change having occurred. A patient or registered designated caregiver is subject to a \$100 fine for failure to notify the commissioner of the change.

152.28 HEALTH CARE PRACTITIONER DUTIES.

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

- (1) determine, in the health care practitioner's medical judgment, whether a patient suffers from a qualifying medical condition, and, if so determined, provide the patient with a certification of that diagnosis;
- (2) advise patients, registered designated caregivers, and parents, legal guardians, or spouses who are acting as caregivers of the existence of any nonprofit patient support groups or organizations;
- (3) provide explanatory information from the commissioner to patients with qualifying medical conditions, including disclosure to all patients about the experimental nature of therapeutic use of medical cannabis; the possible risks, benefits, and side effects of the proposed treatment; the application and other materials from the commissioner; and provide patients with the Tennessen warning as required by section 13.04, subdivision 2; and
- (4) agree to continue treatment of the patient's qualifying medical condition and report medical findings to the commissioner.
- (b) Upon notification from the commissioner of the patient's enrollment in the registry program, the health care practitioner shall:
- (1) participate in the patient registry reporting system under the guidance and supervision of the commissioner;
- (2) report health records of the patient throughout the ongoing treatment of the patient to the commissioner in a manner determined by the commissioner and in accordance with subdivision 2;
- (3) determine, on a yearly basis, if the patient continues to suffer from a qualifying medical condition and, if so, issue the patient a new certification of that diagnosis; and
 - (4) otherwise comply with all requirements developed by the commissioner.
- (c) A health care practitioner may conduct a patient assessment to issue a recertification as required under paragraph (b), clause (3), via telehealth, as defined in section 62A.673, subdivision 2.
 - (d) Nothing in this section requires a health care practitioner to participate in the registry program.
- Subd. 2. **Data.** Data collected on patients by a health care practitioner and reported to the patient registry are health records under section 144.291, and are private data on individuals under section 13.02, but may be used or reported in an aggregated, nonidentifiable form as part of a scientific, peer-reviewed publication of research conducted under section 152.25 or in the creation of summary data, as defined in section 13.02, subdivision 19.

Repealed Minnesota Statutes: 22-07476

- Subd. 3. **Advertising restrictions.** (a) A health care practitioner shall not publish or cause to be published any advertisement that:
- (1) contains false or misleading statements about medical cannabis or about the medical cannabis registry program;
 - (2) uses colloquial terms to refer to medical cannabis, such as pot, weed, or grass;
- (3) states or implies the health care practitioner is endorsed by the Department of Health or by the medical cannabis registry program;
- (4) includes images of cannabis in its plant or leaf form or of cannabis-smoking paraphernalia; or
- (5) contains medical symbols that could reasonably be confused with symbols of established medical associations or groups.
- (b) A health care practitioner found by the commissioner to have violated this subdivision is prohibited from certifying that patients have a qualifying medical condition for purposes of patient participation in the registry program. The commissioner's decision that a health care practitioner has violated this subdivision is a final decision of the commissioner and is not subject to the contested case procedures in chapter 14.

152.29 MANUFACTURER OF MEDICAL CANNABIS DUTIES.

Subdivision 1. **Manufacturer; requirements.** (a) A manufacturer may operate eight distribution facilities, which may include the manufacturer's single location for cultivation, harvesting, manufacturing, packaging, and processing but is not required to include that location. The commissioner shall designate the geographical service areas to be served by each manufacturer based on geographical need throughout the state to improve patient access. A manufacturer shall not have more than two distribution facilities in each geographical service area assigned to the manufacturer by the commissioner. A manufacturer shall operate only one location where all cultivation, harvesting, manufacturing, packaging, and processing of medical cannabis shall be conducted. This location may be one of the manufacturer's distribution facility sites. The additional distribution facilities may dispense medical cannabis and medical cannabis products but may not contain any medical cannabis in a form other than those forms allowed under section 152.22, subdivision 6, and the manufacturer shall not conduct any cultivation, harvesting, manufacturing, packaging, or processing at the other distribution facility sites. Any distribution facility operated by the manufacturer is subject to all of the requirements applying to the manufacturer under sections 152.22 to 152.37, including, but not limited to, security and distribution requirements.

- (b) A manufacturer may acquire hemp grown in this state from a hemp grower, and may acquire hemp products produced by a hemp processor. A manufacturer may manufacture or process hemp and hemp products into an allowable form of medical cannabis under section 152.22, subdivision 6. Hemp and hemp products acquired by a manufacturer under this paragraph are subject to the same quality control program, security and testing requirements, and other requirements that apply to medical cannabis under sections 152.22 to 152.37 and Minnesota Rules, chapter 4770.
- (c) A medical cannabis manufacturer shall contract with a laboratory approved by the commissioner, subject to any additional requirements set by the commissioner, for purposes of testing medical cannabis manufactured or hemp or hemp products acquired by the medical cannabis manufacturer as to content, contamination, and consistency to verify the medical cannabis meets the requirements of section 152.22, subdivision 6. The cost of laboratory testing shall be paid by the manufacturer.
 - (d) The operating documents of a manufacturer must include:
- (1) procedures for the oversight of the manufacturer and procedures to ensure accurate record keeping;
- (2) procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabis and unauthorized entrance into areas containing medical cannabis; and
- (3) procedures for the delivery and transportation of hemp between hemp growers and manufacturers and for the delivery and transportation of hemp products between hemp processors and manufacturers.
- (e) A manufacturer shall implement security requirements, including requirements for the delivery and transportation of hemp and hemp products, protection of each location by a fully

APPENDIX Repealed Minnesota Statutes: 22-07476

operational security alarm system, facility access controls, perimeter intrusion detection systems, and a personnel identification system.

- (f) A manufacturer shall not share office space with, refer patients to a health care practitioner, or have any financial relationship with a health care practitioner.
- (g) A manufacturer shall not permit any person to consume medical cannabis on the property of the manufacturer.
 - (h) A manufacturer is subject to reasonable inspection by the commissioner.
- (i) For purposes of sections 152.22 to 152.37, a medical cannabis manufacturer is not subject to the Board of Pharmacy licensure or regulatory requirements under chapter 151.
- (j) A medical cannabis manufacturer may not employ any person who is under 21 years of age or who has been convicted of a disqualifying felony offense. An employee of a medical cannabis manufacturer must submit a completed criminal history records check consent form, a full set of classifiable fingerprints, and the required fees for submission to the Bureau of Criminal Apprehension before an employee may begin working with the manufacturer. The bureau must conduct a Minnesota criminal history records check and the superintendent is authorized to exchange the fingerprints with the Federal Bureau of Investigation to obtain the applicant's national criminal history record information. The bureau shall return the results of the Minnesota and federal criminal history records checks to the commissioner.
- (k) A manufacturer may not operate in any location, whether for distribution or cultivation, harvesting, manufacturing, packaging, or processing, within 1,000 feet of a public or private school existing before the date of the manufacturer's registration with the commissioner.
- (l) A manufacturer shall comply with reasonable restrictions set by the commissioner relating to signage, marketing, display, and advertising of medical cannabis.
- (m) Before a manufacturer acquires hemp from a hemp grower or hemp products from a hemp processor, the manufacturer must verify that the hemp grower or hemp processor has a valid license issued by the commissioner of agriculture under chapter 18K.
- (n) Until a state-centralized, seed-to-sale system is implemented that can track a specific medical cannabis plant from cultivation through testing and point of sale, the commissioner shall conduct at least one unannounced inspection per year of each manufacturer that includes inspection of:
 - (1) business operations;
 - (2) physical locations of the manufacturer's manufacturing facility and distribution facilities;
 - (3) financial information and inventory documentation, including laboratory testing results; and
 - (4) physical and electronic security alarm systems.
- Subd. 2. **Manufacturer; production.** (a) A manufacturer of medical cannabis shall provide a reliable and ongoing supply of all medical cannabis needed for the registry program through cultivation by the manufacturer and through the purchase of hemp from hemp growers.
- (b) All cultivation, harvesting, manufacturing, packaging, and processing of medical cannabis must take place in an enclosed, locked facility at a physical address provided to the commissioner during the registration process.
- (c) A manufacturer must process and prepare any medical cannabis plant material or hemp plant material into a form allowable under section 152.22, subdivision 6, prior to distribution of any medical cannabis.
- Subd. 3. **Manufacturer**; **distribution**. (a) A manufacturer shall require that employees licensed as pharmacists pursuant to chapter 151 be the only employees to give final approval for the distribution of medical cannabis to a patient. A manufacturer may transport medical cannabis or medical cannabis products that have been cultivated, harvested, manufactured, packaged, and processed by that manufacturer to another registered manufacturer for the other manufacturer to distribute.
- (b) A manufacturer may distribute medical cannabis products, whether or not the products have been manufactured by that manufacturer.
 - (c) Prior to distribution of any medical cannabis, the manufacturer shall:

- (1) verify that the manufacturer has received the registry verification from the commissioner for that individual patient;
- (2) verify that the person requesting the distribution of medical cannabis is the patient, the patient's registered designated caregiver, or the patient's parent, legal guardian, or spouse listed in the registry verification using the procedures described in section 152.11, subdivision 2d;
 - (3) assign a tracking number to any medical cannabis distributed from the manufacturer;
- (4) ensure that any employee of the manufacturer licensed as a pharmacist pursuant to chapter 151 has consulted with the patient to determine the proper dosage for the individual patient after reviewing the ranges of chemical compositions of the medical cannabis and the ranges of proper dosages reported by the commissioner. For purposes of this clause, a consultation may be conducted remotely by secure videoconference, telephone, or other remote means, so long as the employee providing the consultation is able to confirm the identity of the patient and the consultation adheres to patient privacy requirements that apply to health care services delivered through telehealth. A pharmacist consultation under this clause is not required when a manufacturer is distributing medical cannabis to a patient according to a patient-specific dosage plan established with that manufacturer and is not modifying the dosage or product being distributed under that plan and the medical cannabis is distributed by a pharmacy technician;
- (5) properly package medical cannabis in compliance with the United States Poison Prevention Packing Act regarding child-resistant packaging and exemptions for packaging for elderly patients, and label distributed medical cannabis with a list of all active ingredients and individually identifying information, including:
 - (i) the patient's name and date of birth;
- (ii) the name and date of birth of the patient's registered designated caregiver or, if listed on the registry verification, the name of the patient's parent or legal guardian, if applicable;
 - (iii) the patient's registry identification number;
 - (iv) the chemical composition of the medical cannabis; and
 - (v) the dosage; and
- (6) ensure that the medical cannabis distributed contains a maximum of a 90-day supply of the dosage determined for that patient.
- (d) A manufacturer shall require any employee of the manufacturer who is transporting medical cannabis or medical cannabis products to a distribution facility or to another registered manufacturer to carry identification showing that the person is an employee of the manufacturer.
- (e) A manufacturer shall distribute medical cannabis in dried raw cannabis form only to a patient age 21 or older, or to the registered designated caregiver, parent, legal guardian, or spouse of a patient age 21 or older.
- Subd. 3a. **Transportation of medical cannabis; staffing.** (a) A medical cannabis manufacturer may staff a transport motor vehicle with only one employee if the medical cannabis manufacturer is transporting medical cannabis to either a certified laboratory for the purpose of testing or a facility for the purpose of disposal. If the medical cannabis manufacturer is transporting medical cannabis for any other purpose or destination, the transport motor vehicle must be staffed with a minimum of two employees as required by rules adopted by the commissioner.
- (b) Notwithstanding paragraph (a), a medical cannabis manufacturer that is only transporting hemp for any purpose may staff the transport motor vehicle with only one employee.
- Subd. 3b. **Distribution to recipient in a motor vehicle.** A manufacturer may distribute medical cannabis to a patient, registered designated caregiver, or parent, legal guardian, or spouse of a patient who is at the distribution facility but remains in a motor vehicle, provided:
- (1) distribution facility staff receive payment and distribute medical cannabis in a designated zone that is as close as feasible to the front door of the distribution facility;
- (2) the manufacturer ensures that the receipt of payment and distribution of medical cannabis are visually recorded by a closed-circuit television surveillance camera at the distribution facility and provides any other necessary security safeguards;
- (3) the manufacturer does not store medical cannabis outside a restricted access area at the distribution facility, and distribution facility staff transport medical cannabis from a restricted access

Repealed Minnesota Statutes: 22-07476

area at the distribution facility to the designated zone for distribution only after confirming that the patient, designated caregiver, or parent, guardian, or spouse has arrived in the designated zone;

- (4) the payment and distribution of medical cannabis take place only after a pharmacist consultation takes place, if required under subdivision 3, paragraph (c), clause (4);
- (5) immediately following distribution of medical cannabis, distribution facility staff enter the transaction in the state medical cannabis registry information technology database; and
- (6) immediately following distribution of medical cannabis, distribution facility staff take the payment received into the distribution facility.
- Subd. 3c. **Disposal of medical cannabis plant root balls.** Notwithstanding Minnesota Rules, part 4770.1200, subpart 2, item C, a manufacturer is not required to grind root balls of medical cannabis plants or incorporate them with a greater quantity of nonconsumable solid waste before transporting root balls to another location for disposal. For purposes of this subdivision, "root ball" means a compact mass of roots formed by a plant and any attached growing medium.
- Subd. 4. **Report.** Each manufacturer shall report to the commissioner on a monthly basis the following information on each individual patient for the month prior to the report:
 - (1) the amount and dosages of medical cannabis distributed;
 - (2) the chemical composition of the medical cannabis; and
 - (3) the tracking number assigned to any medical cannabis distributed.

152.30 PATIENT DUTIES.

- (a) A patient shall apply to the commissioner for enrollment in the registry program by submitting an application as required in section 152.27 and an annual registration fee as determined under section 152.35.
 - (b) As a condition of continued enrollment, patients shall agree to:
- (1) continue to receive regularly scheduled treatment for their qualifying medical condition from their health care practitioner; and
 - (2) report changes in their qualifying medical condition to their health care practitioner.
- (c) A patient shall only receive medical cannabis from a registered manufacturer but is not required to receive medical cannabis products from only a registered manufacturer.

152.31 DATA PRACTICES.

- (a) Government data in patient files maintained by the commissioner and the health care practitioner, and data submitted to or by a medical cannabis manufacturer, are private data on individuals, as defined in section 13.02, subdivision 12, or nonpublic data, as defined in section 13.02, subdivision 9, but may be used for purposes of complying with chapter 13 and complying with a request from the legislative auditor or the state auditor in the performance of official duties. The provisions of section 13.05, subdivision 11, apply to a registration agreement entered between the commissioner and a medical cannabis manufacturer under section 152.25.
- (b) Not public data maintained by the commissioner may not be used for any purpose not provided for in sections 152.22 to 152.37, and may not be combined or linked in any manner with any other list, dataset, or database.
- (c) The commissioner may execute data sharing arrangements with the commissioner of agriculture to verify licensing, inspection, and compliance information related to hemp growers and hemp processors under chapter 18K.

152.32 PROTECTIONS FOR REGISTRY PROGRAM PARTICIPATION.

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

- (b) The presumption may be rebutted by evidence that conduct related to use of medical cannabis was not for the purpose of treating or alleviating the patient's qualifying medical condition or symptoms associated with the patient's qualifying medical condition.
- Subd. 2. **Criminal and civil protections.** (a) Subject to section 152.23, the following are not violations under this chapter:

- (1) use or possession of medical cannabis or medical cannabis products by a patient enrolled in the registry program, or possession by a registered designated caregiver or the parent, legal guardian, or spouse of a patient if the parent, legal guardian, or spouse is listed on the registry verification;
- (2) possession, dosage determination, or sale of medical cannabis or medical cannabis products by a medical cannabis manufacturer, employees of a manufacturer, a laboratory conducting testing on medical cannabis, or employees of the laboratory; and
- (3) possession of medical cannabis or medical cannabis products by any person while carrying out the duties required under sections 152.22 to 152.37.
- (b) Medical cannabis obtained and distributed pursuant to sections 152.22 to 152.37 and associated property is not subject to forfeiture under sections 609.531 to 609.5316.
- (c) The commissioner, the commissioner's staff, the commissioner's agents or contractors, and any health care practitioner are not subject to any civil or disciplinary penalties by the Board of Medical Practice, the Board of Nursing, or by any business, occupational, or professional licensing board or entity, solely for the participation in the registry program under sections 152.22 to 152.37. A pharmacist licensed under chapter 151 is not subject to any civil or disciplinary penalties by the Board of Pharmacy when acting in accordance with the provisions of sections 152.22 to 152.37. Nothing in this section affects a professional licensing board from taking action in response to violations of any other section of law.
- (d) Notwithstanding any law to the contrary, the commissioner, the governor of Minnesota, or an employee of any state agency may not be held civilly or criminally liable for any injury, loss of property, personal injury, or death caused by any act or omission while acting within the scope of office or employment under sections 152.22 to 152.37.
- (e) Federal, state, and local law enforcement authorities are prohibited from accessing the patient registry under sections 152.22 to 152.37 except when acting pursuant to a valid search warrant.
- (f) Notwithstanding any law to the contrary, neither the commissioner nor a public employee may release data or information about an individual contained in any report, document, or registry created under sections 152.22 to 152.37 or any information obtained about a patient participating in the program, except as provided in sections 152.22 to 152.37.
- (g) No information contained in a report, document, or registry or obtained from a patient under sections 152.22 to 152.37 may be admitted as evidence in a criminal proceeding unless independently obtained or in connection with a proceeding involving a violation of sections 152.22 to 152.37.
- (h) Notwithstanding section 13.09, any person who violates paragraph (e) or (f) is guilty of a gross misdemeanor.
- (i) An attorney may not be subject to disciplinary action by the Minnesota Supreme Court or professional responsibility board for providing legal assistance to prospective or registered manufacturers or others related to activity that is no longer subject to criminal penalties under state law pursuant to sections 152.22 to 152.37.
- (j) Possession of a registry verification or application for enrollment in the program by a person entitled to possess or apply for enrollment in the registry program does not constitute probable cause or reasonable suspicion, nor shall it be used to support a search of the person or property of the person possessing or applying for the registry verification, or otherwise subject the person or property of the person to inspection by any governmental agency.
- Subd. 3. **Discrimination prohibited.** (a) No school or landlord may refuse to enroll or lease to and may not otherwise penalize a person solely for the person's status as a patient enrolled in the registry program under sections 152.22 to 152.37, unless failing to do so would violate federal law or regulations or cause the school or landlord to lose a monetary or licensing-related benefit under federal law or regulations.
- (b) For the purposes of medical care, including organ transplants, a registry program enrollee's use of medical cannabis under sections 152.22 to 152.37 is considered the equivalent of the authorized use of any other medication used at the discretion of a physician or advanced practice registered nurse and does not constitute the use of an illicit substance or otherwise disqualify a patient from needed medical care.
- (c) Unless a failure to do so would violate federal law or regulations or cause an employer to lose a monetary or licensing-related benefit under federal law or regulations, an employer may not

Repealed Minnesota Statutes: 22-07476

discriminate against a person in hiring, termination, or any term or condition of employment, or otherwise penalize a person, if the discrimination is based upon either of the following:

- (1) the person's status as a patient enrolled in the registry program under sections 152.22 to 152.37; or
- (2) a patient's positive drug test for cannabis components or metabolites, unless the patient used, possessed, or was impaired by medical cannabis on the premises of the place of employment or during the hours of employment.
- (d) An employee who is required to undergo employer drug testing pursuant to section 181.953 may present verification of enrollment in the patient registry as part of the employee's explanation under section 181.953, subdivision 6.
- (e) A person shall not be denied custody of a minor child or visitation rights or parenting time with a minor child solely based on the person's status as a patient enrolled in the registry program under sections 152.22 to 152.37. There shall be no presumption of neglect or child endangerment for conduct allowed under sections 152.22 to 152.37, unless the person's behavior is such that it creates an unreasonable danger to the safety of the minor as established by clear and convincing evidence.

152.33 VIOLATIONS.

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

- Subd. 1a. **Intentional diversion outside the state; penalties.** (a) In addition to any other applicable penalty in law, the commissioner may levy a fine of \$250,000 against a manufacturer and may immediately initiate proceedings to revoke the manufacturer's registration, using the procedure in section 152.25, if:
- (1) an officer, director, or controlling person of the manufacturer pleads or is found guilty under subdivision 1 of intentionally transferring medical cannabis, while the person was an officer, director, or controlling person of the manufacturer, to a person other than allowed by law; and
- (2) in intentionally transferring medical cannabis to a person other than allowed by law, the officer, director, or controlling person transported or directed the transport of medical cannabis outside of Minnesota.
- (b) All fines collected under this subdivision shall be deposited in the state government special revenue fund.
- Subd. 2. Diversion by patient, registered designated caregiver, parent, legal guardian, or patient's spouse; criminal penalty. In addition to any other applicable penalty in law, a patient, registered designated caregiver or, if listed on the registry verification, a parent, legal guardian, or spouse of a patient who intentionally sells or otherwise transfers medical cannabis to a person other than a patient, designated registered caregiver or, if listed on the registry verification, a parent, legal guardian, or spouse of a patient is guilty of a felony punishable by imprisonment for not more than two years or by payment of a fine of not more than \$3,000, or both.
- Subd. 3. **False statement; criminal penalty.** A person who intentionally makes a false statement to a law enforcement official about any fact or circumstance relating to the medical use of cannabis to avoid arrest or prosecution is guilty of a misdemeanor punishable by imprisonment for not more than 90 days or by payment of a fine of not more than \$1,000, or both. The penalty is in addition to any other penalties that may apply for making a false statement or for the possession, cultivation, or sale of cannabis not protected by sections 152.22 to 152.37. If a person convicted of violating this subdivision is a patient or a registered designated caregiver, the person is disqualified from further participation under sections 152.22 to 152.37.
- Subd. 4. **Submission of false records; criminal penalty.** A person who knowingly submits false records or documentation required by the commissioner to register as a manufacturer of medical cannabis under sections 152.22 to 152.37 is guilty of a felony and may be sentenced to imprisonment for not more than two years or by payment of a fine of not more than \$3,000, or both.

Repealed Minnesota Statutes: 22-07476

- Subd. 5. Violation by health care practitioner; criminal penalty. A health care practitioner who knowingly refers patients to a manufacturer or to a designated caregiver, who advertises as a manufacturer, or who issues certifications while holding a financial interest in a manufacturer is guilty of a misdemeanor and may be sentenced to imprisonment for not more than 90 days or by payment of a fine of not more than \$1,000, or both.
- Subd. 6. Other violations; civil penalty. A manufacturer shall be fined up to \$1,000 for any violation of sections 152.22 to 152.37, or the regulations issued pursuant to them, where no penalty has been specified. This penalty is in addition to any other applicable penalties in law.

152.34 HEALTH CARE FACILITIES.

- (a) Health care facilities licensed under chapter 144A, hospice providers licensed under chapter 144A, boarding care homes or supervised living facilities licensed under section 144.50, assisted living facilities, facilities owned, controlled, managed, or under common control with hospitals licensed under chapter 144, and other health facilities licensed by the commissioner of health, may adopt reasonable restrictions on the use of medical cannabis by a patient enrolled in the registry program who resides at or is actively receiving treatment or care at the facility. The restrictions may include a provision that the facility will not store or maintain the patient's supply of medical cannabis, that the facility is not responsible for providing the medical cannabis for patients, and that medical cannabis be used only in a place specified by the facility.
- (b) Any employee or agent of a facility listed in this section or a person licensed under chapter 144E is not subject to violations under this chapter for possession of medical cannabis while carrying out employment duties, including providing or supervising care to a registered patient, or distribution of medical cannabis to a registered patient who resides at or is actively receiving treatment or care at the facility with which the employee or agent is affiliated. Nothing in this section shall require the facilities to adopt such restrictions and no facility shall unreasonably limit a patient's access to or use of medical cannabis to the extent that use is authorized by the patient under sections 152.22 to 152.37.

152.35 FEES; DEPOSIT OF REVENUE.

- (a) The commissioner shall collect an enrollment fee of \$200 from patients enrolled under this section. If the patient provides evidence of receiving Social Security disability insurance (SSDI), Supplemental Security Income (SSI), veterans disability, or railroad disability payments, or being enrolled in medical assistance or MinnesotaCare, then the fee shall be \$50. For purposes of this section:
- (1) a patient is considered to receive SSDI if the patient was receiving SSDI at the time the patient was transitioned to retirement benefits by the United States Social Security Administration; and
 - (2) veterans disability payments include VA dependency and indemnity compensation.

Unless a patient provides evidence of receiving payments from or participating in one of the programs specifically listed in this paragraph, the commissioner of health must collect the \$200 enrollment fee from a patient to enroll the patient in the registry program. The fees shall be payable annually and are due on the anniversary date of the patient's enrollment. The fee amount shall be deposited in the state treasury and credited to the state government special revenue fund.

- (b) The commissioner shall collect an application fee of \$20,000 from each entity submitting an application for registration as a medical cannabis manufacturer. Revenue from the fee shall be deposited in the state treasury and credited to the state government special revenue fund.
- (c) The commissioner shall establish and collect an annual fee from a medical cannabis manufacturer equal to the cost of regulating and inspecting the manufacturer in that year. Revenue from the fee amount shall be deposited in the state treasury and credited to the state government special revenue fund.
- (d) A medical cannabis manufacturer may charge patients enrolled in the registry program a reasonable fee for costs associated with the operations of the manufacturer. The manufacturer may establish a sliding scale of patient fees based upon a patient's household income and may accept private donations to reduce patient fees.

Repealed Minnesota Statutes: 22-07476

152.36 IMPACT ASSESSMENT OF MEDICAL CANNABIS THERAPEUTIC RESEARCH.

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

- (1) two members of the house of representatives, one selected by the speaker of the house, the other selected by the minority leader;
- (2) two members of the senate, one selected by the majority leader, the other selected by the minority leader;
- (3) four members representing consumers or patients enrolled in the registry program, including at least two parents of patients under age 18;
 - (4) four members representing health care providers, including one licensed pharmacist;
- (5) four members representing law enforcement, one from the Minnesota Chiefs of Police Association, one from the Minnesota Sheriff's Association, one from the Minnesota Police and Peace Officers Association, and one from the Minnesota County Attorneys Association;
 - (6) four members representing substance use disorder treatment providers; and
 - (7) the commissioners of health, human services, and public safety.
- (b) Task force members listed under paragraph (a), clauses (3), (4), (5), and (6), shall be appointed by the governor under the appointment process in section 15.0597. Members shall serve on the task force at the pleasure of the appointing authority. All members must be appointed by July 15, 2014, and the commissioner of health shall convene the first meeting of the task force by August 1, 2014.
- (c) There shall be two cochairs of the task force chosen from the members listed under paragraph (a). One cochair shall be selected by the speaker of the house and the other cochair shall be selected by the majority leader of the senate. The authority to convene meetings shall alternate between the cochairs.
- (d) Members of the task force other than those in paragraph (a), clauses (1), (2), and (7), shall receive expenses as provided in section 15.059, subdivision 6.
- Subd. 1a. **Administration.** The commissioner of health shall provide administrative and technical support to the task force.
- Subd. 2. **Impact assessment.** The task force shall hold hearings to evaluate the impact of the use of medical cannabis and hemp and Minnesota's activities involving medical cannabis and hemp, including, but not limited to:
 - (1) program design and implementation;
 - (2) the impact on the health care provider community;
 - (3) patient experiences;
 - (4) the impact on the incidence of substance abuse;
 - (5) access to and quality of medical cannabis, hemp, and medical cannabis products;
 - (6) the impact on law enforcement and prosecutions;
 - (7) public awareness and perception; and
 - (8) any unintended consequences.
- Subd. 3. **Cost assessment.** By January 15 of each year, beginning January 15, 2015, and ending January 15, 2019, the commissioners of state departments impacted by the medical cannabis therapeutic research study shall report to the cochairs of the task force on the costs incurred by each department on implementing sections 152.22 to 152.37. The reports must compare actual costs to the estimated costs of implementing these sections and must be submitted to the task force on medical cannabis therapeutic research.
- Subd. 4. **Reports to the legislature.** (a) The cochairs of the task force shall submit the following reports to the chairs and ranking minority members of the legislative committees and divisions with jurisdiction over health and human services, public safety, judiciary, and civil law:

APPENDIX Repealed Minnesota Statutes: 22-07476

- (1) by February 1, 2015, a report on the design and implementation of the registry program; and every two years thereafter, a complete impact assessment report; and
- (2) upon receipt of a cost assessment from a commissioner of a state agency, the completed cost assessment.
- (b) The task force may make recommendations to the legislature on whether to add or remove conditions from the list of qualifying medical conditions.
 - Subd. 5. No expiration. The task force on medical cannabis therapeutic research does not expire.

152.37 FINANCIAL EXAMINATIONS; PRICING REVIEWS.

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

- Subd. 2. Certified annual audit. A medical cannabis manufacturer shall submit the results of an annual certified financial audit to the commissioner no later than May 1 of each year for the calendar year beginning January 2015. The annual audit shall be conducted by an independent certified public accountant and the costs of the audit are the responsibility of the medical cannabis manufacturer. Results of the audit shall be provided to the medical cannabis manufacturer and the commissioner. The commissioner may also require another audit of the medical cannabis manufacturer by a certified public accountant chosen by the commissioner with the costs of the audit paid by the medical cannabis manufacturer.
- Subd. 3. **Power to examine.** (a) The commissioner or designee may examine the business affairs and conditions of any medical cannabis manufacturer, including but not limited to a review of the financing, budgets, revenues, sales, and pricing.
- (b) An examination may cover the medical cannabis manufacturer's business affairs, practices, and conditions including but not limited to a review of the financing, budgets, revenues, sales, and pricing. The commissioner shall determine the nature and scope of each examination and in doing so shall take into account all available relevant factors concerning the financial and business affairs, practices, and conditions of the examinee. The costs incurred by the department in conducting an examination shall be paid for by the medical cannabis manufacturer.
- (c) When making an examination under this section, the commissioner may retain attorneys, appraisers, independent economists, independent certified public accountants, or other professionals and specialists as designees. A certified public accountant retained by the commissioner may not be the same certified public accountant providing the certified annual audit in subdivision 2.
- (d) The commissioner shall make a report of an examination conducted under this section and provide a copy to the medical cannabis manufacturer. The commissioner shall then post a copy of the report on the department's website. All working papers, recorded information, documents, and copies produced by, obtained by, or disclosed to the commissioner or any other person in the course of an examination, other than the information contained in any commissioner official report, made under this section are private data on individuals or nonpublic data, as defined in section 13.02.