

SENATE SUBSTITUTE
FOR
SENATE BILL NO. 386

AN ACT

To repeal sections 192.945, 195.207, and 261.265, RSMo,
and to enact in lieu thereof four new sections relating
to hemp extract.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF MISSOURI,
AS FOLLOWS:

1 Section A. Sections 192.945, 195.207, and 261.265, RSMo,
2 are repealed and four new sections enacted in lieu thereof, to be
3 known as sections 192.945, 192.947, 195.207, and 261.265, to read
4 as follows:

5 192.945. 1. As used in this section, the following terms
6 shall mean:

7 (1) "Department", the department of health and senior
8 services;

9 (2) "Hemp extract", as such term is defined in section
10 195.207;

11 (3) "Hemp extract registration card", a card issued by the
12 department under this section;

13 (4) "Intractable epilepsy", epilepsy that as determined by
14 a neurologist does not respond to three or more treatment options
15 overseen by the neurologist;

16 (5) "Neurologist", a physician who is licensed under
17 chapter 334 and board certified in neurology;

18 (6) "Parent", a parent or legal guardian of a minor who is

1 responsible for the minor's medical care;

2 (7) "Practitioner", a practitioner who is a physician
3 licensed by the state board of registration for the healing arts
4 and practicing within this state and, by training or experience,
5 is qualified to treat a serious condition;

6 ~~[(7)]~~ (8) "Registrant", an individual to whom the
7 department issues a hemp extract registration card under this
8 section;

9 (9) "Serious condition":

10 (a) Cancer, positive status for human immunodeficiency
11 virus or acquired immune deficiency syndrome, amyotrophic lateral
12 sclerosis, Parkinson's disease, multiple sclerosis, damage to the
13 nervous tissue of the spinal cord with objective neurological
14 indication of intractable spasticity, inflammatory bowel disease,
15 neuropathies, Huntington's disease, post-traumatic stress
16 disorder; or

17 (b) Any of the following conditions that is clinically
18 associated with, or a complication of, a condition under this
19 paragraph or its treatment: cachexia or wasting syndrome; severe
20 or chronic pain; severe nausea; seizures; severe or persistent
21 muscle spasms.

22 2. The department shall issue a hemp extract registration
23 card to an individual who:

24 (1) Is eighteen years of age or older;

25 (2) Is a Missouri resident;

26 (3) Provides the department with a [statement]
27 recommendation signed by a neurologist or practitioner that:

28 (a) Indicates that the individual suffers from intractable

1 epilepsy or a serious condition and may benefit from treatment
2 with hemp extract; and

3 (b) Is consistent with a record from the neurologist or
4 practitioner concerning the individual contained in the database
5 described in subsection [9] 10 of this section;

6 (c) Indicates the practitioner or neurologist by training
7 or experience is qualified to treat the serious condition;

8 (d) States that the individual is under the practitioner or
9 neurologist's continuing care for the serious condition or
10 intractable epilepsy; and

11 (e) Recommends the form of hemp extract the patient may
12 consume, including the method of consumption and any particular
13 strain, variety, or quantity;

14 (4) Pays the department a fee in an amount established by
15 the department under subsection 6 of this section; and

16 (5) Submits an application to the department on a form
17 created by the department that contains:

18 (a) The individual's name and address;

19 (b) A copy of the individual's valid photo identification;

20 and

21 (c) Any other information the department considers
22 necessary to implement the provisions of this section.

23 3. The department shall issue a hemp extract registration
24 card to a parent who:

25 (1) Is eighteen years of age or older;

26 (2) Is a Missouri resident;

27 (3) Provides the department with a [statement]
28 recommendation signed by a neurologist or practitioner that:

1 (a) Indicates that a minor in the parent's care suffers
2 from intractable epilepsy or a serious condition and may benefit
3 from treatment with hemp extract; [and]

4 (b) Is consistent with a record from the neurologist or
5 practitioner concerning the minor contained in the database
6 described in subsection [9] 10 of this section;

7 (c) The practitioner or neurologist by training or
8 experience is qualified to treat the serious condition;

9 (d) The minor is under the practitioner or neurologist's
10 continuing care for the serious condition; and

11 (e) Recommends the form of hemp extract the patient may
12 consume, including the method of consumption and any particular
13 strain, variety, or quantity;

14 (4) Pays the department a fee in an amount established by
15 the department under subsection 6 of this section; and

16 (5) Submits an application to the department on a form
17 created by the department that contains:

18 (a) The parent's name and address;

19 (b) The minor's name;

20 (c) A copy of the parent's valid photo identification; and

21 (d) Any other information the department considers
22 necessary to implement the provisions of this section.

23 4. The department shall maintain a record of the name of
24 each registrant and the name of each minor receiving care from a
25 registrant.

26 5. The department may promulgate rules to authorize
27 clinical trials involving hemp extract and shall promulgate rules
28 to:

1 (1) Implement the provisions of this section including
2 establishing the information the applicant is required to provide
3 to the department and establishing in accordance with
4 recommendations from the department of public safety the form and
5 content of the hemp extract registration card; and

6 (2) Regulate the distribution of hemp extract from a
7 cannabidiol oil care center to a registrant, which shall be in
8 addition to any other state or federal regulations[; and

9
10 The department may promulgate rules to authorize clinical trials
11 involving hemp extract].

12 6. The department shall establish fees that are no greater
13 than the amount necessary to cover the cost the department incurs
14 to implement the provisions of this section.

15 7. The registration cards issued under this section shall
16 be valid for one year and renewable if at the time of renewal the
17 registrant meets the requirements of either subsection 2 or 3 of
18 this section. The practitioner or neurologist may state in the
19 recommendation provided to the department that, in the
20 practitioner or neurologist's professional opinion, the patient
21 would benefit from hemp extract only until a specified earlier
22 date and the registration card shall expire on the date provided
23 in the recommendation.

24 8. Only a neurologist or practitioner may recommend hemp
25 extract and sign the statement described in subsection 2 or 3 of
26 this section as part of the treatment plan of a patient diagnosed
27 with intractable epilepsy or a serious condition.

28 9. The neurologist or practitioner who signs the

1 [statement] recommendation described in subsection 2 or 3 of this
2 section shall:

3 (1) Keep a record of the practitioner or neurologist's
4 evaluation and observation of a patient who is a registrant or
5 minor under a registrant's care including the patient's response
6 to hemp extract; [and]

7 (2) Transmit the record described in subdivision (1) of
8 this subsection to the department; and

9 (3) Notify the patient, or the patient's parent or guardian
10 if the patient is a minor, prior to providing a recommendation,
11 that hemp extract has not been approved by the Federal Drug
12 Administration and by using such treatment the patient or parent
13 is accepting the risks involved in using an unapproved product.

14 [9.] 10. The department shall maintain a database of the
15 records described in subsection [8] 9 of this section and treat
16 the records as identifiable health data.

17 [10.] 11. The department may share the records described in
18 subsection [9] 10 of this section with a higher education
19 institution for the purpose of studying hemp extract.

20 [11.] 12. Any rule or portion of a rule, as that term is
21 defined in section 536.010, that is created under the authority
22 delegated in this section shall become effective only if it
23 complies with and is subject to all of the provisions of chapter
24 536 and, if applicable, section 536.028. This section and
25 chapter 536 are nonseverable and if any of the powers vested with
26 the general assembly pursuant to chapter 536 to review, to delay
27 the effective date, or to disapprove and annul a rule are
28 subsequently held unconstitutional, then the grant of rulemaking

1 authority and any rule proposed or adopted after July 14, 2014,
2 shall be invalid and void.

3 192.947. 1. No individual or health care entity organized
4 under the laws of this state shall be subject to any adverse
5 action by the state or any agency, board, or subdivision thereof,
6 including civil or criminal prosecution, denial of any right or
7 privilege, the imposition of a civil or administrative penalty or
8 sanction, or disciplinary action by any accreditation or
9 licensing board or commission if such individual or health care
10 entity, in its normal course of business and within its
11 applicable licenses and regulations, acts in good faith upon or
12 in furtherance of any order, recommendation, or statement by a
13 neurologist or practitioner authorized under section 192.945
14 relating to the medical use and administration of hemp extract
15 with respect to an eligible patient.

16 2. The provisions of subsection 1 of this section shall
17 apply to the possession, handling, storage, transfer,
18 destruction, dispensing, or administration of hemp extract,
19 including any act in preparation of such dispensing or
20 administration.

21 195.207. 1. As used in sections 192.945, 261.265, 261.267,
22 and this section, the term "hemp extract" shall mean an extract
23 from a cannabis plant or a mixture or preparation containing
24 cannabis plant material that:

25 (1) Is composed of no more than three-tenths percent
26 tetrahydrocannabinol by weight;

27 (2) Is composed of at least five percent cannabidiol by
28 weight; and

1 (3) Contains no other psychoactive substance.

2 2. Notwithstanding any other provision of this chapter or
3 chapter 579, an individual who has been issued a valid hemp
4 extract registration card under section 192.945, or is a minor
5 under a registrant's care, and possesses or uses hemp extract is
6 not subject to the penalties described in this chapter or chapter
7 579 for possession or use of the hemp extract if the individual:

8 (1) Possesses or uses the hemp extract only to treat
9 intractable epilepsy or a serious condition as defined in section
10 192.945;

11 (2) Originally obtained the hemp extract from a sealed
12 container with a label indicating the hemp extract's place of
13 origin and a number that corresponds with a certificate of
14 analysis;

15 (3) Possesses, in close proximity to the hemp extract, a
16 certificate of analysis that:

17 (a) Has a number that corresponds with the number on the
18 label described in subdivision (2) of this subsection;

19 (b) Indicates the hemp extract's ingredients including its
20 percentages of tetrahydrocannabinol and cannabidiol by weight;

21 (c) Is created by a laboratory that is not affiliated with
22 the producer of the hemp extract and is licensed in the state
23 where the hemp extract was produced; and

24 (d) Is transmitted by the laboratory to the department of
25 health and senior services; and

26 (4) Has a current hemp extract registration card issued by
27 the department of health and senior services under section
28 192.945;

1 (5) Possesses a form of hemp extract that is in compliance
2 with any recommendation or limitation by the practitioner or
3 neurologist as stated in the recommendation provided to the
4 department.

5 3. Notwithstanding any other provision of this chapter or
6 chapter 579, an individual who possesses hemp extract lawfully
7 under subsection 2 of this section and administers hemp extract
8 to a minor suffering from intractable epilepsy or a serious
9 condition is not subject to the penalties described in this
10 chapter or chapter 579 for administering the hemp extract to the
11 minor if:

12 (1) The individual is the minor's parent or legal guardian;
13 and

14 (2) The individual is registered with the department of
15 health and senior services as the minor's parent under section
16 192.945.

17 4. An individual who has [been issued] a valid hemp extract
18 registration card under section 192.945, or is a minor under a
19 registrant's care, may possess up to twenty ounces of hemp
20 extract pursuant to this section. Subject to any rules or
21 regulations promulgated by the department of health and senior
22 services, an individual may apply for a waiver if a physician
23 provides a substantial medical basis in a signed, written
24 statement asserting that, based on the patient's medical history,
25 in the physician's professional judgment, twenty ounces is an
26 insufficient amount to properly alleviate the patient's medical
27 condition or symptoms associated with such medical condition.

28 261.265. 1. For purposes of this section, the following

1 terms shall mean:

2 (1) "Cannabidiol oil care center", the premises specified
3 in an application for a cultivation and production facility
4 license in which the licensee is authorized to distribute
5 processed hemp extract to persons possessing a hemp extract
6 registration card issued under section 192.945;

7 (2) "Cultivation and production facility", the land and
8 premises specified in an application for a cultivation and
9 production facility license on which the licensee is authorized
10 to grow, cultivate, process, and possess hemp and hemp extract;

11 (3) "Cultivation and production facility license", a
12 license that authorizes the licensee to grow, cultivate, process,
13 and possess hemp and hemp extract, and distribute hemp extract to
14 its cannabidiol oil care centers;

15 (4) "Department", the department of agriculture;

16 (5) "Grower", a nonprofit entity issued a cultivation and
17 production facility license by the department of agriculture that
18 produces hemp extract for the treatment of intractable epilepsy
19 or a serious condition as such terms are defined under section
20 192.945;

21 (6) "Hemp":

22 (a) All nonseed parts and varieties of the cannabis sativa
23 plant, whether growing or not, that contain a crop-wide average
24 tetrahydrocannabinol (THC) concentration that does not exceed the
25 lesser of:

26 a. Three-tenths of one percent on a dry weight basis; or

27 b. The percent based on a dry weight basis determined by
28 the federal Controlled Substances Act under 21 U.S.C. Section

1 801, et seq.;

2 (b) Any cannabis sativa seed that is:

3 a. Part of a growing crop;

4 b. Retained by a grower for future planting; or

5 c. For processing into or use as agricultural hemp seed.

6 This term shall not include industrial hemp commodities or
7 products;

8 (7) "Hemp monitoring system", an electronic tracking system
9 that includes, but is not limited to, testing and data collection
10 established and maintained by the cultivation and production
11 facility and is available to the department for the purposes of
12 documenting the hemp extract production and retail sale of the
13 hemp extract.

14 2. The department shall issue a cultivation and production
15 facility license to a nonprofit entity to grow or cultivate the
16 cannabis plant used to make hemp extract as defined in subsection
17 1 of section 195.207 or hemp on the entity's property if the
18 entity has had its domicile in the state for at least five years,
19 has submitted to the department an application as required by the
20 department under subsection 7 of this section, the entity meets
21 all requirements of this section and the department's rules, and
22 there are fewer than [two] the maximum number of licensed
23 cultivation and production facilities operating in the state as
24 provided under subsection 3 of this section. Any cultivation and
25 production facility license issued before August 28, 2015, shall
26 continue to be valid even if the licensed entity does not meet
27 the domicile requirement under this subsection.

28 3. A grower may produce and manufacture hemp and hemp

1 extract, and distribute hemp extract as defined in section
2 195.207 for the treatment of persons suffering from intractable
3 epilepsy [as defined in section 192.945] or a serious condition,
4 consistent with any and all state or federal regulations
5 regarding the production, manufacture, or distribution of such
6 product. The department shall not issue more than:

7 (1) Two cultivation and production facility licenses for
8 the operation of such facilities at any one time in the year
9 2015;

10 (2) Five cultivation and production facility licenses for
11 the operation of such facilities at any one time in the year
12 2016;

13 (3) Eight cultivation and production facility licenses for
14 the operation of such facilities at any one time in the year
15 2017;

16 (4) Ten cultivation and production facility licenses for
17 the operation of such facilities at any one time in the year 2018
18 and every year thereafter.

19 4. The department shall maintain a list of growers.

20 5. All growers shall keep records in accordance with rules
21 adopted by the department. Upon at least three days' notice, the
22 director of the department may audit the required records during
23 normal business hours. The director may conduct an audit for the
24 purpose of ensuring compliance with this section.

25 6. In addition to an audit conducted in accordance with
26 subsection 5 of this section, the director may inspect
27 independently, or in cooperation with the state highway patrol or
28 a local law enforcement agency, any hemp crop during the crop's

1 growth phase and take a representative composite sample for field
2 analysis. If a crop contains an average tetrahydrocannabinol
3 (THC) concentration exceeding the lesser of:

4 (1) Three-tenths of one percent on a dry weight basis; or

5 (2) The percent based on a dry weight basis determined by
6 the federal Controlled Substances Act under 21 U.S.C. Section
7 801, et seq.,

8
9 the director may detain, seize, or embargo the crop.

10 7. The department shall promulgate rules including, but not
11 limited to:

12 (1) Application requirements for licensing, including
13 requirements for the submission of fingerprints and the
14 completion of a criminal background check;

15 (2) Security requirements for cultivation and production
16 facility premises, including, at a minimum, lighting, physical
17 security, video and alarm requirements;

18 (3) Rules relating to hemp monitoring systems as defined in
19 this section;

20 (4) Other procedures for internal control as deemed
21 necessary by the department to properly administer and enforce
22 the provisions of this section, including reporting requirements
23 for changes, alterations, or modifications of the premises;

24 (5) Requirements that any hemp extract received from a
25 legal source be submitted to a testing facility designated by the
26 department to ensure that such hemp extract complies with the
27 provisions of section 195.207 and to ensure that the hemp extract
28 does not contain any pesticides. Any hemp extract that is not

1 submitted for testing or which after testing is found not to
2 comply with the provisions of section 195.207 shall not be
3 distributed or used and shall be submitted to the department for
4 destruction; and

5 (6) Rules regarding the manufacture, storage, and
6 transportation of hemp and hemp extract, which shall be in
7 addition to any other state or federal regulations.

8 8. Any rule or portion of a rule, as that term is defined
9 in section 536.010, that is created under the authority delegated
10 in this section shall become effective only if it complies with
11 and is subject to all of the provisions of chapter 536 and, if
12 applicable, section 536.028. This section and chapter 536 are
13 nonseverable, and if any of the powers vested with the general
14 assembly under chapter 536 to review, to delay the effective
15 date, or to disapprove and annul a rule are subsequently held
16 unconstitutional, then the grant of rulemaking authority and any
17 rule proposed or adopted after July 14, 2014, shall be invalid
18 and void.

19 9. All hemp waste from the production of hemp extract shall
20 either be destroyed, recycled by the licensee at the hemp
21 cultivation and production facility, or donated to the department
22 or an institution of higher education for research purposes, and
23 shall not be used for commercial purposes.

24 10. In addition to any other liability or penalty provided
25 by law, the director may revoke or refuse to issue or renew a
26 cultivation and production facility license and may impose a
27 civil penalty on a grower for any violation of this section, or
28 section 192.945 or 195.207. The director may not impose a civil

1 penalty under this section that exceeds two thousand five hundred
2 dollars.