

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.

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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2 are repealed and four new sections enacted in lieu thereof, to be  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. The director shall  
6 consider the inclusion of advanced practice registered nurses  
7 under this section based upon considerations including access and  
8 availability. After such consideration the director is  
9 authorized to deem advanced practice registered nurses as  
10 practitioners under this section;

11 ~~[(7)]~~ (8) "Registrant", an individual to whom the  
12 department issues a hemp extract registration card under this  
13 section;

14 (9) "Serious condition":

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

22 (b) Any of the following conditions that is clinically  
23 associated with, or a complication of, a condition under this  
24 paragraph or its treatment: cachexia or wasting syndrome; severe  
25 or chronic pain; severe nausea; seizures; severe or persistent  
26 muscle spasms.

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

- 1 (1) Is eighteen years of age or older;
- 2 (2) Is a Missouri resident;
- 3 (3) Provides the department with a [statement]
- 4 recommendation signed by a neurologist or practitioner that:
- 5 (a) Indicates that the individual suffers from intractable
- 6 epilepsy or a serious condition and may benefit from treatment
- 7 with hemp extract; and
- 8 (b) Is consistent with a record from the neurologist or
- 9 practitioner concerning the individual contained in the database
- 10 described in subsection [9] 10 of this section;
- 11 (c) Indicates the practitioner or neurologist by training
- 12 or experience is qualified to treat the serious condition;
- 13 (d) States that the individual is under the practitioner or
- 14 neurologist's continuing care for the serious condition or
- 15 intractable epilepsy; and
- 16 (e) Recommends the form of hemp extract the patient may
- 17 consume, including the method of consumption and any particular
- 18 strain, variety, or quantity;
- 19 (4) Pays the department a fee in an amount established by
- 20 the department under subsection 6 of this section; and
- 21 (5) Submits an application to the department on a form
- 22 created by the department that contains:
- 23 (a) The individual's name and address;
- 24 (b) A copy of the individual's valid photo identification;
- 25 and
- 26 (c) Any other information the department considers
- 27 necessary to implement the provisions of this section.
- 28 3. The department shall issue a hemp extract registration

1 card to a parent who:

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

3 (2) Is a Missouri resident;

4 (3) Provides the department with a [statement]

5 recommendation signed by a neurologist or practitioner that:

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

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

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

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

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

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

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

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

24 (b) The minor's name;

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

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

28 4. The department shall maintain a record of the name of

1 each registrant and the name of each minor receiving care from a  
2 registrant.

3 5. The department may promulgate rules to authorize  
4 clinical trials involving hemp extract and shall promulgate rules  
5 to:

6 (1) Implement the provisions of this section including  
7 establishing the information the applicant is required to provide  
8 to the department and establishing in accordance with  
9 recommendations from the department of public safety the form and  
10 content of the hemp extract registration card; and

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

14  
15 The department may promulgate rules to authorize clinical trials  
16 involving hemp extract].

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

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

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

5           9. The neurologist or practitioner who signs the  
6 [statement] recommendation described in subsection 2 or 3 of this  
7 section shall:

8           (1) Keep a record of the practitioner or neurologist's  
9 evaluation and observation of a patient who is a registrant or  
10 minor under a registrant's care including the patient's response  
11 to hemp extract; [and]

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

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

19           [9.] 10. The department shall maintain a database of the  
20 records described in subsection [8] 9 of this section and treat  
21 the records as identifiable health data.

22           [10.] 11. The department may share the records described in  
23 subsection [9] 10 of this section with a higher education  
24 institution for the purpose of studying hemp extract.

25           [11.] 12. Any rule or portion of a rule, as that term is  
26 defined in section 536.010, that is created under the authority  
27 delegated in this section shall become effective only if it  
28 complies with and is subject to all of the provisions of chapter

1 536 and, if applicable, section 536.028. This section and  
2 chapter 536 are nonseverable and if any of the powers vested with  
3 the general assembly pursuant to chapter 536 to review, to delay  
4 the effective date, or to disapprove and annul a rule are  
5 subsequently held unconstitutional, then the grant of rulemaking  
6 authority and any rule proposed or adopted after July 14, 2014,  
7 shall be invalid and void.

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

21 2. The provisions of subsection 1 of this section shall  
22 apply to the possession, handling, storage, transfer,  
23 destruction, dispensing, or administration of hemp extract,  
24 including any act in preparation of such dispensing or  
25 administration.

26 195.207. 1. As used in sections 192.945, 261.265, 261.267,  
27 and this section, the term "hemp extract" shall mean an extract  
28 from a cannabis plant or a mixture or preparation containing

1 cannabis plant material that:

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

4 (2) Is composed of at least five percent cannabidiol by  
5 weight; and

6 (3) Contains no other psychoactive substance.

7 2. Notwithstanding any other provision of this chapter or  
8 chapter 579, an individual who has been issued a valid hemp  
9 extract registration card under section 192.945, or is a minor  
10 under a registrant's care, and possesses or uses hemp extract is  
11 not subject to the penalties described in this chapter or chapter  
12 579 for possession or use of the hemp extract if the individual:

13 (1) Possesses or uses the hemp extract only to treat  
14 intractable epilepsy or a serious condition as defined in section  
15 192.945;

16 (2) Originally obtained the hemp extract from a sealed  
17 container with a label indicating the hemp extract's place of  
18 origin and a number that corresponds with a certificate of  
19 analysis;

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

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

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

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



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

3 (4) Has a current hemp extract registration card issued by  
4 the department of health and senior services under section  
5 192.945;

6 (5) Possesses a form of hemp extract that is in compliance  
7 with any recommendation or limitation by the practitioner or  
8 neurologist as stated in the recommendation provided to the  
9 department.

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

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

19 (2) The individual is registered with the department of  
20 health and senior services as the minor's parent under section  
21 192.945.

22 4. An individual who has **[been issued]** a valid hemp extract  
23 registration card under section 192.945, or is a minor under a  
24 registrant's care, may possess up to twenty ounces of hemp  
25 extract pursuant to this section. Subject to any rules or  
26 regulations promulgated by the department of health and senior  
27 services, an individual may apply for a waiver if a physician  
28 provides a substantial medical basis in a signed, written

1 statement asserting that, based on the patient's medical history,  
2 in the physician's professional judgment, twenty ounces is an  
3 insufficient amount to properly alleviate the patient's medical  
4 condition or symptoms associated with such medical condition.

5 261.265. 1. For purposes of this section, the following  
6 terms shall mean:

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

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

16 (3) "Cultivation and production facility license", a  
17 license that authorizes the licensee to grow, cultivate, process,  
18 and possess hemp and hemp extract, and distribute hemp extract to  
19 its cannabidiol oil care centers;

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

21 (5) "Grower", a nonprofit entity issued a cultivation and  
22 production facility license by the department of agriculture that  
23 produces hemp extract for the treatment of intractable epilepsy  
24 or a serious condition as such terms are defined under section  
25 192.945;

26 (6) "Hemp":

27 (a) All nonseed parts and varieties of the cannabis sativa  
28 plant, whether growing or not, that contain a crop-wide average

1 tetrahydrocannabinol (THC) concentration that does not exceed the  
2 lesser of:

- 3 a. Three-tenths of one percent on a dry weight basis; or
- 4 b. The percent based on a dry weight basis determined by  
5 the federal Controlled Substances Act under 21 U.S.C. Section  
6 801, et seq.;

7 (b) Any cannabis sativa seed that is:

- 8 a. Part of a growing crop;
- 9 b. Retained by a grower for future planting; or
- 10 c. For processing into or use as agricultural hemp seed.

11 This term shall not include industrial hemp commodities or  
12 products;

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

19 2. The department shall issue a cultivation and production  
20 facility license to a nonprofit entity to grow or cultivate the  
21 cannabis plant used to make hemp extract as defined in subsection  
22 1 of section 195.207 or hemp on the entity's property if the  
23 entity has had its domicile in the state for at least five years,  
24 has submitted to the department an application as required by the  
25 department under subsection 7 of this section, the entity meets  
26 all requirements of this section and the department's rules, and  
27 there are fewer than ~~two~~ ten licensed cultivation and  
28 production facilities operating in the state. Any cultivation

1 and production facility license issued before August 28, 2015,  
2 shall continue to be valid even if the licensed entity does not  
3 meet the domicile requirement under this subsection.

4 3. A grower may produce and manufacture hemp and hemp  
5 extract, and distribute hemp extract as defined in section  
6 195.207 for the treatment of persons suffering from intractable  
7 epilepsy [as defined in section 192.945] or a serious condition,  
8 consistent with any and all state or federal regulations  
9 regarding the production, manufacture, or distribution of such  
10 product. The department shall not issue more than [two] ten  
11 cultivation and production facility licenses for the operation of  
12 such facilities at any one time.

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

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

19 6. In addition to an audit conducted in accordance with  
20 subsection 5 of this section, the director may inspect  
21 independently, or in cooperation with the state highway patrol or  
22 a local law enforcement agency, any hemp crop during the crop's  
23 growth phase and take a representative composite sample for field  
24 analysis. If a crop contains an average tetrahydrocannabinol  
25 (THC) concentration exceeding the lesser of:

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

27 (2) 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  
3 the director may detain, seize, or embargo the crop.

4 7. The department shall promulgate rules including, but not  
5 limited to:

6 (1) Application requirements for licensing, including  
7 requirements for the submission of fingerprints and the  
8 completion of a criminal background check;

9 (2) Security requirements for cultivation and production  
10 facility premises, including, at a minimum, lighting, physical  
11 security, video and alarm requirements;

12 (3) Rules relating to hemp monitoring systems as defined in  
13 this section;

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

18 (5) Requirements that any hemp extract received from a  
19 legal source be submitted to a testing facility designated by the  
20 department to ensure that such hemp extract complies with the  
21 provisions of section 195.207 and to ensure that the hemp extract  
22 does not contain any pesticides. Any hemp extract that is not  
23 submitted for testing or which after testing is found not to  
24 comply with the provisions of section 195.207 shall not be  
25 distributed or used and shall be submitted to the department for  
26 destruction; and

27 (6) Rules regarding the manufacture, storage, and  
28 transportation of hemp and hemp extract, which shall be in

1 addition to any other state or federal regulations.

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

13 9. All hemp waste from the production of hemp extract shall  
14 either be destroyed, recycled by the licensee at the hemp  
15 cultivation and production facility, or donated to the department  
16 or an institution of higher education for research purposes, and  
17 shall not be used for commercial purposes.

18 10. In addition to any other liability or penalty provided  
19 by law, the director may revoke or refuse to issue or renew a  
20 cultivation and production facility license and may impose a  
21 civil penalty on a grower for any violation of this section, or  
22 section 192.945 or 195.207. The director may not impose a civil  
23 penalty under this section that exceeds two thousand five hundred  
24 dollars.