

House _____ Amendment NO. _____

Offered By _____

1 AMEND House Committee Substitute for Senate Committee Substitute for Senate Bill No. 718,
2 Page 1, Section A, Line 2, by inserting after all of said section and line the following:

3
4 "192.945. 1. As used in this section, the following terms shall mean:

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

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

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

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

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

12 (6) "Parent", a parent or legal guardian of a minor who is responsible for the minor's
13 medical care;

14 (7) "Physician", any person currently licensed to practice medicine under chapter 334;

15 [(7)] (8) "Registrant", an individual to whom the department issues a hemp extract
16 registration card under this section;

17 (9) "Serious condition":

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

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

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

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

28 (2) Is a Missouri resident;

29 (3) Provides the department with a [statement] recommendation signed by a neurologist or
30 physician that:

31 (a) Indicates that the individual suffers from intractable epilepsy or a serious condition and
32 may benefit from treatment with hemp extract; and

33 (b) Is consistent with a record from the neurologist or physician concerning the individual
34 contained in the database described in subsection [9] 10 of this section;

35 (c) Indicates the physician or neurologist by training or experience is qualified to treat the
36 serious condition;

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1 (d) States that the individual is under the physician or neurologist's continuing care for the
 2 serious condition or intractable epilepsy; and

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

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

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

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

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

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

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

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

15 (2) Is a Missouri resident;

16 (3) Provides the department with a ~~[statement]~~ recommendation signed by a neurologist or
 17 physician that:

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

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

22 (c) The physician or neurologist by training or experience is qualified to treat the serious
 23 condition;

24 (d) The minor is under the physician or neurologist's continuing care for the serious
 25 condition; and

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

28 (4) Pays the department a fee in an amount established by the department under subsection
 29 6 of this section; and

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

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

33 (b) The minor's name;

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

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

37 4. The department shall maintain a record of the name of each registrant and the name of
 38 each minor receiving care from a registrant.

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

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

45 (2) Regulate the distribution of hemp extract from a cannabidiol oil care center to a
 46 registrant, which shall be in addition to any other state or federal regulations~~[-and~~

47
 48 ~~The department may promulgate rules to authorize clinical trials involving hemp extract].~~

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

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

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

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

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

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

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

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

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

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

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

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

3. This section shall not be construed to limit the rights provided under law for a patient to bring a civil action for damages against a physician, hospital, registered or licensed practical nurse, pharmacist, any other individual or entity providing health care services, or an employee of any entity listed in this subsection.

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

- (1) Is composed of no more than three-tenths percent tetrahydrocannabinol by weight;
- (2) Is composed of at least five percent cannabidiol by weight; and
- (3) Contains no other psychoactive substance.

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

- (1) Possesses or uses the hemp extract only to treat intractable epilepsy or a serious condition as defined in section 192.945;
- (2) Originally obtained the hemp extract from a sealed container with a label indicating the hemp extract's place of origin and a number that corresponds with a certificate of analysis;
- (3) Possesses, in close proximity to the hemp extract, a certificate of analysis that:
 - (a) Has a number that corresponds with the number on the label described in subdivision (2) of this subsection;
 - (b) Indicates the hemp extract's ingredients including its percentages of tetrahydrocannabinol and cannabidiol by weight;
 - (c) Is created by a laboratory that is not affiliated with the producer of the hemp extract and is licensed in the state where the hemp extract was produced; and
 - (d) Is transmitted by the laboratory to the department of health and senior services; and
- (4) Has a current hemp extract registration card issued by the department of health and senior services under section 192.945;
- (5) Possesses a form of hemp extract that is in compliance with any recommendation or limitation by the physician or neurologist as stated in the recommendation provided to the department.

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

- (1) The individual is the minor's parent or legal guardian; and
- (2) The individual is registered with the department of health and senior services as the minor's parent under section 192.945.

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

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

- (1) "Cannabidiol oil care center", the premises specified in an application for a cultivation and production facility license in which the licensee is authorized to distribute processed hemp extract to persons possessing a hemp extract registration card issued under section 192.945;
- (2) "Cultivation and production facility", the land and premises specified in an application for a cultivation and production facility license on which the licensee is authorized to grow, cultivate, process, and possess hemp and hemp extract;

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

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

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

(6) "Hemp":

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

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

b. The percent based on a dry weight basis determined by the federal Controlled Substances Act under 21 U.S.C. Section 801, et seq.;

(b) Any cannabis sativa seed that is:

a. Part of a growing crop;

b. Retained by a grower for future planting; or

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

This term shall not include industrial hemp commodities or products;

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

2. The department shall issue a cultivation and production facility license to a nonprofit entity to grow or cultivate the cannabis plant used to make hemp extract as defined in subsection 1 of section 195.207 or hemp on the entity's property if the entity has had its domicile in the state for at least five years, has submitted to the department an application as required by the department under subsection 7 of this section, the entity meets all requirements of this section and the department's rules, and there are fewer than ~~two~~ the maximum number of licensed cultivation and production facilities operating in the state as provided under subsection 3 of this section. Any cultivation and production facility license issued before August 28, 2018, shall continue to be valid even if the licensed entity does not meet the domicile requirement under this subsection.

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

(1) Two cultivation and production facility licenses for the operation of such facilities at any one time in the year 2018;

(2) Five cultivation and production facility licenses for the operation of such facilities at any one time in the year 2019;

(3) Eight cultivation and production facility licenses for the operation of such facilities at any one time in the year 2020;

(4) Ten cultivation and production facility licenses for the operation of such facilities at any one time in the year 2021 and every year thereafter.

4. The department shall maintain a list of growers.

5. All growers shall keep records in accordance with rules adopted by the department.

Upon at least three days' notice, the director of the department may audit the required records during

1 normal business hours. The director may conduct an audit for the purpose of ensuring compliance
2 with this section.

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

- 8 (1) Three-tenths of one percent on a dry weight basis; or
9 (2) The percent based on a dry weight basis determined by the federal Controlled
10 Substances Act under 21 U.S.C. Section 801, et seq.,

11
12 the director may detain, seize, or embargo the crop.

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

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

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

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

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

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

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

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

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

40 10. In addition to any other liability or penalty provided by law, the director may revoke or
41 refuse to issue or renew a cultivation and production facility license and may impose a civil penalty
42 on a grower for any violation of this section, or section 192.945 or 195.207. The director may not
43 impose a civil penalty under this section that exceeds two thousand five hundred dollars."; and

44
45 Further amend said bill by amending the title, enacting clause, and intersectional references
46 accordingly.