

House _____ Amendment NO. _____

Offered By _____

1 AMEND House Committee Substitute for Senate Committee Substitute for Senate Bill No. 139,
2 Page 1, Section A, Line 3, 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)] (5) "Parent", a parent or legal guardian of a minor who is responsible for the minor's~~
13 ~~medical care;~~

14 ~~(6) "Physician", a person who is a physician licensed by the state board of registration for~~
15 ~~the healing arts and practicing within this state and, by training or experience, is qualified to~~
16 ~~diagnose and treat a serious condition;~~

17 (7) "Registrant", an individual to whom the department issues a hemp extract registration
18 card under this section;

19 (8) "Seizure disorders", epilepsy or nonepileptic seizures that are triggered by other physical
20 or psychological disorders and conditions;

21 (9) "Serious condition":

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

27 (b) Any of the following conditions clinically associated with, or a complication of, a
28 condition under this subdivision or its treatment: cachexia or wasting syndrome, severe or chronic
29 pain, severe nausea, seizures, severe or persistent muscle spasms.

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

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

32 (2) Is a Missouri resident;

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

35 (a) Indicates that the individual suffers from ~~[intractable epilepsy]~~ a serious condition or
36 seizure disorder and may benefit from treatment with hemp extract; and

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

(c) Indicates the neurologist or physician, by training or experience, is qualified to treat the serious condition or seizure disorder; and

(d) States that the individual is under the neurologist's or physician's continuing care for the serious condition or seizure disorder;

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

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

(a) The individual's name and address;

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

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

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

(1) Is eighteen years of age or older;

(2) Is a Missouri resident;

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

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

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

(c) The neurologist or physician, by training or experience, is qualified to treat the serious condition or seizure disorder; and

(d) The minor is under the neurologist's or physician's continuing care for the serious condition or seizure disorder;

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

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

(a) The parent's name and address;

(b) The minor's name;

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

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

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

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

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

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

1 the cost the department incurs to implement the provisions of this section.

2 7. The registration cards issued under this section shall be valid for one year and renewable
3 if at the time of renewal the registrant meets the requirements of either subsection 2 or 3 of this
4 section.

5 8. Only the neurologist or physician may recommend hemp extract and sign the
6 recommendation described in subsection 2 or 3 of this section as part of the treatment plan of a
7 patient diagnosed with a serious condition or seizure disorder.

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

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

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

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

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

21 ~~[40-]~~ 11. The department may share the records described in subsection 9 of this section
22 with a higher education institution for the purpose of studying hemp extract.

23 ~~[44-]~~ 12. Any rule or portion of a rule, as that term is defined in section 536.010, that is
24 created under the authority delegated in this section shall become effective only if it complies with
25 and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This
26 section and chapter 536 are nonseverable and if any of the powers vested with the general assembly
27 pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are
28 subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or
29 adopted after July 14, 2014, shall be invalid and void.

30 192.947. 1. No individual or health care entity organized under the laws of this state shall
31 be subject to any adverse action by the state or any agency, board, or subdivision thereof, including
32 civil or criminal prosecution, denial of any right or privilege, the imposition of a civil or
33 administrative penalty or sanction, or disciplinary action by any accreditation or licensing board or
34 commission if such individual or health care entity, in its normal course of business and within its
35 applicable licenses and regulations, acts in good faith upon or in furtherance of any order or
36 recommendation by a neurologist or physician authorized under section 192.945 relating to the
37 medical use and administration of hemp extract with respect to an eligible patient.

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

41 ~~[3- This section shall not be construed to limit the rights provided under law for a patient to~~
42 ~~bring a civil action for damages against a physician, hospital, registered or licensed practical nurse,~~
43 ~~pharmacist, any other individual or entity providing health care services, or an employee of any~~
44 ~~entity listed in this subsection.]~~

45 195.207. 1. As used in sections 192.945, 261.265, 261.267, and this section, the term
46 "hemp extract" shall mean an extract from a cannabis plant or a mixture or preparation containing
47 cannabis plant material that:

48 (1) Is composed of no more than ~~[three-tenths]~~ nine-tenths percent tetrahydrocannabinol by

weight;

(2) Is composed of at least ~~[five]~~ one and one-half 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]~~ a serious condition or seizure disorder 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.

3. Notwithstanding any other provision of this chapter or chapter 579, an individual who possesses hemp extract lawfully under subsection [2] 1 of this section and administers hemp extract to a minor suffering from ~~[intractable epilepsy]~~ a serious condition or seizure disorder 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 neurologist or 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."; and

Further amend said bill, Page 6, Section 208.798, Line 2, by inserting after all of said section and line the following:

"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) "Entity", a person, corporation, nonprofit corporation, limited liability corporation, general or limited partnership, or other legal entity;

(6) "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]~~ a serious condition or seizure disorder as such terms are defined under section 192.945;

~~[(6)]~~ (7) "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]~~ Nine-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)]~~ (8) "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]~~ an 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 been a resident of the state for at least five years, has completed a state and federal fingerprint-based criminal record check in accordance with section 43.543 and has paid all applicable criminal background check fees in accordance with section 43.530, 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]~~ ten licensed cultivation and production facilities operating in the state. Any cultivation and production facility license issued before August 28, 2017, shall continue to be valid even if the licensed entity does not meet the residency requirement under this subsection, and the licensed entity may implement the new provisions defined in this section upon its enactment.

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]~~ a serious condition or seizure disorder, 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 ~~[two]~~ five cultivation and production facility licenses for the operation of such facilities at any one time in 2018, and not more than ten cultivation and production facility licenses for the operation of such facilities at any one time in 2019.

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

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

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

- (1) ~~Three-tenths~~ Nine-tenths of one percent on a dry weight basis; or
 - (2) The percent based on a dry weight basis determined by the federal Controlled Substances Act under 21 U.S.C. Section 801, et seq.,
- the director may detain, seize, or embargo the crop.

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

- (1) Application requirements for licensing, including requirements for the submission of fingerprints and the completion of a criminal background check;
- (2) Security requirements for cultivation and production facility premises, including, at a minimum, lighting, physical security, video and alarm requirements;
- (3) Rules relating to hemp monitoring systems as defined in this section;
- (4) Other procedures for internal control as deemed necessary by the department to properly administer and enforce the provisions of this section, including reporting requirements for changes, alterations, or modifications of the premises;
- (5) Requirements that any hemp extract received from a legal source be submitted to a testing facility designated by the department to ensure that such hemp extract complies with the provisions of section 195.207 and to ensure that the hemp extract does not contain any pesticides. Any hemp extract that is not submitted for testing or which after testing is found not to comply with the provisions of section 195.207 shall not be distributed or used and shall be submitted to the department for destruction; and
- (6) Rules regarding the manufacture, storage, and transportation of hemp and hemp extract, which shall be in addition to any other state or federal regulations.

8. 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 under 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.

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

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

11. 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."; and

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