

SENATE AMENDMENT NO. _____

Offered by _____ of _____

Amend _____ House _____ Bill No. 1568, Page 1, Section title, Line 3,

2 of the title, by striking "dispensing opioid antagonist drugs"
 3 and inserting in lieu thereof the following: "products for the
 4 treatment of health conditions"; and

5 Further amend said bill and page, Section A, Line 2, by
 6 inserting after all of said line the following:

7 "192.945. 1. As used in this section, the following terms
 8 shall mean:

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

11 (2) "Hemp extract", as such term is defined in section
 12 195.207;

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

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

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

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

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

5 [(7)] (8) "Registrant", an individual to whom the
6 department issues a hemp extract registration card under this
7 section;

8 (9) "Serious condition":

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

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

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

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

24 (2) Is a Missouri resident;

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

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

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

4 (c) Indicates the physician or neurologist by training or
5 experience is qualified to treat the serious condition; and

6 (d) States that the individual is under the physician or
7 neurologist's continuing care for the serious condition or
8 intractable epilepsy;

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

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

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

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

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

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

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

21 (2) Is a Missouri resident;

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

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

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

1 (c) The physician or neurologist by training or experience
2 is qualified to treat the serious condition; and

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

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

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

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

10 (b) The minor's name;

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

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

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

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

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

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

28
29 The department may promulgate rules to authorize clinical trials

1 involving hemp extract].

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

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

9 8. Only a neurologist or physician may recommend hemp
10 extract and sign the recommendation described in subsection 2 or
11 3 of this section as part of the treatment plan of a patient
12 diagnosed with intractable epilepsy or a serious condition.

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

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

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

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

27 [9.] 10. The department shall maintain a database of the
28 records described in subsection [8] 9 of this section and treat
29 the records as identifiable health data.

1 [10.] 11. The department may share the records described in
2 subsection [9] 10 of this section with a higher education
3 institution for the purpose of studying hemp extract.

4 [11.] 12. The department shall establish a public registry
5 of physicians and neurologists who recommend hemp extract. A
6 physician or neurologist recommending hemp extract shall be
7 included on the registry by submitting an application to the
8 department stating that the physician or neurologist's license
9 from the state board of registration for the healing arts is
10 active, unrestricted, and in good standing. The application
11 shall also include the physician or neurologist's full name,
12 Social Security number, office name, address, phone number,
13 current email address, his or her state board of registration for
14 the healing arts license number, and area of practice.

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

26 192.947. 1. No individual or health care entity organized
27 under the laws of this state shall be subject to any adverse
28 action by the state or any agency, board, or subdivision thereof,
29 including civil or criminal prosecution, denial of any right or

1 privilege, the imposition of a civil or administrative penalty or
2 sanction, or disciplinary action by any accreditation or
3 licensing board or commission if such individual or health care
4 entity, in its normal course of business and within its
5 applicable licenses and regulations, acts in good faith upon or
6 in furtherance of any order or recommendation by a neurologist or
7 physician authorized under section 192.945 relating to the
8 medical use and administration of hemp extract with respect to an
9 eligible patient.

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

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

21 Further amend said bill, Page 2, Section 195.206, Line 26,
22 by inserting after all of said line the following:

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

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

29 (2) Is composed of at least five percent cannabidiol by

1 weight; and

2 (3) Contains no other psychoactive substance.

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

9 (1) Possesses or uses the hemp extract only to treat
10 intractable epilepsy or a serious condition as defined in section
11 192.945;

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

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

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

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

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

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

27 (4) Has a current hemp extract registration card issued by
28 the department of health and senior services under section
29 192.945.

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

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

10 (2) The individual is registered with the department of
11 health and senior services as the minor's parent under section
12 192.945.

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

24 261.265. 1. For purposes of this section, the following
25 terms shall mean:

26 (1) "Cannabidiol oil care center", the premises specified
27 in an application for a cultivation and production facility
28 license in which the licensee is authorized to distribute
29 processed hemp extract to persons possessing a hemp extract

1 registration card issued under section 192.945;

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

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

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

11 (5) "Grower", a nonprofit entity issued a cultivation and
12 production facility license by the department of agriculture that
13 produces hemp extract for the treatment of intractable epilepsy
14 or a serious condition as such terms are defined under section
15 192.945;

16 (6) "Hemp":

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

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

22 b. The percent based on a dry weight basis determined by
23 the federal Controlled Substances Act under 21 U.S.C. Section
24 801, et seq.;

25 (b) Any cannabis sativa seed that is:

26 a. Part of a growing crop;

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

28 c. For processing into or use as agricultural hemp seed.
29

1 This term shall not include industrial hemp commodities or
2 products;

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

9 2. The department shall issue a cultivation and production
10 facility license to a nonprofit entity to grow or cultivate the
11 cannabis plant used to make hemp extract as defined in subsection
12 1 of section 195.207 or hemp on the entity's property if the
13 entity has been a resident of the state for at least five years,
14 has completed a state and federal fingerprint-based criminal
15 record check in accordance with section 43.543 and has paid all
16 applicable criminal background check fees in accordance with
17 section 43.530, has submitted to the department an application as
18 required by the department under subsection 7 of this section,
19 the entity meets all requirements of this section and the
20 department's rules, and there are fewer than [two] ten licensed
21 cultivation and production facilities operating in the state.
22 Any cultivation and production facility license issued before
23 August 28, 2016, shall continue to be valid as originally
24 licensed even if the licensed entity does not meet the residency
25 requirement under this subsection.

26 3. A grower may produce and manufacture hemp and hemp
27 extract, and distribute hemp extract as defined in section
28 195.207 for the treatment of persons suffering from intractable
29 epilepsy [as defined in section 192.945] or a serious condition,

1 consistent with any and all state or federal regulations
2 regarding the production, manufacture, or distribution of such
3 product. The department shall not issue more than ~~two~~ ten
4 cultivation and production facility licenses for the operation of
5 such facilities at any one time.

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

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

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

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

20 (2) The percent based on a dry weight basis determined by
21 the federal Controlled Substances Act under 21 U.S.C. Section
22 801, et seq.,

23
24 the director may detain, seize, or embargo the crop.

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

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

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

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

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

10 (5) Requirements that any hemp extract received from a
11 legal source be submitted to a testing facility designated by the
12 department to ensure that such hemp extract complies with the
13 provisions of section 195.207 and to ensure that the hemp extract
14 does not contain any pesticides. Any hemp extract that is not
15 submitted for testing or which after testing is found not to
16 comply with the provisions of section 195.207 shall not be
17 distributed or used and shall be submitted to the department for
18 destruction; [and]

19 (6) Rules regarding the manufacture, storage, and
20 transportation of hemp and hemp extract, which shall be in
21 addition to any other state or federal regulations; and

22 (7) Rules establishing fees that are no greater than the
23 amount necessary to cover the cost the department incurs to
24 administer the provisions of this section.

25 8. Any rule or portion of a rule, as that term is defined
26 in section 536.010, that is created under the authority delegated
27 in this section shall become effective only if it complies with
28 and is subject to all of the provisions of chapter 536 and, if
29 applicable, section 536.028. This section and chapter 536 are

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

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

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

19 Further amend the title and enacting clause accordingly.