

FIRST REGULAR SESSION

SENATE BILL NO. 371

99TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SCHAAF.

Read 1st time January 31, 2017, and ordered printed.

ADRIANE D. CROUSE, Secretary.

1746S.011

AN ACT

To repeal sections 192.945, 192.947, 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:

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2 repealed and four new sections enacted in lieu thereof, to be known as sections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

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

- 2 (1) "Department", the department of health and senior services;
- 3 (2) "Hemp extract", as such term is defined in section 195.207;
- 4 (3) "Hemp extract registration card", a card issued by the department
5 under this section;
- 6 (4) ["Intractable epilepsy", epilepsy that as determined by a neurologist
7 does not respond to three or more treatment options overseen by the neurologist;
- 8 (5)] "Neurologist", a physician who is licensed under chapter 334 and
9 board certified in neurology;
- 10 [(6)] **(5)** "Parent", a parent or legal guardian of a minor who is
11 responsible for the minor's medical care;
- 12 **(6) "Physician", a person who is a physician licensed by the state
13 board of registration for the healing arts and practicing within this
14 state and, by training or experience, is qualified to diagnose and treat
15 a serious condition;**
- 16 (7) "Registrant", an individual to whom the department issues a hemp
17 extract registration card under this section;
- 18 **(8) "Seizure disorders", epilepsy or nonepileptic seizures which**

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

19 are triggered by other physical or psychological disorders and
20 conditions;

21 (9) "Serious condition":

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

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

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

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

36 (2) Is a Missouri resident;

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

39 (a) Indicates that the individual suffers from [intractable epilepsy] a
40 **serious condition or seizure disorder** and may benefit from treatment with
41 hemp extract; and

42 (b) Is consistent with a record from the neurologist **or physician**
43 concerning the individual contained in the database described in subsection 9 of
44 this section;

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

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

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

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

55 (a) The individual's name and address;
56 (b) A copy of the individual's valid photo identification; and
57 (c) Any other information the department considers necessary to
58 implement the provisions of this section.

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

61 (1) Is eighteen years of age or older;
62 (2) Is a Missouri resident;
63 (3) Provides the department with a [statement] **recommendation** signed
64 by a neurologist **or physician** that:

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

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

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

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

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

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

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

80 (b) The minor's name;

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

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

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

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

88 (1) Implement the provisions of this section including establishing the
89 information the applicant is required to provide to the department and
90 establishing in accordance with recommendations from the department of public

91 safety the form and content of the hemp extract registration card; and

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

95 The department may promulgate rules to authorize clinical trials involving hemp
96 extract].

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

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

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

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

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

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

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

119 [9.] 10. The department shall maintain a database of the records
120 described in subsection [8] 9 of this section and treat the records as identifiable
121 health data.

122 [10.] 11. The department may share the records described in subsection
123 [9] 10 of this section with a higher education institution for the purpose of
124 studying hemp extract.

125 [11.] 12. Any rule or portion of a rule, as that term is defined in section
126 536.010, that is created under the authority delegated in this section shall

127 become effective only if it complies with and is subject to all of the provisions of
128 chapter 536 and, if applicable, section 536.028. This section and chapter 536 are
129 nonseverable and if any of the powers vested with the general assembly pursuant
130 to chapter 536 to review, to delay the effective date, or to disapprove and annul
131 a rule are subsequently held unconstitutional, then the grant of rulemaking
132 authority and any rule proposed or adopted after July 14, 2014, shall be invalid
133 and void.

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

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

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

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

4 (1) Is composed of no more than [three-tenths] **nine-tenths** percent
5 tetrahydrocannabinol by weight;

6 (2) Is composed of at least [five] **one and one half** percent cannabidiol
7 by weight; and

8 (3) Contains no other psychoactive substance.

9 2. Notwithstanding any other provision of this chapter **or chapter 579**,
10 an individual who has been issued a valid hemp extract registration card under

11 section 192.945, or is a minor under a registrant's care, and possesses or uses
12 hemp extract is not subject to the penalties described in this chapter **or chapter**
13 **579** for possession or use of the hemp extract if the individual:

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

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

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

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

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

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

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

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

32 3. Notwithstanding any other provision of this chapter **or chapter 579**,
33 an individual who possesses hemp extract lawfully under subsection [2] 1 of this
34 section and administers hemp extract to a minor suffering from [intractable
35 epilepsy] **a serious condition or seizure disorder** is not subject to the
36 penalties described in this chapter **or chapter 579** for administering the hemp
37 extract to the minor if:

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

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

41 4. An individual who has [been issued] a valid hemp extract registration
42 card under section 192.945, or is a minor under a registrant's care, may possess
43 up to twenty ounces of hemp extract pursuant to this section. Subject to any
44 rules or regulations promulgated by the department of health and senior services,
45 an individual may apply for a waiver if a **neurologist or** physician provides a
46 substantial medical basis in a signed, written statement asserting that, based on

47 the patient's medical history, in the physician's professional judgment, twenty
48 ounces is an insufficient amount to properly alleviate the patient's medical
49 condition or symptoms associated with such medical condition.

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

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

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

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

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

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

18 (6) "Hemp":

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

22 a. [Three-tenths] **Nine-tenths** of one percent on a dry weight basis; or
23 b. The percent based on a dry weight basis determined by the federal
24 Controlled Substances Act under 21 U.S.C. Section 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 This term shall not include industrial hemp commodities or products;

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

34 retail sale of the hemp extract.

35 2. The department shall issue a cultivation and production facility license
36 to a nonprofit entity to grow or cultivate the cannabis plant used to make hemp
37 extract as defined in subsection 1 of section 195.207 or hemp on the entity's
38 property if the entity **has been a resident of the state for at least five**
39 **years, has completed a state and federal fingerprint-based criminal**
40 **record check in accordance with section 43.543 and has paid all**
41 **applicable criminal background check fees in accordance with section**
42 **43.530**, has submitted to the department an application as required by the
43 department under subsection 7 of this section, the entity meets all requirements
44 of this section and the department's rules, and there are fewer than [two] **ten**
45 licensed cultivation and production facilities operating in the state. **Any**
46 **cultivation and production facility license issued before August 28,**
47 **2017, shall continue to be valid even if the licensed entity does not meet**
48 **the residency requirement under this subsection, and the licensed**
49 **entity may implement the new provisions defined in this section upon**
50 **its enactment.**

51 3. A grower may produce and manufacture hemp and hemp extract, and
52 distribute hemp extract as defined in section 195.207 for the treatment of persons
53 suffering from [intractable epilepsy as defined in section 192.945] **a serious**
54 **condition or seizure disorder**, consistent with any and all state [or federal]
55 regulations regarding the production, manufacture, or distribution of such
56 product. The department shall not issue more than [two] **ten** cultivation and
57 production facility licenses for the operation of such facilities at any one time.

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

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

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

69 (1) [Three-tenths] **Nine-tenths** of one percent on a dry weight basis; or

70 (2) The percent based on a dry weight basis determined by the federal
71 Controlled Substances Act under 21 U.S.C. Section 801, et seq.,
72 the director may detain, seize, or embargo the crop.

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

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

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

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

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

84 (5) Requirements that any hemp extract received from a legal source be
85 submitted to a testing facility designated by the department to ensure that such
86 hemp extract complies with the provisions of section 195.207 and to ensure that
87 the hemp extract does not contain any pesticides. Any hemp extract that is not
88 submitted for testing or which after testing is found not to comply with the
89 provisions of section 195.207 shall not be distributed or used and shall be
90 submitted to the department for destruction; and

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

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

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

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

111 **11. The department shall establish fees that are no greater than**
112 **the amount necessary to cover the cost the department incurs to**
113 **implement the provisions of this section.**

✓
Unofficial

Bill

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