

FIRST REGULAR SESSION

[P E R F E C T E D]

SENATE SUBSTITUTE NO. 2 FOR

SENATE BILL NO. 386

98TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR KEAVENY.

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ADRIANE D. CROUSE, Secretary.

0274S.10P

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.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 192.945, 195.207, and 261.265, RSMo, are repealed
2 and four new sections enacted in lieu thereof, to be known as sections 192.945,
3 192.947, 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 board
9 certified in neurology;
- 10 (6) "Parent", a parent or legal guardian of a minor who is responsible for
11 the minor's medical care;
- 12 (7) "Practitioner", a practitioner who is a physician licensed by
13 the state board of registration for the healing arts and practicing
14 within this state and, by training or experience, is qualified to treat a

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

15 **serious condition;**

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

18 (9) "Serious condition":

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

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

29 2. The department shall issue a hemp extract registration card to an
30 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
34 by a neurologist **or practitioner** that:

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

37 (b) Is consistent with a record from the neurologist **or practitioner**
38 concerning the individual contained in the database described in subsection [9]
39 **10** of this section;

40 (c) **Indicates the practitioner or neurologist by training or**
41 **experience is qualified to treat the serious condition;**

42 (d) **States that the individual is under the practitioner or**
43 **neurologist's continuing care for the serious condition or intractable**
44 **epilepsy; and**

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

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

50 (5) Submits an application to the department on a form created by the

51 department that contains:

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

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

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

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

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

59 (2) Is a Missouri resident;

60 (3) Provides the department with a [statement] **recommendation** signed
61 by a neurologist **or practitioner** that:

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

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

68 (c) **The practitioner or neurologist by training or experience is**
69 **qualified to treat the serious condition;**

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

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

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. **The practitioner or**
103 **neurologist may state in the recommendation provided to the**
104 **department that, in the practitioner or neurologist's professional**
105 **opinion, the patient would benefit from hemp extract only until a**
106 **specified earlier date and the registration card shall expire on the date**
107 **provided in the recommendation.**

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

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

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

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

119 (3) **Notify the patient, or the patient's parent or guardian if the**
120 **patient is a minor, prior to providing a recommendation, that hemp**
121 **extract has not been approved by the Federal Drug Administration and**
122 **by using such treatment the patient or parent is accepting the risks**

123 **involved in using an unapproved product.**

124 [9.] **10.** The department shall maintain a database of the records
125 described in subsection [8] **9** of this section and treat the records as identifiable
126 health data.

127 [10.] **11.** The department may share the records described in subsection
128 **[9] 10** of this section with a higher education institution for the purpose of
129 studying hemp extract.

130 [11.] **12.** Any rule or portion of a rule, as that term is defined in section
131 536.010, that is created under the authority delegated in this section shall
132 become effective only if it complies with and is subject to all of the provisions of
133 chapter 536 and, if applicable, section 536.028. This section and chapter 536 are
134 nonseverable and if any of the powers vested with the general assembly pursuant
135 to chapter 536 to review, to delay the effective date, or to disapprove and annul
136 a rule are subsequently held unconstitutional, then the grant of rulemaking
137 authority and any rule proposed or adopted after July 14, 2014, shall be invalid
138 and void.

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

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

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 percent

5 tetrahydrocannabinol by weight;

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

7 (3) Contains no other psychoactive substance.

8 2. Notwithstanding any other provision of this chapter **or chapter 579**,
9 an individual who has been issued a valid hemp extract registration card under
10 section 192.945, or is a minor under a registrant's care, and possesses or uses
11 hemp extract is 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 intractable epilepsy
14 **or a serious condition** as defined in section 192.945;

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

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

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

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

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

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

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

31 **(5) Possesses a form of hemp extract that is in compliance with**
32 **any recommendation or limitation by the practitioner or neurologist as**
33 **stated in the recommendation provided to the department.**

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

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

40 (2) The individual is registered with the department of health and senior

41 services as the minor's parent under section 192.945.

42 4. An individual who has [been issued] a valid hemp extract registration
43 card under section 192.945, or is a minor under a registrant's care, may possess
44 up to twenty ounces of hemp extract pursuant to this section. Subject to any
45 rules or regulations promulgated by the department of health and senior services,
46 an individual may apply for a waiver if a physician provides a substantial
47 medical basis in a signed, written statement asserting that, based on the patient's
48 medical history, in the physician's professional judgment, twenty ounces is an
49 insufficient amount to properly alleviate the patient's medical condition or
50 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 **or a serious condition as such terms are**
17 **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 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 had its domicile in the state for at least five**
39 **years**, has submitted to the department an application as required by the
40 department under subsection 7 of this section, the entity meets all requirements
41 of this section and the department's rules, and there are fewer than [two] **the**
42 **maximum number of** licensed cultivation and production facilities operating
43 in the state **as provided under subsection 3 of this section. Any**
44 **cultivation and production facility license issued before August 28,**
45 **2015, shall continue to be valid even if the licensed entity does not meet**
46 **the domicile requirement under this subsection.**

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

53 (1) Two cultivation and production facility licenses for the operation of
54 such facilities at any one time **in the year 2015;**

55 (2) **Five cultivation and production facility licenses for the**
56 **operation of such facilities at any one time in the year 2016;**

57 (3) **Eight cultivation and production facility licenses for the**
58 **operation of such facilities at any one time in the year 2017;**

59 (4) **Ten cultivation and production facility licenses for the**
60 **operation of such facilities at any one time in the year 2018 and every**
61 **year thereafter.**

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

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

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

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

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

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

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

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

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

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

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

98 8. Any rule or portion of a rule, as that term is defined in section 536.010,

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

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

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

✓
Bill

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