

SECOND REGULAR SESSION

SENATE BILL NO. 822

98TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR KEAVENY.

Pre-filed December 17, 2015, and ordered printed.

ADRIANE D. CROUSE, Secretary.

4385S.02I

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Section A. Sections 192.945, 195.207, and 261.265, RSMo, are repealed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) **"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)] (8) "Registrant", an individual to whom the department issues a
17 hemp extract registration card under this section;
- 18 (9) **"Serious condition":**

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

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 subdivision 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**
34 **signed by a neurologist or physician 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 physician**
38 **concerning the individual contained in the database described in subsection 9 of**
39 **this section;**

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

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

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

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

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

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

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

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

55 (1) Is eighteen years of age or older;
56 (2) Is a Missouri resident;
57 (3) Provides the department with a [statement] **recommendation**
58 signed by a neurologist **or physician** that:

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

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

65 (c) **The physician or neurologist by training or experience is**
66 **qualified to treat the serious condition; and**

67 (d) **The minor is under the physician or neurologist's continuing**
68 **care for the serious condition;**

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

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

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

74 (b) The minor's name;

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

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

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

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

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

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

89 The department may promulgate rules to authorize clinical trials involving hemp
90 extract].

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

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

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

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

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

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

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

113 [9.] 10. The department shall maintain a database of the records
114 described in subsection [8] 9 of this section and treat the records as identifiable
115 health data.

116 [10.] 11. The department may share the records described in subsection
117 [9] 10 of this section with a higher education institution for the purpose of
118 studying hemp extract.

119 [11.] 12. **The department shall establish a public registry of**
120 **physicians and neurologists who recommend hemp extract. A physician**
121 **or neurologist recommending hemp extract shall be included on the**
122 **registry by submitting an application to the department stating that the**
123 **physician or neurologist's license from the state board of registration**
124 **for the healing arts is active, unrestricted, and in good standing. The**
125 **application shall also include the physician or neurologist's full name,**
126 **Social Security number, office name, address, phone number, current**

127 **email address, his or her state board of registration for the healing arts**
128 **license number, and area of practice.**

129 **13.** Any rule or portion of a rule, as that term is defined in section
130 536.010, that is created under the authority delegated in this section shall
131 become effective only if it complies with and is subject to all of the provisions of
132 chapter 536 and, if applicable, section 536.028. This section and chapter 536 are
133 nonseverable and if any of the powers vested with the general assembly pursuant
134 to chapter 536 to review, to delay the effective date, or to disapprove and annul
135 a rule are subsequently held unconstitutional, then the grant of rulemaking
136 authority and any rule proposed or adopted after July 14, 2014, shall be invalid
137 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 or recommendation by a neurologist or**
10 **physician authorized under section 192.945 relating to the medical use**
11 **and administration of hemp extract with respect to an eligible patient.**

12 **2.** The provisions of subsection 1 of this section shall apply to the
13 **recommendation, possession, handling, storage, transfer, destruction,**
14 **dispensing, or administration of hemp extract, including any act in**
15 **preparation of 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 3. Notwithstanding any other provision of this chapter **or chapter 579**,
32 an individual who possesses hemp extract lawfully under subsection 2 of this
33 section and administers hemp extract to a minor suffering from intractable
34 epilepsy **or a serious condition** is not subject to the penalties described in this
35 chapter **or chapter 579** for administering the hemp extract to the minor if:

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

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

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

47 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 been a resident of 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] **ten**
42 licensed cultivation and production facilities operating in the state. **Any**
43 **cultivation and production facility license issued before August 28,**
44 **2016, shall continue to be valid as originally licensed even if the**
45 **licensed entity does not meet the residency requirement under this**
46 **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 [two] **ten** cultivation and production facility licenses for the
53 operation of such facilities at any one time.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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