

SECOND REGULAR SESSION

HOUSE BILL NO. 1441

99TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE BARINGER.

5208H.011

D. ADAM CRUMBLISS, Chief Clerk

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Section A. Sections 192.945, 192.947, 195.207, and 261.265, RSMo, are repealed and four new sections enacted in lieu thereof, to be known as sections 192.945, 192.947, 195.207, and 261.265, to read as follows: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

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

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

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

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

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

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

(5) "Physician", any person currently licensed to practice medicine under chapter 334;

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

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

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

17 **(8) "Serious condition":**

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

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

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

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

28 (2) Is a Missouri resident;

29 (3) Provides the department with a **[statement] recommendation** signed by a
30 **[neurologist] physician** that:

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

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

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

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

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

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

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

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

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

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

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

49 (2) Is a Missouri resident;

50 (3) Provides the department with a **[statement] recommendation** signed by a
51 **[neurologist] physician** that:

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

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

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

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

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

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

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

65 (b) The minor's name;

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

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

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

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

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

77 (2) Regulate the distribution of hemp extract from a cannabidiol oil care center to a
78 registrant, which shall be in addition to any other state [~~or federal~~] regulations[~~; and~~
79 ~~The department may promulgate rules to authorize clinical trials involving hemp extract~~].

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

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

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

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

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

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

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

99 ~~[9-]~~ **10.** The department shall maintain a database of the records described in subsection
100 ~~[8]~~ **9** of this section and treat the records as identifiable health data.

101 ~~[10-]~~ **11.** The department may share the records described in subsection ~~[9]~~ **10** of this
102 section with a higher education institution for the purpose of studying hemp extract.

103 ~~[11-]~~ **12.** Any rule or portion of a rule, as that term is defined in section 536.010, that
104 is created under the authority delegated in this section shall become effective only if it complies
105 with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028.
106 This section and chapter 536 are nonseverable and if any of the powers vested with the general
107 assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and
108 annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and
109 any rule proposed or adopted after July 14, 2014, shall be invalid and void.

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

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

12 3. ~~[This section shall not be construed to limit the rights provided under law for a patient~~
13 ~~to bring a civil action for damages against a physician, hospital, registered or licensed practical~~
14 ~~nurse, pharmacist, any other individual or entity providing health care services, or an employee~~

15 ~~of any entity listed in this subsection]~~ **Notwithstanding the provisions of section 538.210 or**
16 **any other law to the contrary, a physician licensed under chapter 334, or a hospital, who**
17 **provides medical treatment to any patient under section 192.945 shall not be liable for any**
18 **civil damages for acts or omissions unless the damages were occasioned by gross negligence**
19 **or willful or wanton acts or omissions by such physician, or hospital, in rendering such**
20 **treatment.**

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

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

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

7 (3) Contains no other psychoactive substance.

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

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

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

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

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

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

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

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

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

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

30 is not subject to the penalties described in this chapter **or chapter 579** for administering the
31 hemp extract to the minor if:

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

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

35 4. An individual who has ~~[been issued]~~ a valid hemp extract registration card under
36 section 192.945, or is a minor under a registrant's care, may possess up to twenty ounces of hemp
37 extract pursuant to this section. Subject to any rules or regulations promulgated by the
38 department of health and senior services, an individual may apply for a waiver if a physician
39 provides a substantial medical basis in a signed, written statement asserting that, based on the
40 patient's medical history, in the physician's professional judgment, twenty ounces is an
41 insufficient amount to properly alleviate the patient's medical condition or symptoms associated
42 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 for a
3 cultivation and production facility license in which the licensee is authorized to distribute
4 processed hemp extract to persons possessing a hemp extract registration card issued under
5 section 192.945;

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

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

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

13 (5) **"Entity", a person, corporation, nonprofit corporation, limited liability
14 corporation, general or limited partnership, or other legal entity;**

15 (6) "Grower", a nonprofit entity issued a cultivation and production facility license by
16 the department of agriculture that produces hemp extract for the treatment of ~~[intractable
17 epilepsy]~~ **a serious condition or seizure disorder as such terms are defined under section
18 192.945;**

19 ~~[(6)]~~ (7) "Hemp":

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

23 a. ~~[Three-tenths]~~ **Nine-tenths** of one percent on a dry weight basis; or

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

26 (b) Any *cannabis sativa* seed that is:

27 a. Part of a growing crop;

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

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

30 This term shall not include industrial hemp commodities or products;

31 ~~[(7)]~~ (8) "Hemp monitoring system", an electronic tracking system that includes, but is
32 not limited to, testing and data collection established and maintained by the cultivation and
33 production facility and is available to the department for the purposes of documenting the hemp
34 extract production and retail sale of the hemp extract.

35 2. The department shall issue a cultivation and production facility license to ~~[a nonprofit]~~
36 **an** entity to grow or cultivate the cannabis plant used to make hemp extract as defined in
37 subsection 1 of section 195.207 or hemp on the entity's property if the entity has submitted to the
38 department an application as required by the department under subsection 7 of this section, ~~[the~~
39 **entity]** meets all requirements of this section and the department's rules, and there are fewer than
40 ~~[two]~~ **ten** licensed cultivation and production facilities operating in the state. **Any cultivation**
41 **and production facility license issued before August 28, 2018, shall continue to be valid**
42 **even if the licensed entity does not meet the residency requirement under this subsection,**
43 **and the licensed entity may implement the new provisions defined in this section upon its**
44 **enactment.**

45 3. A grower may produce and manufacture hemp and hemp extract, and distribute hemp
46 extract as defined in section 195.207 for the treatment of persons suffering from ~~[intractable~~
47 **epilepsy as defined in section 192.945]** **a serious condition or seizure disorder**, consistent with
48 any and all state ~~[or federal]~~ regulations regarding the production, manufacture, or distribution
49 of such product. The department shall not issue more than ~~[two]~~ **five** cultivation and production
50 facility licenses for the operation of such facilities at any one time **in 2018, and not more than**
51 **ten cultivation and production facility licenses for the operation of such facilities at any one**
52 **time in 2019.**

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

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

58 6. In addition to an audit conducted in accordance with subsection 5 of this section, the
59 director may inspect independently, or in cooperation with the state highway patrol or a local law

60 enforcement agency, any hemp crop during the crop's growth phase and take a representative
61 composite sample for field analysis. If a crop contains an average tetrahydrocannabinol (THC)
62 concentration exceeding the lesser of:

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

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

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

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

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

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

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

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

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

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

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

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

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

✓