SECOND REGULAR SESSION

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 1554

99TH GENERAL ASSEMBLY

5285H.04C D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal sections 191.480, 192.945, 192.947, 195.207, 261.265, and 263.250, RSMo, and to enact in lieu thereof six new sections relating to the use of investigational drugs, with penalty provisions.

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

Section A. Sections 191.480, 192.945, 192.947, 195.207, 261.265, and 263.250, RSMo, are repealed and six new sections enacted in lieu thereof, to be known as sections 191.480, 192.945, 192.947, 195.207, 261.265, and 263.250, to read as follows:

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

(1) **"Dispensing organization", an entity licensed under chapter 261 to distribute medical cannabis;**

(2) "Eligible patient", a person who meets all of the following:

(a) Has a terminal illness;

(b) Has considered all other treatment options currently approved by the **[**~~United States~~**]** **federal** Food and Drug Administration and all relevant clinical trials conducted in this state;

(c) Has received a prescription or recommendation from the person's physician for an investigational drug, biological product, or device;

(d) Has given written informed consent which shall be at least as comprehensive as the consent used in clinical trials for the use of the investigational drug, biological product, or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written informed consent on the patient's behalf; and

(e) Has documentation from the person's physician that the person has met the requirements of this subdivision;

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.

[~~(2)~~**] (3)** "Investigational drug, biological product, or device", a drug, biological product, or device, any of which are used to treat the patient's terminal illness, that has successfully completed phase one of a clinical trial but has not been approved for general use by the **[**~~United States~~**] federal** Food and Drug Administration and remains under investigation in a clinical trial. The term shall not include Schedule I controlled substances **except for medical cannabis. The term shall include medical cannabis from a dispensing organization**;

[~~(3)~~**] (4)** "Terminal illness", a disease that without life-sustaining procedures will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

2. A **dispensing organization or** manufacturer of an investigational drug, biological product, or device may make available the **dispensing organization's or** manufacturer's investigational drug, biological product, or device to eligible patients under this section. This section does not require that a **dispensing organization or** manufacturer make available an investigational drug, biological product, or device to an eligible patient. A **dispensing organization or** manufacturer may:

(1) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation; or

(2) Require an eligible patient to pay the costs of or associated with the manufacture of the investigational drug, biological product, or device.

3. This section does not require a health care insurer to provide coverage for the cost of any investigational drug, biological product, or device. A health care insurer may provide coverage for an investigational drug, biological product, or device.

4. This section does not require the department of corrections to provide coverage for the cost of any investigational drug, biological product, or device.

5. Notwithstanding any other provision of law to the contrary, no state agency or regulatory board shall revoke, fail to renew, or take any other action against a physician's license issued under chapter 334 based solely on the physician's recommendation to an eligible patient regarding prescription for or treatment with an investigational drug, biological product, or device. Action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device is prohibited.

6. **[**~~If a provision of this section or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this section that can be given effect without the invalid provision or application, and to this end the provisions of this section are severable~~**] Notwithstanding any other provision of law to the contrary, no state agency or regulatory board shall revoke, fail to renew, or take any other action against a**

dispensing organization's license issued under chapter 261 based solely on the dispensing organization's sale of medical cannabis to an eligible patient under this section.

7. If the clinical trial is closed due to lack of efficacy or toxicity, the drug shall not be offered. If notice is given on a drug, product, or device taken by a patient outside of a clinical trial, the pharmaceutical company or patient's physician shall notify the patient of the information from the safety committee of the clinical trial.

8. Except in the case of gross negligence or willful misconduct, any person who manufactures, imports, distributes, prescribes, dispenses, or administers an investigational drug or device to an eligible patient with a terminal illness in accordance with this section shall not be liable in any action under state law for any loss, damage, or injury arising out of, relating to, or resulting from:

(1) The design, development, clinical testing and investigation, manufacturing, labeling, distribution, sale, purchase, donation, dispensing, prescription, administration, or use of the drug or device; or

(2) The safety or effectiveness of the drug or device.

9. Any official, employee, or agent of this state who blocks or attempts to block access of an eligible patient to an investigational drug, biological product, or device is guilty of a class A misdemeanor.

10. If any provision of this section or its application to any person or circumstance is held invalid, such determination shall not affect the provisions or applications of this section which may be given effect without the invalid provision or application, and to that end the provisions of this section are severable.

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) "Medical cannabis", as such term is defined in section 195.207;

(6) "Medical cannabis registration card", a card issued by the department under this section;

[~~(5)~~**] (7)** "Neurologist", a physician who is licensed under chapter 334 and board certified in neurology;

[~~(6)~~**] (8)** "Parent", a parent or legal guardian of a minor who is responsible for the minor's medical care;

[~~(7)~~**] (9)** "Registrant", an individual to whom the department issues a hemp extract **or medical cannabis** registration card under this section**;**

(10) "Terminal illness", a disease or condition as defined in section 191.480.

2. The department shall issue a hemp extract **or medical cannabis** registration card to an individual who:

(1) Is eighteen years of age or older;

(2) Is a Missouri resident;

(3) Provides the department with a statement signed by a neurologist **or physician** that:

(a) Indicates that the individual suffers from intractable epilepsy and may benefit from treatment with hemp extract **or that the individual suffers from a terminal illness and may benefit from treatment with medical cannabis at the same dosage and with the same method of smokeless administration used in a clinical trial**; **[**~~and~~**]**

(b) **Indicates that the individual has considered all other treatment options currently approved by the federal Food and Drug Administration and all relevant clinical trials conducted in this state; and**

(c) Is consistent with a record from the neurologist **or physician** concerning the individual contained in the database described in subsection **[**~~9~~**] 11** of this section;

(4) Pays the department a fee in an amount established by the department under subsection **[**~~6~~**] 8** of this section; and

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

(a) The individual's name and address;

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

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

3. The department shall issue a hemp extract **or medical cannabis** registration card to a parent who:

(1) Is eighteen years of age or older;

(2) Is a Missouri resident;

(3) Provides the department with a statement signed by a neurologist **or physician** that:

(a) Indicates that a minor in the parent's care suffers from intractable epilepsy and may benefit from treatment with hemp extract **or suffers from a terminal illness and may benefit from medical cannabis at the same dosage and with the same method of smokeless administration used in a clinical trial**; **[**~~and~~**]**

(b) **Indicates that the individual has considered all other treatment options currently approved by the federal Food and Drug Administration and all relevant clinical trials conducted in this state; and**

(c) Is consistent with a record from the neurologist **or physician** concerning the minor contained in the database described in subsection **[**~~9~~**] 11** of this section;

(4) Pays the department a fee in an amount established by the department under subsection **[**~~6~~**] 8** of this section; and

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

(a) The parent's name and address;

(b) The minor's name;

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

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

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

5. The department shall promulgate rules to:

(1) Implement the provisions of this section including establishing the information the applicant is required to provide to the department and establishing in accordance with recommendations from the department of public safety the form and content of the hemp extract **and medical cannabis** registration **[**~~card~~**] cards**; and

(2) Regulate the distribution of hemp extract from a cannabidiol oil care center **and medical cannabis from a cannabis care center, as defined in section 261.265,** to a registrant, which shall be in addition to any other state or federal regulations**[**~~; and~~**] .**

6. The department shall publish a list of diseases and conditions for which a medical cannabis registration card may be issued. The list shall only contain terminal illnesses as defined under section 191.480. The department shall publish a list of diseases and conditions for which a hemp extract registration card may be issued. The list shall only contain intractable epilepsy.

7. The department may promulgate rules to authorize clinical trials involving hemp extract **and medical cannabis**.

[~~6.~~**] 8.** The department shall establish fees that are no greater than the amount necessary to cover the cost the department incurs to implement the provisions of this section.

[~~7.~~**] 9.** The registration cards issued under this section shall be valid for one year and renewable if at the time of renewal the registrant meets the requirements of either subsection 2 or 3 of this section.

[~~8.~~] 10. The neurologist **or physician** who signs the statement described in subsection 2 or 3 of this section shall:

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

(2) Transmit the record described in subdivision (1) of this subsection to the department.

[~~9.~~] 11. The department shall maintain a database of the records described in subsection **[~~8~~] 10** of this section and treat the records as identifiable health data.

[~~10.~~] 12. The department may share the records described in subsection **[~~9~~] 11** of this section with a higher education institution for the purpose of studying hemp extract **or medical cannabis**.

[~~11.~~] 13. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and 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 shall be subject to any adverse action by the state or any agency, board, or subdivision thereof, including civil or criminal prosecution, denial of any right or privilege, the imposition of a civil or administrative penalty or sanction, or disciplinary action by any accreditation or licensing board or commission if such individual or health care entity, in its normal course of business and within its applicable licenses and regulations, acts in good faith upon or in furtherance of any order or recommendation by a neurologist **or physician** authorized under section 192.945 relating to the medical use and administration of hemp extract **or medical cannabis** with respect to an eligible patient.

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

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

195.207. 1. As used in sections 192.945, 261.265, 261.267, and this section, the term **[~~"hemp extract"~~] "medical cannabis"** shall mean **[~~an~~] a noncombustible** extract from a

cannabis plant or a **noncombustible** mixture or preparation containing cannabis plant material**. "Hemp extract" shall mean the same, except** that **it**:

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

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

(3) Contains no other psychoactive substance.

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

(1) Possesses or uses the hemp extract only to treat intractable epilepsy **or medical cannabis only to treat a terminal illness,** as **such terms are** defined in section 192.945;

(2) Originally obtained the hemp extract **or medical cannabis** from a sealed container with a label indicating the hemp extract's **or medical cannabis'** place of origin and a number that corresponds with a certificate of analysis **and a warning label with all possible side effects**;

(3) Possesses, in close proximity to the hemp extract **or medical cannabis**, a certificate of analysis that:

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

(b) Indicates the hemp extract's **or medical cannabis'** ingredients including its percentages of tetrahydrocannabinol and cannabidiol by weight;

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

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

(4) Has a current hemp extract **or medical cannabis** registration card issued by the department of health and senior services under section 192.945.

3. Notwithstanding any other provision of this chapter, an individual who possesses hemp extract **or medical cannabis** lawfully under subsection 2 of this section and administers hemp extract **or medical cannabis** to a minor suffering from intractable epilepsy **or a terminal illness** is not subject to the penalties described in this chapter for administering the hemp extract **or medical cannabis** to the minor if:

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

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

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

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

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

(2) **"Cannabis care center", the premises specified in an application for a cultivation and production facility license in which the licensee is authorized to distribute processed medical cannabis to persons possessing a medical cannabis registration card issued under section 192.945;**

(3) "Cannabis cultivation and production facility", the land and premises in which the licensee is authorized to distribute processed medical cannabis to persons possessing a medical cannabis registration card issued under section 192.945;

(4) "Cannabis cultivation and production facility license", a license that authorizes the licensee to grow, cultivate, process, and possess medical cannabis;

(5) "Cannabis grower", an entity issued a cultivation and production facility license by the department of agriculture that produces medical cannabis for the treatment of terminal illnesses;

(6) "Department", the department of agriculture;

(7) "Hemp":

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

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

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

(b) Any cannabis sativa seed that is:

a. Part of a growing crop;

b. Retained by a grower for future planting; or

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

This term shall not include industrial hemp commodities or products;

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

[~~(3)~~**] (9)** "**Hemp** cultivation and production facility license", a license that authorizes the licensee to grow, cultivate, process, and possess hemp and hemp extract, and distribute hemp extract to its cannabidiol oil care centers;

[~~(4) "Department", the department of agriculture;~~

~~(5)~~**] (10)** "**Hemp** grower", a nonprofit entity issued a cultivation and production facility license by the department of agriculture that produces hemp extract for the treatment of intractable epilepsy;

[~~(6) "Hemp":~~

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

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

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

~~(b) Any cannabis sativa seed that is:~~

~~a. Part of a growing crop;~~

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

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

~~This term shall not include industrial hemp commodities or products;~~**]**

[~~(7)~~**] (11)** "Hemp monitoring system", an electronic tracking system that includes, but is not limited to, testing and data collection established and maintained by the cultivation and production facility and is available to the department for the purposes of documenting the hemp extract production and retail sale of the hemp extract**;**

(12) "Medical cannabis":

(a) All nonseed parts and varieties of the cannabis plant, whether growing or not; and

(b) Any cannabis seed that is:

a. Part of a growing crop;

b. Retained by a grower for future planting; or

c. For processing into or use as agricultural cannabis seed.

2. **The department shall issue a cultivation and production facility license to an entity to grow or cultivate the cannabis plant used to make medical cannabis, as defined in subsection 1 of section 195.207, on the entity's property if the entity has submitted to the department an application as required by the department under subsection 9 of this section and the entity meets all requirements of this section and the department's rules.**

3. A cannabis grower may produce, manufacture, and distribute medical cannabis as defined in section 195.207 for the treatment of persons suffering from a terminal illness consistent with any and all state and local regulations regarding the production, manufacture, or distribution of such product.

4. The department shall issue a **hemp** cultivation and production facility license to a nonprofit entity to grow or cultivate the cannabis plant used to make hemp extract as defined in subsection 1 of section 195.207 or hemp on the entity's property if the entity has submitted to the department an application as required by the department under subsection **[**~~7~~**] 9** of this section**[**~~,~~**]** **and** the entity meets all requirements of this section and the department's rules**[**~~, and there are fewer than two licensed cultivation and production facilities operating in the state~~**]**.

[~~3.~~**] 5.** A **hemp** grower may produce and manufacture hemp and hemp extract, and distribute hemp extract as defined in section 195.207 for the treatment of persons suffering from intractable epilepsy as defined in section 192.945 consistent with any and all state or federal regulations regarding the production, manufacture, or distribution of such product. **[**~~The department shall not issue more than two cultivation and production facility licenses for the operation of such facilities at any one time.~~**]**

[~~4.~~**] 6.** The department shall maintain a list of growers.

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

[~~6.~~**] 8.** In addition to an audit conducted in accordance with subsection **[**~~5~~**] 7** of this section, the director may inspect independently, or in cooperation with the state highway patrol or a local law enforcement agency, any hemp **or medical cannabis** crop during the crop's growth phase and take a representative composite sample for field analysis. If a **hemp** crop contains an average tetrahydrocannabinol (THC) concentration exceeding the lesser of:

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

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

the director may detain, seize, or embargo the **hemp** crop.

[~~7.~~**] 9.** The department shall promulgate rules including, but not limited to:

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

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

(3) Rules relating to hemp **and cannabis** monitoring systems as defined in this section;

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

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

(6) Rules regarding the manufacture, storage, and transportation of hemp**, [**~~and~~**]** hemp extract**, and medical cannabis**, which shall be in addition to any other state or federal regulations.

[~~8.~~**] 10.** Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable, and if any of the powers vested with the general assembly under chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after July 14, 2014.

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

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

13. Notwithstanding any other provision of law to the contrary, a person who commits any acts that are unlawful under section 191.480, 192.945, 192.947, 195.207, 261.265, or 263.250 with the intent to distribute medical cannabis to minors shall be guilty of a class D felony.

14. Any manufacturing, storage, or testing of medical cannabis or any medical cannabis product shall meet all requirements of the department of health and senior services and all local health departments.

263.250. 1. The plant "marijuana", botanically known as cannabis sativa, is hereby declared to be a noxious weed and all owners and occupiers of land shall destroy all such plants growing upon their land. Any person who knowingly allows such plants to grow on his land or refuses to destroy such plants after being notified to do so shall allow any sheriff or such other persons as designated by the county commission to enter upon any land in this state and destroy such plants.

2. Entry to such lands shall not be made, by any sheriff or other designated person to destroy such plants, until fifteen days' notice by certified mail shall be given the owner or occupant to destroy such plants or a search warrant shall be issued on probable cause shown. In all such instances, the county commission shall bear the cost of destruction and notification.

3. The provisions of this section shall not apply to the licensed production of hemp oil or medical cannabis under chapter 261.

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