

SENATE CHAMBER
STATE OF OKLAHOMA

DISPOSITION

☐ FLOOR AMENDMENT

No. _____

☐ COMMITTEE AMENDMENT

(Date)

Mr./Madame President:

I move to amend House Bill No. 2154, by substituting the attached floor substitute for the title, enacting clause and entire body of the measure.

Submitted by:

Senator Crain

Crain-AM-FS-Req#1698
2/18/2016 4:56 PM

(Floor Amendments Only) Date and Time Filed: _____

☐ Untimely

☐ Amendment Cycle Extended

☐ Secondary Amendment

STATE OF OKLAHOMA

1st Session of the 55th Legislature (2015)

FLOOR SUBSTITUTE

FOR ENGROSSED

HOUSE BILL NO. 2154

By: Echols, Grau, Montgomery,
Casey, Jordan, Cannaday,
Roberts (Sean), Perryman
and Nollan of the House

and

Crain, Standridge and Sharp
of the Senate

FLOOR SUBSTITUTE

An Act relating to public health and safety; creating Katie and Cayman's Law; amending 63 O.S. 2011, Section 2-101, as last amended by Section 1, Chapter 154, O.S.L. 2014 (63 O.S. Supp. 2014, Section 2-101), which relates to definitions of the Uniform Controlled Dangerous Substances Act; modifying exception to certain definition; defining terms; providing for the establishment of statewide investigational new drug applications for certain clinical trials; authorizing physicians to serve as principal investigators for clinical trials under certain circumstances; providing for subinvestigators; directing investigators and subinvestigators to adhere to certain rules and regulations; permitting Oklahoma State Bureau of Narcotics and Dangerous Drugs Control to inspect certain samples; providing guidelines for conducting clinical trials; providing exemptions from criminal or civil penalties; permitting State Commissioner of Health to perform certain acts; requiring clinical trials to comply with certain standards; providing termination date; requiring certain approval for continuation of clinical trials; requiring submission of certain report; specifying contents of report; permitting Commissioner to disclose certain data;

1 directing promulgation of rules by certain entities;
2 providing for codification; providing for
3 noncodification; providing an effective date; and
4 declaring an emergency.

5 BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

6 SECTION 1. NEW LAW A new section of law not to be
7 codified in the Oklahoma Statutes reads as follows:

8 This act shall be known and may be cited as "Katie and Cayman's
9 Law".

10 SECTION 2. AMENDATORY 63 O.S. 2011, Section 2-101, as
11 last amended by Section 1, Chapter 154, O.S.L. 2014 (63 O.S. Supp.
12 2014, Section 2-101), is amended to read as follows:

13 Section 2-101. As used in the Uniform Controlled Dangerous
14 Substances Act:

15 1. "Administer" means the direct application of a controlled
16 dangerous substance, whether by injection, inhalation, ingestion or
17 any other means, to the body of a patient, animal or research
18 subject by:

19 a. a practitioner (or, in the presence of the
20 practitioner, by the authorized agent of the
21 practitioner), or

22 b. the patient or research subject at the direction and
23 in the presence of the practitioner;
24

1 2. "Agent" means a peace officer appointed by and who acts in
2 behalf of the Director of the Oklahoma State Bureau of Narcotics and
3 Dangerous Drugs Control or an authorized person who acts on behalf
4 of or at the direction of a person who manufactures, distributes,
5 dispenses, prescribes, administers or uses for scientific purposes
6 controlled dangerous substances but does not include a common or
7 contract carrier, public warehouser or employee thereof, or a person
8 required to register under the Uniform Controlled Dangerous
9 Substances Act;

10 3. "Board" means the Advisory Board to the Director of the
11 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control;

12 4. "Bureau" means the Oklahoma State Bureau of Narcotics and
13 Dangerous Drugs Control;

14 5. "Coca leaves" includes cocaine and any compound,
15 manufacture, salt, derivative, mixture or preparation of coca
16 leaves, except derivatives of coca leaves which do not contain
17 cocaine or ecgonine;

18 6. "Commissioner" or "Director" means the Director of the
19 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control;

20 7. "Control" means to add, remove or change the placement of a
21 drug, substance or immediate precursor under the Uniform Controlled
22 Dangerous Substances Act;

23 8. "Controlled dangerous substance" means a drug, substance or
24 immediate precursor in Schedules I through V of the Uniform

1 Controlled Dangerous Substances Act or any drug, substance or
2 immediate precursor listed either temporarily or permanently as a
3 federally controlled substance. Any conflict between state and
4 federal law with regard to the particular schedule in which a
5 substance is listed shall be resolved in favor of state law;

6 9. "Counterfeit substance" means a controlled substance which,
7 or the container or labeling of which without authorization, bears
8 the trademark, trade name or other identifying marks, imprint,
9 number or device or any likeness thereof of a manufacturer,
10 distributor or dispenser other than the person who in fact
11 manufactured, distributed or dispensed the substance;

12 10. "Deliver" or "delivery" means the actual, constructive or
13 attempted transfer from one person to another of a controlled
14 dangerous substance or drug paraphernalia, whether or not there is
15 an agency relationship;

16 11. "Dispense" means to deliver a controlled dangerous
17 substance to an ultimate user or human research subject by or
18 pursuant to the lawful order of a practitioner, including the
19 prescribing, administering, packaging, labeling or compounding
20 necessary to prepare the substance for such distribution.

21 "Dispenser" is a practitioner who delivers a controlled dangerous
22 substance to an ultimate user or human research subject;

23 12. "Distribute" means to deliver other than by administering
24 or dispensing a controlled dangerous substance;

1 13. "Distributor" means a commercial entity engaged in the
2 distribution or reverse distribution of narcotics and dangerous
3 drugs and who complies with all regulations promulgated by the
4 federal Drug Enforcement Administration and the Oklahoma State
5 Bureau of Narcotics and Dangerous Drugs Control;

6 14. "Drug" means articles:

- 7 a. recognized in the official United States
8 Pharmacopoeia, official Homeopathic Pharmacopoeia of
9 the United States, or official National Formulary, or
10 any supplement to any of them,
- 11 b. intended for use in the diagnosis, cure, mitigation,
12 treatment or prevention of disease in man or other
13 animals,
- 14 c. other than food, intended to affect the structure or
15 any function of the body of man or other animals, and
- 16 d. intended for use as a component of any article
17 specified in this paragraph;

18 provided, however, the term "drug" does not include devices or their
19 components, parts or accessories;

20 15. "Drug-dependent person" means a person who is using a
21 controlled dangerous substance and who is in a state of psychic or
22 physical dependence, or both, arising from administration of that
23 controlled dangerous substance on a continuous basis. Drug
24 dependence is characterized by behavioral and other responses which

1 include a strong compulsion to take the substance on a continuous
2 basis in order to experience its psychic effects, or to avoid the
3 discomfort of its absence;

4 16. "Home care agency" means any sole proprietorship,
5 partnership, association, corporation, or other organization which
6 administers, offers, or provides home care services, for a fee or
7 pursuant to a contract for such services, to clients in their place
8 of residence;

9 17. "Home care services" means skilled or personal care
10 services provided to clients in their place of residence for a fee;

11 18. "Hospice" means a centrally administered, nonprofit or
12 profit, medically directed, nurse-coordinated program which provides
13 a continuum of home and inpatient care for the terminally ill
14 patient and the patient's family. Such term shall also include a
15 centrally administered, nonprofit or profit, medically directed,
16 nurse-coordinated program if such program is licensed pursuant to
17 the provisions of this act. A hospice program offers palliative and
18 supportive care to meet the special needs arising out of the
19 physical, emotional and spiritual stresses which are experienced
20 during the final stages of illness and during dying and bereavement.
21 This care is available twenty-four (24) hours a day, seven (7) days
22 a week, and is provided on the basis of need, regardless of ability
23 to pay. "Class A" Hospice refers to Medicare certified hospices.
24 "Class B" refers to all other providers of hospice services;

1 19. "Imitation controlled substance" means a substance that is
2 not a controlled dangerous substance, which by dosage unit
3 appearance, color, shape, size, markings or by representations made,
4 would lead a reasonable person to believe that the substance is a
5 controlled dangerous substance. In the event the appearance of the
6 dosage unit is not reasonably sufficient to establish that the
7 substance is an "imitation controlled substance", the court or
8 authority concerned should consider, in addition to all other
9 factors, the following factors as related to "representations made"
10 in determining whether the substance is an "imitation controlled
11 substance":

- 12 a. statements made by an owner or by any other person in
13 control of the substance concerning the nature of the
14 substance, or its use or effect,
- 15 b. statements made to the recipient that the substance
16 may be resold for inordinate profit,
- 17 c. whether the substance is packaged in a manner normally
18 used for illicit controlled substances,
- 19 d. evasive tactics or actions utilized by the owner or
20 person in control of the substance to avoid detection
21 by law enforcement authorities,
- 22 e. prior convictions, if any, of an owner, or any other
23 person in control of the object, under state or
24

1 federal law related to controlled substances or fraud,
2 and

3 f. the proximity of the substances to controlled
4 dangerous substances;

5 20. "Immediate precursor" means a substance which the Director
6 has found to be and by regulation designates as being the principal
7 compound commonly used or produced primarily for use, and which is
8 an immediate chemical intermediary used, or likely to be used, in
9 the manufacture of a controlled dangerous substance, the control of
10 which is necessary to prevent, curtail or limit such manufacture;

11 21. "Laboratory" means a laboratory approved by the Director as
12 proper to be entrusted with the custody of controlled dangerous
13 substances and the use of controlled dangerous substances for
14 scientific and medical purposes and for purposes of instruction;

15 22. "Manufacture" means the production, preparation,
16 propagation, compounding or processing of a controlled dangerous
17 substance, either directly or indirectly by extraction from
18 substances of natural or synthetic origin, or independently by means
19 of chemical synthesis or by a combination of extraction and chemical
20 synthesis. "Manufacturer" includes any person who packages,
21 repackages or labels any container of any controlled dangerous
22 substance, except practitioners who dispense or compound
23 prescription orders for delivery to the ultimate consumer;
24

1 23. "Marihuana" means all parts of the plant Cannabis sativa
2 L., whether growing or not; the seeds thereof; the resin extracted
3 from any part of such plant; and every compound, manufacture, salt,
4 derivative, mixture or preparation of such plant, its seeds or
5 resin, but shall not include:

6 a. the mature stalks of such plant, ~~or~~ or fiber produced
7 from such stalks,

8 b. oil or cake made from the seeds of such plant,
9 including cannabidiol derived from the seeds of the
10 marihuana plant,

11 c. any other compound, manufacture, salt, derivative,
12 mixture or preparation of such mature stalks (except
13 the resin extracted therefrom), including cannabidiol
14 derived from mature stalks, fiber, oil or cake, ~~or~~

15 d. the sterilized seed of such plant which is incapable
16 of germination,

17 e. for persons eighteen (18) years of age or younger
18 participating in a clinical trial to administering
19 cannabidiol for the treatment of severe forms of
20 epilepsy pursuant to Section 4 of this act, a drug or
21 substance approved by the federal Food and Drug
22 Administration for use by those participants, or

23 f. for persons eighteen (18) years of age or younger, or
24 the parents, legal guardians, or caretakers of the

person, who have received a written certification from
a physician licensed in this state that the person has
been diagnosed by a physician as having Lennox-Gastaut
Syndrome, Dravet Syndrome, also known as Severe
Myoclonic Epilepsy of Infancy, or any other severe
form of epilepsy that is not adequately treated by
traditional medical therapies, the substance
cannabidiol, a nonpsychoactive cannabinoid, found in
the plant Cannabis sativa L. or any other preparation
thereof, that has a tetrahydrocannabinol concentration
of not more than three-tenths of one percent (0.3%)
and that is delivered to the patient in the form of a
liquid, or

g. industrial hemp, from the plant Cannabis sativa L. and
any part of such plant, whether growing or not, with a
delta-9 tetrahydrocannabinol concentration of not more
than three-tenths of one percent (0.3%) on a dry
weight basis which shall not be grown anywhere in the
State of Oklahoma but may be shipped to Oklahoma
pursuant to the provisions of subparagraph e or f of
this paragraph;

24. "Medical purpose" means an intention to utilize a
controlled dangerous substance for physical or mental treatment, for
diagnosis, or for the prevention of a disease condition not in

1 violation of any state or federal law and not for the purpose of
2 satisfying physiological or psychological dependence or other abuse;

3 25. "Mid-level practitioner" means an advanced practice nurse
4 as defined and within parameters specified in Section 567.3a of
5 Title 59 of the Oklahoma Statutes, or a certified animal euthanasia
6 technician as defined in Section 698.2 of Title 59 of the Oklahoma
7 Statutes, or an animal control officer registered by the Oklahoma
8 State Bureau of Narcotics and Dangerous Drugs Control under
9 subsection B of Section 2-301 of this title within the parameters of
10 such officer's duty under Sections 501 through 508 of Title 4 of the
11 Oklahoma Statutes;

12 26. "Narcotic drug" means any of the following, whether
13 produced directly or indirectly by extraction from substances of
14 vegetable origin, or independently by means of chemical synthesis,
15 or by a combination of extraction and chemical synthesis:

- 16 a. opium, coca leaves and opiates,
- 17 b. a compound, manufacture, salt, derivative or
18 preparation of opium, coca leaves or opiates,
- 19 c. cocaine, its salts, optical and geometric isomers, and
20 salts of isomers,
- 21 d. ecgonine, its derivatives, their salts, isomers and
22 salts of isomers, and
- 23 e. a substance, and any compound, manufacture, salt,
24 derivative or preparation thereof, which is chemically

1 identical with any of the substances referred to in
2 subparagraphs a through d of this paragraph, except
3 that the words "narcotic drug" as used in Section 2-
4 101 et seq. of this title shall not include
5 decocainized coca leaves or extracts of coca leaves,
6 which extracts do not contain cocaine or ecgonine;

7 27. "Opiate" means any substance having an addiction-forming or
8 addiction-sustaining liability similar to morphine or being capable
9 of conversion into a drug having such addiction-forming or
10 addiction-sustaining liability. It does not include, unless
11 specifically designated as controlled under the Uniform Controlled
12 Dangerous Substances Act, the dextrorotatory isomer of 3-methoxy-n-
13 methyl-morphinan and its salts (dextromethorphan). It does include
14 its racemic and levorotatory forms;

15 28. "Opium poppy" means the plant of the species *Papaver*
16 *somniferum* L., except the seeds thereof;

17 29. "Peace officer" means a police officer, sheriff, deputy
18 sheriff, district attorney's investigator, investigator from the
19 Office of the Attorney General, or any other person elected or
20 appointed by law to enforce any of the criminal laws of this state
21 or of the United States;

22 30. "Person" means an individual, corporation, government or
23 governmental subdivision or agency, business trust, estate, trust,
24 partnership or association, or any other legal entity;

1 31. "Poppy straw" means all parts, except the seeds, of the
2 opium poppy, after mowing;

3 32. "Practitioner" means:

- 4 a. (1) a medical doctor or osteopathic physician,
5 (2) a dentist,
6 (3) a podiatrist,
7 (4) an optometrist,
8 (5) a veterinarian,
9 (6) a physician assistant under the supervision of a
10 licensed medical doctor or osteopathic physician,
11 (7) a scientific investigator, or
12 (8) any other person,
13 licensed, registered or otherwise permitted to
14 prescribe, distribute, dispense, conduct research with
15 respect to, use for scientific purposes or administer
16 a controlled dangerous substance in the course of
17 professional practice or research in this state, or
18 b. a pharmacy, hospital, laboratory or other institution
19 licensed, registered or otherwise permitted to
20 distribute, dispense, conduct research with respect
21 to, use for scientific purposes or administer a
22 controlled dangerous substance in the course of
23 professional practice or research in this state;

1 33. "Production" includes the manufacture, planting,
2 cultivation, growing or harvesting of a controlled dangerous
3 substance;

4 34. "State" means the State of Oklahoma or any other state of
5 the United States;

6 35. "Ultimate user" means a person who lawfully possesses a
7 controlled dangerous substance for the person's own use or for the
8 use of a member of the person's household or for administration to
9 an animal owned by the person or by a member of the person's
10 household;

11 36. "Drug paraphernalia" means all equipment, products and
12 materials of any kind which are used, intended for use, or fashioned
13 specifically for use in planting, propagating, cultivating, growing,
14 harvesting, manufacturing, compounding, converting, producing,
15 processing, preparing, testing, analyzing, packaging, repackaging,
16 storing, containing, concealing, injecting, ingesting, inhaling or
17 otherwise introducing into the human body, a controlled dangerous
18 substance in violation of the Uniform Controlled Dangerous
19 Substances Act including, but not limited to:

- 20 a. kits used, intended for use, or fashioned specifically
21 for use in planting, propagating, cultivating, growing
22 or harvesting of any species of plant which is a
23 controlled dangerous substance or from which a
24 controlled dangerous substance can be derived,

- 1 b. kits used, intended for use, or fashioned specifically
2 for use in manufacturing, compounding, converting,
3 producing, processing or preparing controlled
4 dangerous substances,
- 5 c. isomerization devices used, intended for use, or
6 fashioned specifically for use in increasing the
7 potency of any species of plant which is a controlled
8 dangerous substance,
- 9 d. testing equipment used, intended for use, or fashioned
10 specifically for use in identifying, or in analyzing
11 the strength, effectiveness or purity of controlled
12 dangerous substances,
- 13 e. scales and balances used, intended for use, or
14 fashioned specifically for use in weighing or
15 measuring controlled dangerous substances,
- 16 f. diluents and adulterants, such as quinine
17 hydrochloride, mannitol, mannite, dextrose and
18 lactose, used, intended for use, or fashioned
19 specifically for use in cutting controlled dangerous
20 substances,
- 21 g. separation gins and sifters used, intended for use, or
22 fashioned specifically for use in removing twigs and
23 seeds from, or in otherwise cleaning or refining,
24 marihuana,

- 1 h. blenders, bowls, containers, spoons and mixing devices
2 used, intended for use, or fashioned specifically for
3 use in compounding controlled dangerous substances,
- 4 i. capsules, balloons, envelopes and other containers
5 used, intended for use, or fashioned specifically for
6 use in packaging small quantities of controlled
7 dangerous substances,
- 8 j. containers and other objects used, intended for use,
9 or fashioned specifically for use in parenterally
10 injecting controlled dangerous substances into the
11 human body,
- 12 k. hypodermic syringes, needles and other objects used,
13 intended for use, or fashioned specifically for use in
14 parenterally injecting controlled dangerous substances
15 into the human body,
- 16 l. objects used, intended for use, or fashioned
17 specifically for use in ingesting, inhaling or
18 otherwise introducing marihuana, cocaine, hashish or
19 hashish oil into the human body, such as:
- 20 (1) metal, wooden, acrylic, glass, stone, plastic or
21 ceramic pipes with or without screens, permanent
22 screens, hashish heads or punctured metal bowls,
- 23 (2) water pipes,
- 24 (3) carburetion tubes and devices,

- (4) smoking and carburetion masks,
- (5) roach clips, meaning objects used to hold burning material, such as a marihuana cigarette, that has become too small or too short to be held in the hand,
- (6) miniature cocaine spoons and cocaine vials,
- (7) chamber pipes,
- (8) carburetor pipes,
- (9) electric pipes,
- (10) air-driven pipes,
- (11) chillums,
- (12) bongs, or
- (13) ice pipes or chillers,
- m. all hidden or novelty pipes, and
- n. any pipe that has a tobacco bowl or chamber of less than one-half (1/2) inch in diameter in which there is any detectable residue of any controlled dangerous substance as defined in this section or any other substances not legal for possession or use;
- provided, however, the term "drug paraphernalia" shall not include separation gins intended for use in preparing tea or spice, clamps used for constructing electrical equipment, water pipes designed for ornamentation in which no detectable amount of an illegal substance is found or pipes designed and used solely for smoking tobacco,

1 traditional pipes of an American Indian tribal religious ceremony,
2 or antique pipes that are thirty (30) years of age or older;

3 37. a. "Synthetic controlled substance" means a substance:

- 4 (1) the chemical structure of which is substantially
5 similar to the chemical structure of a controlled
6 dangerous substance in Schedule I or II,
7 (2) which has a stimulant, depressant, or
8 hallucinogenic effect on the central nervous
9 system that is substantially similar to or
10 greater than the stimulant, depressant or
11 hallucinogenic effect on the central nervous
12 system of a controlled dangerous substance in
13 Schedule I or II, or
14 (3) with respect to a particular person, which such
15 person represents or intends to have a stimulant,
16 depressant, or hallucinogenic effect on the
17 central nervous system that is substantially
18 similar to or greater than the stimulant,
19 depressant, or hallucinogenic effect on the
20 central nervous system of a controlled dangerous
21 substance in Schedule I or II.

22 b. The designation of gamma butyrolactone or any other
23 chemical as a precursor, pursuant to Section 2-322 of
24 this title, does not preclude a finding pursuant to

1 subparagraph a of this paragraph that the chemical is
2 a synthetic controlled substance.

3 c. "Synthetic controlled substance" does not include:

- 4 (1) a controlled dangerous substance,
5 (2) any substance for which there is an approved new
6 drug application,
7 (3) with respect to a particular person any
8 substance, if an exemption is in effect for
9 investigational use, for that person under the
10 provisions of Section 505 of the Federal Food,
11 Drug and Cosmetic Act, Title 21 of the United
12 States Code, Section 355, to the extent conduct
13 with respect to such substance is pursuant to
14 such exemption, or
15 (4) any substance to the extent not intended for
16 human consumption before such an exemption takes
17 effect with respect to that substance.

18 d. Prima facie evidence that a substance containing
19 salvia divinorum has been enhanced, concentrated or
20 chemically or physically altered shall give rise to a
21 rebuttable presumption that the substance is a
22 synthetic controlled substance;
23
24

1 38. "Tetrahydrocannabinols" means all substances that have been
2 chemically synthesized to emulate the tetrahydrocannabinols of
3 marihuana;

4 39. "Isomer" means the optical isomer, except as used in
5 subsections C and F of Section 2-204 of this title and paragraph 4
6 of subsection A of Section 2-206 of this title. As used in
7 subsections C and F of Section 2-204 of this title, "isomer" means
8 the optical, positional or geometric isomer. As used in paragraph 4
9 of subsection A of Section 2-206 of this title, the term "isomer"
10 means the optical or geometric isomer;

11 40. "Hazardous materials" means materials, whether solid,
12 liquid or gas, which are toxic to human, animal, aquatic or plant
13 life, and the disposal of which materials is controlled by state or
14 federal guidelines; and

15 41. "Anhydrous ammonia" means any substance that exhibits
16 cryogenic evaporative behavior and tests positive for ammonia.

17 SECTION 3. NEW LAW A new section of law to be codified
18 in the Oklahoma Statutes as Section 2-801 of Title 63, unless there
19 is created a duplication in numbering, reads as follows:

20 As used in this act:

21 1. "Academic medical center" means a medical school and its
22 affiliated teaching hospitals and clinics in this state that:

- 23 a. operate a medical residency program for physicians,
24 and

1 b. conduct research that is overseen by the federal
2 Department of Health and Human Services and involves
3 human subjects;

4 2. "Approved source" means a provider approved by the United
5 States Food and Drug Administration which produces cannabidiol that:

6 a. has been manufactured and tested in a facility
7 approved or certified by the United States Food and
8 Drug Administration or similar national regulatory
9 agency in another country which has been approved by
10 the United States Food and Drug Administration, and

11 b. has been tested on animals to demonstrate preliminary
12 effectiveness and to ensure that it is safe to
13 administer to humans;

14 3. "Cannabidiol" means a nonpsychoactive cannabinoid found in
15 the plant Cannabis sativa L. or any other preparation thereof, that
16 has a tetrahydrocannabinol concentration of not more than three-
17 tenths of one percent (0.3%) and that is delivered to the patient in
18 the form of a liquid;

19 4. "Physician" means a doctor of medicine or doctor of
20 osteopathic medicine licensed by the State Board of Medical
21 Licensure and Supervision or the State Board of Osteopathic
22 Examiners; and

23 5. "Qualifying patient" means any person eighteen (18) years of
24 age or younger who suffers from Lennox-Gastaut Syndrome, Dravet

1 Syndrome, also known as Severe Myoclonic Epilepsy of Infancy, or any
2 other form of refractory epilepsy that is not adequately treated by
3 traditional medical therapies.

4 SECTION 4. NEW LAW A new section of law to be codified
5 in the Oklahoma Statutes as Section 2-802 of Title 63, unless there
6 is created a duplication in numbering, reads as follows:

7 A. A statewide investigational new drug application may be
8 established in this state, if approved by the United States Food and
9 Drug Administration, to conduct clinical trials using cannabidiol on
10 qualifying patients with severe forms of epilepsy.

11 B. Any physician licensed by the State Board of Medical
12 Licensure and Supervision or the State Board of Osteopathic
13 Examiners, practicing in this state, and treating patients with
14 severe forms of epilepsy may serve as the principal investigator for
15 such clinical trials if such physician:

16 1. Applies to and is approved by the United States Food and
17 Drug Administration as the principal investigator in a statewide
18 investigational new drug application;

19 2. Receives a license from the United States Drug Enforcement
20 Administration; and

21 3. Receives a registration from the Oklahoma State Bureau of
22 Narcotics and Dangerous Drugs Control.

23 C. Such physician, acting as principal investigator, may
24 include subinvestigators who are also board certified, practice in

1 an academic medical center in this state, and treat patients with
2 severe forms of epilepsy. Such subinvestigators shall be required
3 to comply with the licensing requirement provided in paragraphs 2
4 and 3 of subsection B of this section.

5 D. The principal investigator and all subinvestigators shall
6 adhere to the rules and regulations established by the relevant
7 institutional review board for each participating academic medical
8 center and by the United States Food and Drug Administration, the
9 United States Drug Enforcement Administration, the Oklahoma State
10 Bureau of Narcotics and Dangerous Drugs Control, and the National
11 Institute on Drug Abuse.

12 E. Nothing in this section shall be construed to prohibit a
13 physician licensed in Oklahoma from applying for Investigational New
14 Drug authorization from the United States Food and Drug
15 Administration.

16 F. The Oklahoma State Bureau of Narcotics and Dangerous Drugs
17 Control shall have the authority to inspect and test samples of
18 cannabidiol used in this state pursuant to the provisions of this
19 act.

20 SECTION 5. NEW LAW A new section of law to be codified
21 in the Oklahoma Statutes as Section 2-803 of Title 63, unless there
22 is created a duplication in numbering, reads as follows:
23
24

1 A. Clinical trials conducted pursuant to a statewide
2 investigational new drug application established pursuant to the
3 provisions of this act shall only utilize cannabidiol which is:

4 1. From an approved source; and

5 2. Approved by the United States Food and Drug Administration
6 to be used for treatment of a condition specified in an
7 investigational new drug application.

8 B. The principal investigator and any subinvestigator may
9 receive cannabidiol directly from an approved source or authorized
10 distributor for an approved source for use in the clinical trials.

11 SECTION 6. NEW LAW A new section of law to be codified
12 in the Oklahoma Statutes as Section 2-804 of Title 63, unless there
13 is created a duplication in numbering, reads as follows:

14 A person acting in compliance with the provisions of this act
15 shall not be subject to arrest, prosecution, or any civil or
16 administrative penalty, including a civil penalty or disciplinary
17 action by a professional licensing board, or be denied any right or
18 privilege, for the use, prescription, administration, possession,
19 manufacture, or distribution of medical cannabidiol.

20 SECTION 7. NEW LAW A new section of law to be codified
21 in the Oklahoma Statutes as Section 2-805 of Title 63, unless there
22 is created a duplication in numbering, reads as follows:

23 A. The State Commissioner of Health shall have the authority to
24 approve physicians conducting clinical trials performed pursuant to

1 the provisions of this act. In the event of a substantial violation
2 of this act, the Commissioner shall provide written notice to the
3 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control and
4 the Governor. The Governor, upon receipt of a notice from the
5 Commissioner, shall have the authority to terminate the operations
6 of a clinical trial found to be in violation of any provision of
7 this act.

8 B. The clinical trials and related research authorized by this
9 act shall adhere to the highest standards of academic research
10 including, but not limited to, peer review of research conducted
11 pursuant to this act.

12 C. Clinical trials and related research authorized by this act
13 shall conclude no later than December 31, 2017. Nothing in this act
14 shall be construed as to permit the continuation of clinical trials
15 after December 31, 2017, without approval by a concurrent resolution
16 approved by the Legislature expressing approval of such
17 continuation.

18 D. The State Commissioner of Health shall submit a report to
19 the Chair and Vice Chair of the Senate Health and Human Services
20 Committee, the Chair and Vice Chair of the House Alcohol, Tobacco
21 and Dangerous Drugs Committee, and the Chair and Vice Chair of the
22 House Public Health Committee on or before December 31, 2017. Such
23 report shall include a summary of findings from clinical trials
24 authorized by this act. The Commissioner shall, upon request by the

1 Chair and Vice Chair of the Committees specified in this subsection,
2 make available any data, excluding individual health records,
3 relating to clinical trials authorized by this act.

4 E. The Oklahoma State Bureau of Narcotics and Dangerous Drugs
5 Control, the State Board of Health, and the Oklahoma State Regents
6 for Higher Education shall promulgate rules to implement the
7 provisions of this act.

8 SECTION 8. This act shall become effective July 1, 2015.

9 SECTION 7. It being immediately necessary for the preservation
10 of the public peace, health and safety, an emergency is hereby
11 declared to exist, by reason whereof this act shall take effect and
12 be in full force from and after its passage and approval.

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