

1 **SENATE FLOOR VERSION**

2 February 27, 2017

3 COMMITTEE SUBSTITUTE
4 FOR

5 SENATE BILL NO. 745

By: Yen

6
7 An Act relating to controlled substances; amending 63
8 O.S. 2011, Section 2-101, as last amended by Section
9 1, Chapter 299, O.S.L. 2016 (63 O.S. Supp. 2016,
10 Section 2-101), which relates to definitions;
11 modifying certain exemption; specifying qualifying
12 conditions; providing for the establishment of
13 statewide investigational new drug applications for
14 certain clinical trials; authorizing physicians to
15 serve as principal investigators for clinical trials
16 under certain circumstances; providing for
17 subinvestigators; directing investigators and
18 subinvestigators to adhere to certain rules and
19 regulations; permitting Oklahoma State Bureau of
20 Narcotics and Dangerous Drugs Control to inspect
21 certain samples; providing guidelines for conducting
22 clinical trials; providing exemptions from criminal
23 or civil penalties; permitting State Commissioner of
24 Health to perform certain acts; requiring clinical
trials to comply with certain standards; providing
termination date; providing certain construction;
requiring submission of certain report; specifying
contents of report; permitting Commissioner to
disclose certain data; directing promulgation of
rules by certain entities; providing for
codification; and providing an effective date.

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

1 SECTION 1. AMENDATORY 63 O.S. 2011, Section 2-101, as
2 last amended by Section 1, Chapter 299, O.S.L. 2016 (63 O.S. Supp.
3 2016, Section 2-101), is amended to read as follows:

4 Section 2-101. As used in the Uniform Controlled Dangerous
5 Substances Act:

6 1. "Administer" means the direct application of a controlled
7 dangerous substance, whether by injection, inhalation, ingestion or
8 any other means, to the body of a patient, animal or research
9 subject by:

10 a. a practitioner (or, in the presence of the
11 practitioner, by the authorized agent of the
12 practitioner), or

13 b. the patient or research subject at the direction and
14 in the presence of the practitioner;

15 2. "Agent" means a peace officer appointed by and who acts in
16 behalf of the Director of the Oklahoma State Bureau of Narcotics and
17 Dangerous Drugs Control or an authorized person who acts on behalf
18 of or at the direction of a person who manufactures, distributes,
19 dispenses, prescribes, administers or uses for scientific purposes
20 controlled dangerous substances but does not include a common or
21 contract carrier, public warehouser or employee thereof, or a person
22 required to register under the Uniform Controlled Dangerous
23 Substances Act;

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

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

5 5. "Coca leaves" includes cocaine and any compound,
6 manufacture, salt, derivative, mixture or preparation of coca
7 leaves, except derivatives of coca leaves which do not contain
8 cocaine or ecgonine;

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

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

14 8. "Controlled dangerous substance" means a drug, substance or
15 immediate precursor in Schedules I through V of the Uniform
16 Controlled Dangerous Substances Act or any drug, substance or
17 immediate precursor listed either temporarily or permanently as a
18 federally controlled substance. Any conflict between state and
19 federal law with regard to the particular schedule in which a
20 substance is listed shall be resolved in favor of state law;

21 9. "Counterfeit substance" means a controlled substance which,
22 or the container or labeling of which without authorization, bears
23 the trademark, trade name or other identifying marks, imprint,
24 number or device or any likeness thereof of a manufacturer,

distributor or dispenser other than the person who in fact
manufactured, distributed or dispensed the substance;

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

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

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

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

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

14. "Drug" means articles:

a. recognized in the official United States

Pharmacopoeia, official Homeopathic Pharmacopoeia of

1 the United States, or official National Formulary, or
2 any supplement to any of them,

3 b. intended for use in the diagnosis, cure, mitigation,
4 treatment or prevention of disease in man or other
5 animals,

6 c. other than food, intended to affect the structure or
7 any function of the body of man or other animals, and

8 d. intended for use as a component of any article
9 specified in this paragraph;

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

12 15. "Drug-dependent person" means a person who is using a
13 controlled dangerous substance and who is in a state of psychic or
14 physical dependence, or both, arising from administration of that
15 controlled dangerous substance on a continuous basis. Drug
16 dependence is characterized by behavioral and other responses which
17 include a strong compulsion to take the substance on a continuous
18 basis in order to experience its psychic effects, or to avoid the
19 discomfort of its absence;

20 16. "Home care agency" means any sole proprietorship,
21 partnership, association, corporation, or other organization which
22 administers, offers, or provides home care services, for a fee or
23 pursuant to a contract for such services, to clients in their place
24 of residence;

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

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

17 19. "Imitation controlled substance" means a substance that is
18 not a controlled dangerous substance, which by dosage unit
19 appearance, color, shape, size, markings or by representations made,
20 would lead a reasonable person to believe that the substance is a
21 controlled dangerous substance. In the event the appearance of the
22 dosage unit is not reasonably sufficient to establish that the
23 substance is an "imitation controlled substance", the court or
24 authority concerned should consider, in addition to all other

1 factors, the following factors as related to "representations made"
2 in determining whether the substance is an "imitation controlled
3 substance":

- 4 a. statements made by an owner or by any other person in
5 control of the substance concerning the nature of the
6 substance, or its use or effect,
- 7 b. statements made to the recipient that the substance
8 may be resold for inordinate profit,
- 9 c. whether the substance is packaged in a manner normally
10 used for illicit controlled substances,
- 11 d. evasive tactics or actions utilized by the owner or
12 person in control of the substance to avoid detection
13 by law enforcement authorities,
- 14 e. prior convictions, if any, of an owner, or any other
15 person in control of the object, under state or
16 federal law related to controlled substances or fraud,
17 and
- 18 f. the proximity of the substances to controlled
19 dangerous substances;

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

3 21. "Laboratory" means a laboratory approved by the Director as
4 proper to be entrusted with the custody of controlled dangerous
5 substances and the use of controlled dangerous substances for
6 scientific and medical purposes and for purposes of instruction;

7 22. "Manufacture" means the production, preparation,
8 propagation, compounding or processing of a controlled dangerous
9 substance, either directly or indirectly by extraction from
10 substances of natural or synthetic origin, or independently by means
11 of chemical synthesis or by a combination of extraction and chemical
12 synthesis. "Manufacturer" includes any person who packages,
13 repackages or labels any container of any controlled dangerous
14 substance, except practitioners who dispense or compound
15 prescription orders for delivery to the ultimate consumer;

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

- 21 a. the mature stalks of such plant or fiber produced from
22 such stalks,
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- 1 b. oil or cake made from the seeds of such plant,
2 including cannabidiol derived from the seeds of the
3 marihuana plant,
- 4 c. any other compound, manufacture, salt, derivative,
5 mixture or preparation of such mature stalks (except
6 the resin extracted therefrom), including cannabidiol
7 derived from mature stalks, fiber, oil or cake,
- 8 d. the sterilized seed of such plant which is incapable
9 of germination,
- 10 e. for any person participating in a clinical trial to
11 administer cannabidiol for the treatment of severe
12 forms of epilepsy pursuant to Section 2-802 of this
13 title, a drug or substance approved by the federal
14 Food and Drug Administration for use by those
15 participants,
- 16 f. for any person or the parents, legal guardians or
17 caretakers of the person who have received a written
18 certification from a physician licensed in this state
19 that the person has been diagnosed by a physician as
20 having Lennox-Gastaut Syndrome, Dravet Syndrome, also
21 known as Severe Myoclonic Epilepsy of Infancy, or any
22 other severe form of epilepsy that is not adequately
23 treated by traditional medical therapies, spasticity
24 due to multiple sclerosis or due to paraplegia,

1 intractable nausea and vomiting, appetite stimulation
2 with chronic wasting diseases, the substance
3 cannabidiol, a nonpsychoactive cannabinoid, found in
4 the plant Cannabis sativa L. or any other preparation
5 thereof, that has a tetrahydrocannabinol concentration
6 of not more than three-tenths of one percent (0.3%)
7 and that is delivered to the patient in the form of a
8 liquid, ~~or~~

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

17 h. marihuana for use by any person age eighteen (18) or
18 older, or the parents, legal guardians or caretakers
19 of the person who has received a written certification
20 from a physician licensed in this state that the
21 person has:

22 (1) neuropathic pain,

23 (2) persistent muscle spasms due to multiple
24 sclerosis or paraplegia,

- 1 (3) nausea or vomiting due to chemotherapy,
2 (4) loss of weight or appetite due to cancer or
3 HIV/AIDS, or
4 (5) chronic pain when other treatments have failed;

5 24. "Medical purpose" means an intention to utilize a
6 controlled dangerous substance for physical or mental treatment, for
7 diagnosis, or for the prevention of a disease condition not in
8 violation of any state ~~or federal law~~ and not for the purpose of
9 satisfying physiological or psychological dependence or other abuse;

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

19 26. "Narcotic drug" means any of the following, whether
20 produced directly or indirectly by extraction from substances of
21 vegetable origin, or independently by means of chemical synthesis,
22 or by a combination of extraction and chemical synthesis:

- 23 a. opium, coca leaves and opiates,
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- 1 b. a compound, manufacture, salt, derivative or
2 preparation of opium, coca leaves or opiates,
3 c. cocaine, its salts, optical and geometric isomers, and
4 salts of isomers,
5 d. ecgonine, its derivatives, their salts, isomers and
6 salts of isomers, and
7 e. a substance, and any compound, manufacture, salt,
8 derivative or preparation thereof, which is chemically
9 identical with any of the substances referred to in
10 subparagraphs a through d of this paragraph, except
11 that the words "narcotic drug" as used in Section 2-
12 101 et seq. of this title shall not include
13 decocainized coca leaves or extracts of coca leaves,
14 which extracts do not contain cocaine or ecgonine;

15 27. "Opiate" means any substance having an addiction-forming or
16 addiction-sustaining liability similar to morphine or being capable
17 of conversion into a drug having such addiction-forming or
18 addiction-sustaining liability. It does not include, unless
19 specifically designated as controlled under the Uniform Controlled
20 Dangerous Substances Act, the dextrorotatory isomer of 3-methoxy-n-
21 methyl-morphinan and its salts (dextromethorphan). It does include
22 its racemic and levorotatory forms;

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

1 29. "Peace officer" means a police officer, sheriff, deputy
2 sheriff, district attorney's investigator, investigator from the
3 Office of the Attorney General, or any other person elected or
4 appointed by law to enforce any of the criminal laws of this state
5 or of the United States;

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

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

11 32. "Practitioner" means:

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

9 33. "Production" includes the manufacture, planting,
10 cultivation, growing or harvesting of a controlled dangerous
11 substance;

12 34. "State" means the State of Oklahoma or any other state of
13 the United States;

14 35. "Ultimate user" means a person who lawfully possesses a
15 controlled dangerous substance for the person's own use or for the
16 use of a member of the person's household or for administration to
17 an animal owned by the person or by a member of the person's
18 household;

19 36. "Drug paraphernalia" means all equipment, products and
20 materials of any kind which are used, intended for use, or fashioned
21 specifically for use in planting, propagating, cultivating, growing,
22 harvesting, manufacturing, compounding, converting, producing,
23 processing, preparing, testing, analyzing, packaging, repackaging,
24 storing, containing, concealing, injecting, ingesting, inhaling or

1 otherwise introducing into the human body, a controlled dangerous
2 substance in violation of the Uniform Controlled Dangerous
3 Substances Act including, but not limited to:

- 4 a. kits used, intended for use, or fashioned specifically
5 for use in planting, propagating, cultivating, growing
6 or harvesting of any species of plant which is a
7 controlled dangerous substance or from which a
8 controlled dangerous substance can be derived,
- 9 b. kits used, intended for use, or fashioned specifically
10 for use in manufacturing, compounding, converting,
11 producing, processing or preparing controlled
12 dangerous substances,
- 13 c. isomerization devices used, intended for use, or
14 fashioned specifically for use in increasing the
15 potency of any species of plant which is a controlled
16 dangerous substance,
- 17 d. testing equipment used, intended for use, or fashioned
18 specifically for use in identifying, or in analyzing
19 the strength, effectiveness or purity of controlled
20 dangerous substances,
- 21 e. scales and balances used, intended for use, or
22 fashioned specifically for use in weighing or
23 measuring controlled dangerous substances,

- 1 f. diluents and adulterants, such as quinine
2 hydrochloride, mannitol, mannite, dextrose and
3 lactose, used, intended for use, or fashioned
4 specifically for use in cutting controlled dangerous
5 substances,
- 6 g. separation gins and sifters used, intended for use, or
7 fashioned specifically for use in removing twigs and
8 seeds from, or in otherwise cleaning or refining,
9 marihuana,
- 10 h. blenders, bowls, containers, spoons and mixing devices
11 used, intended for use, or fashioned specifically for
12 use in compounding controlled dangerous substances,
- 13 i. capsules, balloons, envelopes and other containers
14 used, intended for use, or fashioned specifically for
15 use in packaging small quantities of controlled
16 dangerous substances,
- 17 j. containers and other objects used, intended for use,
18 or fashioned specifically for use in parenterally
19 injecting controlled dangerous substances into the
20 human body,
- 21 k. hypodermic syringes, needles and other objects used,
22 intended for use, or fashioned specifically for use in
23 parenterally injecting controlled dangerous substances
24 into the human body,

1. objects used, intended for use, or fashioned specifically for use in ingesting, inhaling or otherwise introducing marihuana, cocaine, hashish or hashish oil into the human body, such as:
- (1) metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens, permanent screens, hashish heads or punctured metal bowls,
 - (2) water pipes,
 - (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

1 n. any pipe that has a tobacco bowl or chamber of less
2 than one-half (1/2) inch in diameter in which there is
3 any detectable residue of any controlled dangerous
4 substance as defined in this section or any other
5 substances not legal for possession or use;

6 provided, however, the term "drug paraphernalia" shall not include
7 separation gins intended for use in preparing tea or spice, clamps
8 used for constructing electrical equipment, water pipes designed for
9 ornamentation in which no detectable amount of an illegal substance
10 is found or pipes designed and used solely for smoking tobacco,
11 traditional pipes of an American Indian tribal religious ceremony,
12 or antique pipes that are thirty (30) years of age or older;

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

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

9 b. The designation of gamma butyrolactone or any other
10 chemical as a precursor, pursuant to Section 2-322 of
11 this title, does not preclude a finding pursuant to
12 subparagraph a of this paragraph that the chemical is
13 a synthetic controlled substance.

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

- 15 (1) a controlled dangerous substance,
16 (2) any substance for which there is an approved new
17 drug application,
18 (3) with respect to a particular person any
19 substance, if an exemption is in effect for
20 investigational use, for that person under the
21 provisions of Section 505 of the Federal Food,
22 Drug and Cosmetic Act, Title 21 of the United
23 States Code, Section 355, to the extent conduct
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1 with respect to such substance is pursuant to
2 such exemption, or

3 (4) any substance to the extent not intended for
4 human consumption before such an exemption takes
5 effect with respect to that substance.

6 d. Prima facie evidence that a substance containing
7 salvia divinorum has been enhanced, concentrated or
8 chemically or physically altered shall give rise to a
9 rebuttable presumption that the substance is a
10 synthetic controlled substance;

11 38. "Tetrahydrocannabinols" means all substances that have been
12 chemically synthesized to emulate the tetrahydrocannabinols of
13 marihuana;

14 39. "Isomer" means the optical isomer, except as used in
15 subsections C and F of Section 2-204 of this title and paragraph 4
16 of subsection A of Section 2-206 of this title. As used in
17 subsections C and F of Section 2-204 of this title, "isomer" means
18 the optical, positional or geometric isomer. As used in paragraph 4
19 of subsection A of Section 2-206 of this title, the term "isomer"
20 means the optical or geometric isomer;

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

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

3 SECTION 2. NEW LAW A new section of law to be codified
4 in the Oklahoma Statutes as Section 2-806 of Title 63, unless there
5 is created a duplication in numbering, reads as follows:

6 A. A statewide investigational new drug application may be
7 established in this state, if approved by the United States Food and
8 Drug Administration, to conduct clinical trials using marihuana, as
9 such term is defined by subparagraph h of paragraph 23 of Section 1
10 of this act, for qualifying patients with:

11 1. Neuropathic pain;

12 2. Persistent muscle spasms due to multiple sclerosis or
13 paraplegia;

14 3. Nausea or vomiting due to chemotherapy;

15 4. Loss of weight or appetite due to cancer or HIV/AIDS; or

16 5. Chronic pain when other treatments have failed.

17 B. Any physician licensed by the State Board of Medical
18 Licensure and Supervision or the State Board of Osteopathic
19 Examiners, practicing in this state, and treating patients with any
20 of the conditions specified by subsection A of this section may
21 serve as the principal investigator for such clinical trials if such
22 physician:

23 1. Applies to and is approved by the United States Food and
24 Drug Administration in a manner consistent with federal law;

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

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

5 C. Such physician, acting as principal investigator, may
6 include subinvestigators who are also board certified, practice in
7 an academic medical center in this state, and treat patients with
8 any of the conditions specified by subsection A of this section.

9 Such subinvestigators shall be required to comply with the licensing
10 requirement provided in paragraphs 2 and 3 of subsection B of this
11 section.

12 D. The principal investigator and all subinvestigators shall
13 adhere to the rules and regulations established by the relevant
14 institutional review board for each participating academic medical
15 center and by the United States Food and Drug Administration, the
16 United States Drug Enforcement Administration, the Oklahoma State
17 Bureau of Narcotics and Dangerous Drugs Control, and the National
18 Institute on Drug Abuse.

19 E. The Oklahoma State Bureau of Narcotics and Dangerous Drugs
20 Control shall have the authority to inspect and test samples of
21 marihuana used in this state pursuant to the provisions of this act.

22 SECTION 3. NEW LAW A new section of law to be codified
23 in the Oklahoma Statutes as Section 2-807 of Title 63, unless there
24 is created a duplication in numbering, reads as follows:

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 marihuana 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 marihuana directly from an approved source or authorized
10 distributor for an approved source for use in the clinical trials.

11 C. A person acting in compliance with the provisions of this
12 act shall not be subject to arrest, prosecution, or any civil or
13 administrative penalty, including a civil penalty or disciplinary
14 action by a professional licensing board, or be denied any right or
15 privilege, for the use, prescription, administration, possession,
16 manufacture, or distribution of marihuana; provided, the immunity
17 provided by this subsection shall not apply to persons participating
18 in the clinical trial authorized by this act when the person
19 possesses or uses marihuana for purposes other than those authorized
20 by this act.

21 D. The State Commissioner of Health shall have the authority to
22 approve physicians conducting clinical trials performed pursuant to
23 the provisions of this act. In the event of a substantial violation
24 of this act, the Commissioner shall provide written notice to the

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

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

10 F. Clinical trials and related research authorized by this act
11 shall conclude no later than December 31, 2019. Nothing in this act
12 shall be construed as to permit the continuation of clinical trials
13 after December 31, 2019.

14 G. The State Commissioner of Health shall submit a report to
15 the President Pro Tempore of the Oklahoma State Senate, the Speaker
16 of the Oklahoma House of Representatives and the Governor on or
17 before December 31, 2019. Such report shall include a summary of
18 findings from clinical trials authorized by this act. The
19 Commissioner shall, upon request by the Chair and Vice Chair of the
20 Committees specified in this subsection, make available any data,
21 excluding individual health records, relating to clinical trials
22 authorized by this act.

23 H. The Oklahoma State Bureau of Narcotics and Dangerous Drugs
24 Control, the State Board of Health, and the Oklahoma State Regents

1 for Higher Education shall promulgate rules to implement the
2 provisions of this act.

3 SECTION 4. This act shall become effective November 1, 2017.

4 COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES
5 February 27, 2017 - DO PASS AS AMENDED
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