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LEGISLATURE OF NEBRASKA

ONE HUNDRED FOURTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 390

Introduced by Crawford, 45; Bloomfield, 17; Chambers, 11; Coash, 27; Davis, 43; Garrett, 3; Howard, 9; Pansing Brooks, 28; Scheer, 19; Watermeier, 1.

Read first time January 16, 2015

Committee:

A BILL FOR AN ACT relating to marijuana; to amend sections 28-101, 28-401, and 28-401.01, Revised Statutes Cumulative Supplement, 2014; to provide for the medical use of cannabidiol as prescribed; to create the Medical Cannabidiol Pilot Study; to provide powers and duties for the Department of Health and Human Services and the University of Nebraska Medical Center; to define and redefine terms; to change provisions of the Uniform Controlled Substances Act; to harmonize provisions; to provide a termination date; and to repeal the original sections.

Be it enacted by the people of the State of Nebraska,

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Section 1. Section 28-101, Revised Statutes Cumulative Supplement, 2014, is amended to read:

28-101 Sections 28-101 to 28-1357, 28-1418.01, and 28-1429.03 and sections 4 to 11 of this act shall be known and may be cited as the Nebraska Criminal Code.

Sec. 2. Section 28-401, Revised Statutes Cumulative Supplement, 2014, is amended to read:

28-401 As used in the Uniform Controlled Substances Act, unless the context otherwise requires:

(1) Administer means to directly apply a controlled substance by injection, inhalation, ingestion, or any other means to the body of a patient or research subject;

(2) Agent means an authorized person who acts on behalf of or at the direction of another person but does not include a common or contract carrier, public warehouse keeper, or employee of a carrier or warehouse keeper;

(3) Administration means the Drug Enforcement Administration of the United States Department of Justice;

(4) Cannabidiol means processed cannabis plant extract, oil, or resin that contains more than ten percent cannabidiol by weight, but not more than three-tenths of one percent tetrahydrocannabinols by weight, and delivered in the form of (a) a liquid, including, but not limited to, oil, or (b) a pill;

(5 4) Controlled substance means a drug, biological, substance, or immediate precursor in Schedules I to V of section 28-405. Controlled substance does not include distilled spirits, wine, malt beverages, tobacco, or any nonnarcotic substance if such substance may, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., as such act existed on January 1, 2014, and the law of this state, be lawfully sold over the counter without a prescription;

(6 ~~5~~) Counterfeit substance means a controlled substance which, or

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the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser;

(7 ~~6~~) Department means the Department of Health and Human Services;

(8 ~~7~~) Division of Drug Control means the personnel of the Nebraska State Patrol who are assigned to enforce the Uniform Controlled Substances Act;

(9 ~~8~~) Dispense means to deliver a controlled substance to an ultimate user or a research subject pursuant to a medical order issued by a practitioner authorized to prescribe, including the packaging, labeling, or compounding necessary to prepare the controlled substance for such delivery;

(10 ~~9~~) Distribute means to deliver other than by administering or dispensing a controlled substance;

(11 ~~10~~) Prescribe means to issue a medical order;

(12 ~~11~~) Drug means (a) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them, (b) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals, and (c) substances intended for use as a component of any article specified in subdivision (a) or (b) of this subdivision, but does not include devices or their components, parts, or accessories;

(13 ~~12~~) Deliver or delivery means the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship;

(14 ~~13~~) Marijuana means all parts of the plant of the genus

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cannabis, whether growing or not, the seeds thereof, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds, but does not include the mature stalks of such plant, hashish, tetrahydrocannabinols extracted or isolated from the plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks, ~~or~~ the sterilized seed of such plant which is incapable of germination, or cannabidiol obtained pursuant to sections 4 to 11 of this act. When the weight of marijuana is referred to in the Uniform Controlled Substances Act, it means its weight at or about the time it is seized or otherwise comes into the possession of law enforcement authorities, whether cured or uncured at that time. When industrial hemp as defined in section 2-5701 is in the possession of a person as authorized under section 2-5701, it is not considered marijuana for purposes of the Uniform Controlled Substances Act;

(15 ~~14~~) Manufacture means the production, preparation, propagation, conversion, or processing of a controlled substance, either directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. Manufacture does not include the preparation or compounding of a controlled substance by an individual for his or her own use, except for the preparation or compounding of components or ingredients used for or intended to be used for the manufacture of methamphetamine, or the preparation, compounding, conversion, packaging, or labeling of a controlled substance: (a) By a practitioner as an incident to his or her prescribing, administering, or dispensing of a controlled substance in the course of his or her professional practice; or (b) by a practitioner, or by his or her authorized agent under his or her supervision, for the purpose of, or as an incident to, research, teaching, or chemical

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analysis and not for sale;

(16 ~~15~~) Narcotic drug means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (a) Opium, opium poppy and poppy straw, coca leaves, and opiates; (b) a compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates; or (c) a substance and any compound, manufacture, salt, derivative, or preparation thereof which is chemically equivalent to or identical with any of the substances referred to in subdivisions (a) and (b) of this subdivision, except that the words narcotic drug as used in the Uniform Controlled Substances Act does not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine, or isoquinoline alkaloids of opium;

(17 ~~16~~) Opiate means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. Opiate does not include the dextrorotatory isomer of 3-methoxy-n methylmorphinan and its salts. Opiate includes its racemic and levorotatory forms;

(18 ~~17~~) Opium poppy means the plant of the species Papaver somniferum L., except the seeds thereof;

(19 ~~18~~) Poppy straw means all parts, except the seeds, of the opium poppy after mowing;

(20 ~~19~~) Person means any corporation, association, partnership, limited liability company, or one or more persons;

(21 ~~20~~) Practitioner means a physician, a physician assistant, a dentist, a veterinarian, a pharmacist, a podiatrist, an optometrist, a certified nurse midwife, a certified registered nurse anesthetist, a nurse practitioner, a scientific investigator, a pharmacy, a hospital, or any other person licensed, registered, or otherwise permitted to

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distribute, dispense, prescribe, conduct research with respect to, or administer a controlled substance in the course of practice or research in this state, including an emergency medical service as defined in section 38-1207;

(22 ~~21~~) Production includes the manufacture, planting, cultivation, or harvesting of a controlled substance;

(23 ~~22~~) Immediate precursor means a substance which is the principal compound commonly used or produced primarily for use and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit such manufacture;

(24 ~~23~~) State means the State of Nebraska;

(25 ~~24~~) Ultimate user means a person who lawfully possesses a controlled substance for his or her own use, for the use of a member of his or her household, or for administration to an animal owned by him or her or by a member of his or her household;

(26 ~~25~~) Hospital has the same meaning as in section 71-419;

(27 ~~26~~) Cooperating individual means any person, other than a commissioned law enforcement officer, who acts on behalf of, at the request of, or as agent for a law enforcement agency for the purpose of gathering or obtaining evidence of offenses punishable under the Uniform Controlled Substances Act;

(28 ~~27~~) Hashish or concentrated cannabis means (a) the separated resin, whether crude or purified, obtained from a plant of the genus cannabis or (b) any material, preparation, mixture, compound, or other substance which contains ten percent or more by weight of tetrahydrocannabinols. When resins extracted from industrial hemp as defined in section 2-5701 are in the possession of a person as authorized under section 2-5701, they are not considered hashish or concentrated cannabis for purposes of the Uniform Controlled Substances Act;

(29 ~~28~~) Exceptionally hazardous drug means (a) a narcotic drug, (b)

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thiophene analog of phencyclidine, (c) phencyclidine, (d) amobarbital, (e) secobarbital, (f) pentobarbital, (g) amphetamine, or (h) methamphetamine;

(30 ~~29~~) Imitation controlled substance means a substance which is not a controlled substance or controlled substance analogue but which, by way of express or implied representations and consideration of other relevant factors including those specified in section 28-445, would lead a reasonable person to believe the substance is a controlled substance or controlled substance analogue. A placebo or registered investigational drug manufactured, distributed, possessed, or delivered in the ordinary course of practice or research by a health care professional shall not be deemed to be an imitation controlled substance;

(31 ~~30~~)(a) Controlled substance analogue means a substance (i) the chemical structure of which is substantially similar to the chemical structure of a Schedule I or Schedule II controlled substance as provided in section 28-405 or (ii) which has a stimulant, depressant, analgesic, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, analgesic, or hallucinogenic effect on the central nervous system of a Schedule I or Schedule II controlled substance as provided in section 28-405. A controlled substance analogue shall, to the extent intended for human consumption, be treated as a controlled substance under Schedule I of section 28-405 for purposes of the Uniform Controlled Substances Act; and

(b) Controlled substance analogue does not include (i) a controlled substance, (ii) any substance generally recognized as safe and effective within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., as such act existed on January 1, 2014, (iii) any substance for which there is an approved new drug application, or (iv) with respect to a particular person, any substance if an exemption is in effect for investigational use for that person, under section 505 of the Federal

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Food, Drug, and Cosmetic Act, 21 U.S.C. 355, as such section existed on January 1, 2014, to the extent conduct with respect to such substance is pursuant to such exemption;

(32 ~~31~~) Anabolic steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids), that promotes muscle growth and includes any controlled substance in Schedule III(d) of section 28-405. Anabolic steroid does not include any anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and has been approved by the Secretary of Health and Human Services for such administration, but if any person prescribes, dispenses, or distributes such a steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this subdivision;

(33 ~~32~~) Chart order means an order for a controlled substance issued by a practitioner for a patient who is in the hospital where the chart is stored or for a patient receiving detoxification treatment or maintenance treatment pursuant to section 28-412. Chart order does not include a prescription;

(34 ~~33~~) Medical order means a prescription, a chart order, or an order for pharmaceutical care issued by a practitioner;

(35 ~~34~~) Prescription means an order for a controlled substance issued by a practitioner. Prescription does not include a chart order;

(36 ~~35~~) Registrant means any person who has a controlled substances registration issued by the state or the administration;

(37 ~~36~~) Reverse distributor means a person whose primary function is to act as an agent for a pharmacy, wholesaler, manufacturer, or other entity by receiving, inventorying, and managing the disposition of outdated, expired, or otherwise nonsaleable controlled substances;

(38 ~~37~~) Signature means the name, word, or mark of a person written in his or her own hand with the intent to authenticate a writing or other

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form of communication or a digital signature which complies with section 86-611 or an electronic signature;

(39 ~~38~~) Facsimile means a copy generated by a system that encodes a document or photograph into electrical signals, transmits those signals over telecommunications lines, and reconstructs the signals to create an exact duplicate of the original document at the receiving end;

(40 ~~39~~) Electronic signature has the definition found in section 86-621;

(41 ~~40~~) Electronic transmission means transmission of information in electronic form. Electronic transmission includes computer-to-computer transmission or computer-to-facsimile transmission;

(42 ~~41~~) Long-term care facility means an intermediate care facility, an intermediate care facility for persons with developmental disabilities, a long-term care hospital, a mental health center, a nursing facility, or a skilled nursing facility, as such terms are defined in the Health Care Facility Licensure Act;

(43 ~~42~~) Compounding has the same meaning as in section 38-2811; and

(44 ~~43~~) Cannabinoid receptor agonist shall mean any chemical compound or substance that, according to scientific or medical research, study, testing, or analysis, demonstrates the presence of binding activity at one or more of the CB1 or CB2 cell membrane receptors located within the human body.

Sec. 3. Section 28-401.01, Revised Statutes Cumulative Supplement, 2014, is amended to read:

28-401.01 Sections 28-401 to 28-456.01 and 28-458 to 28-462 and sections 4 to 11 of this act shall be known and may be cited as the Uniform Controlled Substances Act.

Sec. 4. (1) For purposes of sections 4 to 9 of this act:

(a) Intractable seizures means intractable, catastrophic genetic, or metabolic epilepsies; Lennox-Gastaut Syndrome; epilepsies consisting of drop seizures at risk for significant bodily injury; or cluster seizures

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that result in significant life-threatening apnea after the trial and failure of at least three antiepileptic pharmacotherapies that directly address the epilepsy in question; and

(b) Treatment resistant seizures means epileptic disorders, other than those listed in subdivision (1)(a) of this section, which are resistant to treatment. For purposes of this subdivision, resistant to treatment means a trial and failure of at least three antiepileptic therapies, such as neurostimulation or epilepsy surgery.

(2) The Legislature finds:

(a) There are individuals in Nebraska who suffer from intractable seizures and treatment resistant seizures for which currently available treatment options have been ineffective. Cannabidiol shows promise in treating individuals with intractable seizures and treatment resistant seizures; and

(b) Additional study of cannabidiol for the treatment of intractable seizures and treatment resistant seizures should be undertaken.

(3) The purpose of sections 4 to 10 of this act is to permit medical professionals to conduct limited-scope, evidence-based studies exploring the safety and efficacy of treating intractable seizures and treatment resistant seizures using cannabidiol.

Sec. 5. (1) The University of Nebraska and Nebraska Medicine shall be the only entity in this state authorized to produce or possess cannabidiol for research.

(2) Cannabidiol shall be obtained from or tested at the University of Nebraska Medical Center and dispensed by the Nebraska Medicine Research Pharmacy.

(3) Cannabidiol may only be obtained by patients with intractable seizures and treatment resistant seizures and on the order of a neurologist who is licensed to practice medicine and surgery in Nebraska and designated as a medical provider under section 6 of this act and administered to a patient by or under the direction or supervision of

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such medical provider participating in the Medical Cannabidiol Pilot Study.

Sec. 6. (1) The University of Nebraska Medical Center shall create the Medical Cannabidiol Pilot Study. The pilot study shall designate at least two medical providers to conduct research on the efficacy of cannabidiol to treat patients with intractable seizures and treatment resistant seizures. The medical providers shall be neurologists licensed to practice medicine and surgery in Nebraska, and at least one shall be a pediatric neurologist. The medical providers shall adhere to the rules and regulations established by the University of Nebraska Medical Center for the study.

(2) A neurologist designated as a medical provider or a licensed pharmacist participating in the pilot study shall not be subject to arrest or prosecution, penalized or disciplined in any manner, or denied any right or privilege for approving or recommending the use of cannabidiol under the Medical Cannabidiol Pilot Study.

(3)(a) A neurologist designated as a medical provider conducting research under the Medical Cannabidiol Pilot Study shall:

(i) Determine eligibility for participation in the study;

(ii) Keep a record of the evaluation and observation of a patient under the neurologist's care, including the patient's response to cannabidiol treatment; and

(iii) Transmit the record described in subdivision (a)(i) of this subsection to the department upon request.

(b) All medical records received or maintained by the department pursuant to this section are confidential and may not be disclosed to the public.

(4) The University of Nebraska Medical Center shall create a risks and benefits form to be signed by the medical provider conducting the cannabidiol trial and by the patient who is to be administered cannabidiol or a parent or legal guardian of the patient if the patient

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is under nineteen years of age. The risks and benefits form shall document their discussion of the risks and benefits of invasive therapies, including, but not limited to, neurostimulation such as vagus nerve stimulation and responsive neurostimulation and epilepsy surgery, including corpus callosotomy, if indicated. The form shall also include a hold-harmless provision that releases from liability the state and any division, agency, institution, or employee thereof involved in the research, ordering, dispensing, or administration of cannabidiol, including its cultivation and processing. This form shall be completed and on file with the University of Nebraska Medical Center before the patient begins the cannabidiol trial.

(5) The University of Nebraska Medical Center shall provide a document to patients who are to be administered cannabidiol or a parent or legal guardian of such patients confirming participation in the Medical Cannabidiol Pilot Study. The document shall include, at a minimum, the patient's name, date of birth, and address, as well as the name and contact information of the patient's medical provider. If the patient is under nineteen years of age, the document shall also include the name, date of birth, and address of the parent or legal guardian of the patient. The document shall be accessible to law enforcement agencies in order to verify participation in the Medical Cannabidiol Pilot Study.

Sec. 7. (1) The University of Nebraska Medical Center, when using cannabidiol for research, shall comply with the Uniform Controlled Substances Act regarding possession of controlled substances, record-keeping requirements relative to the dispensing, use, or administration of controlled substances, and inventory requirements, as applicable.

(2) The University of Nebraska Medical Center College of Pharmacy and the University of Nebraska are authorized to pursue any federal permits or waivers necessary to conduct the activities authorized under sections 4 to 11 of this act.

Sec. 8. (1) In a prosecution for the unlawful possession of

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marijuana under the Uniform Controlled Substances Act, it is an affirmative and complete defense to prosecution that:

(a) The defendant suffered from intractable seizures or treatment resistant seizures and the use or possession of cannabidiol was pursuant to the order of a neurologist designated as a medical provider under section 6 of this act; or

(b) The defendant is the parent or legal guardian of an individual who suffers from intractable seizures or treatment resistant seizures and the use or possession of cannabidiol was pursuant to the order of a neurologist designated as a medical provider under section 6 of this act.

(2) An agency of this state or a political subdivision thereof, including any law enforcement agency, may not initiate proceedings to remove a child from a home based solely upon the possession or use of cannabidiol by the child or possession of cannabidiol by a parent or legal guardian for use by the child as authorized under sections 4 to 11 of this act.

(3) An employee of the state or any division, agency, or institution thereof involved in the research, ordering, dispensing, and administration of cannabidiol under sections 4 to 11 of this act, including its cultivation and processing, shall not be subject to prosecution for unlawful possession, use, distribution, or dispensing of marijuana under the Uniform Controlled Substances Act for activities arising from or related to the use of cannabidiol in the treatment of individuals diagnosed with intractable seizures or treatment resistant seizures.

Sec. 9. The University of Nebraska Medical Center shall submit a report electronically to the Judiciary Committee of the Legislature and the Health and Human Services Committee of the Legislature on or before September 15, 2016, and each September 15 thereafter, containing the following performance measures:

(1) The number of patients enrolled in the pilot study, including

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the number of patients under nineteen years of age;

(2) The number of patients previously enrolled in the pilot study and no longer receiving treatment under the pilot study;

(3) Any changes in intractable seizure or treatment resistant seizure frequency and severity;

(4) Any adverse health outcomes for patients; and

(5) A summary of findings concerning appropriate dosing.

Sec. 10. It is the intent of the Legislature to appropriate two hundred fifty thousand dollars for each fiscal year for FY2015-16 and FY2016-17 from the General Fund for the Medical Cannabidiol Pilot Study.

Sec. 11. Sections 4 to 11 of this act terminate on October 1, 2019.

Sec. 12. Original sections 28-101, 28-401, and 28-401.01, Revised Statutes Cumulative Supplement, 2014, are repealed.