Session of 2017

SENATE BILL No. 51

By Committee on Public Health and Welfare

1-20

AN ACT concerning the state board of pharmacy; relating to emergency scheduling of controlled substance analogs and new drugs; amending K.S.A. 2016 Supp. 21-5701, 65-4101 and 65-4102 and repealing the existing sections.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 2016 Supp. 21-5701 is hereby amended to read as follows: 21-5701. As used in K.S.A. 2016 Supp. 21-5701 through 21-5717, and amendments thereto: (a) "Controlled substance" means any drug, substance or immediate precursor included in any of the schedules designated in K.S.A. 65-4105, 65-4107, 65-4109, 65-4111 and 65-4113, and amendments thereto.

(b) (1) "Controlled substance analog" means a substance that is intended for human consumption, and *at least one of the following*:

(A) The chemical structure of ~~which~~ *the substance* is substantially similar to the chemical structure of a controlled substance listed in or added to the schedules designated in K.S.A. 65-4105 or 65-4107, and amendments thereto;

(B) ~~which~~ *the substance* has a stimulant, depressant or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant or hallucinogenic effect on the central nervous system of a controlled substance included in the schedules designated in K.S.A. 65-4105 or 65-4107, and amendments thereto; or

(C) with respect to a particular individual, ~~which the~~ *such* individual represents or intends *the substance* to have a stimulant, depressant or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant or hallucinogenic effect on the central nervous system of a controlled substance included in the schedules designated in K.S.A. 65-4105 or 65-4107, and amendments thereto.

(2) "Controlled substance analog" does not include:

(A) A controlled substance;

(B) a substance for which there is an approved new drug application; or

(C) a substance with respect to which an exemption is in effect for investigational use by a particular person under section 505 of the federal food, drug, and cosmetic act (21 U.S.C. § 355) to the extent conduct with

respect to the substance is permitted by the exemption.

(c) "Cultivate" means the planting or promotion of growth of five or more plants which contain or can produce controlled substances.

(d) "Distribute" means the actual, constructive or attempted transfer from one person to another of some item whether or not there is an agency relationship. "Distribute" includes, but is not limited to, sale, offer for sale or any act that causes some item to be transferred from one person to another. "Distribute" does not include acts of administering, dispensing or prescribing a controlled substance as authorized by the pharmacy act of the state of Kansas, the uniform controlled substances act or otherwise authorized by law.

(e) "Drug" means:

(1) Substances recognized as drugs in the official United States ~~pharmacopoeia~~ *pharmacopeia*, official homeopathic pharmacopoeia of the United States or official national formulary or any supplement to any of them;

(2) substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals;

(3) substances, other than food, intended to affect the structure or any function of the body of man or animals; and

(4) substances intended for use as a component of any article specified in paragraph (1), (2) or (3). It does not include devices or their components, parts or accessories.

(f) "Drug paraphernalia" means all equipment and materials of any kind which are used, or primarily intended or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling or otherwise introducing into the human body a controlled substance and in violation of this act. "Drug paraphernalia" shall include, but is not limited to:

(1) Kits used or intended for use in planting, propagating, cultivating, growing or harvesting any species of plant which is a controlled substance or from which a controlled substance can be derived;

(2) kits used or intended for use in manufacturing, compounding, converting, producing, processing or preparing controlled substances;

(3) isomerization devices used or intended for use in increasing the potency of any species of plant which is a controlled substance;

(4) testing equipment used or intended for use in identifying or in analyzing the strength, effectiveness or purity of controlled substances;

(5) scales and balances used or intended for use in weighing or measuring controlled substances;

(6) diluents and adulterants, including, but not limited to, quinine

hydrochloride, mannitol, mannite, dextrose and lactose, which are used or intended for use in cutting controlled substances;

(7) separation gins and sifters used or intended for use in removing twigs and seeds from or otherwise cleaning or refining marijuana;

(8) blenders, bowls, containers, spoons and mixing devices used or intended for use in compounding controlled substances;

(9) capsules, balloons, envelopes, bags and other containers used or intended for use in packaging small quantities of controlled substances;

(10) containers and other objects used or intended for use in storing or concealing controlled substances;

(11) hypodermic syringes, needles and other objects used or intended for use in parenterally injecting controlled substances into the human body;

(12) objects used or primarily intended or designed for use in ingesting, inhaling or otherwise introducing marijuana, cocaine, hashish, hashish oil, phencyclidine (PCP), methamphetamine or amphetamine into the human body, such as:

(A) Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens, permanent screens, hashish heads or punctured metal bowls;

(B) water pipes, bongs or smoking pipes designed to draw smoke through water or another cooling device;

(C) carburetion pipes, glass or other heat resistant tubes or any other device used ~~or~~, intended to be used~~;~~ *or* designed to be used to cause vaporization of a controlled substance for inhalation;

(D) smoking and carburetion masks;

(E) roach clips, objects used to hold burning material, such as a marijuana cigarette, that has become too small or too short to be held in the hand;

(F) miniature cocaine spoons and cocaine vials;

(G) chamber smoking pipes;

(H) carburetor smoking pipes;

(I) electric smoking pipes;

(J) air-driven smoking pipes;

(K) chillums;

(L) bongs;

(M) ice pipes or chillers;

(N) any smoking pipe manufactured to disguise its intended purpose;

(O) wired cigarette papers; or

(P) cocaine freebase kits.

"Drug paraphernalia" shall not include any products, chemicals or materials described in ~~subsection (a) of~~ K.S.A. 2016 Supp. 21-5709*(a)*, and amendments thereto.

(g) "Immediate precursor" means a substance which the *state* board of pharmacy has found to be and by rules and regulations designates as being 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 manufacture.

(h) "Isomer" means all enantiomers and diastereomers.

(i) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance either directly or indirectly or by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. "Manufacture" does not include:

(1) The preparation or compounding of a controlled substance by an individual for the individual's own lawful use or the preparation, compounding, packaging or labeling of a controlled substance:

(A) By a practitioner or the practitioner's agent pursuant to a lawful order of a practitioner as an incident to the practitioner's administering or dispensing of a controlled substance in the course of the practitioner's professional practice; or

(B) by a practitioner or by the practitioner's authorized agent under such practitioner's supervision for the purpose of or as an incident to research, teaching or chemical analysis or by a pharmacist or medical care facility as an incident to dispensing of a controlled substance; or

(2) the addition of diluents or adulterants, including, but not limited to, quinine hydrochloride, mannitol, mannite, dextrose or lactose, which are intended for use in cutting a controlled substance.

(j) "Marijuana" means all parts of all varieties of the plant Cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin. "Marijuana" does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, except the resin extracted therefrom, fiber, oil or cake or the sterilized seed of the plant which is incapable of germination.

(k) "Minor" means a person under 18 years of age.

(l) "Narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(1) Opium and opiate and any salt, compound, derivative or preparation of opium or opiate;

(2) any salt, compound, isomer, derivative or preparation thereof

which is chemically equivalent or identical with any of the substances referred to in paragraph (1) but not including the isoquinoline alkaloids of opium;

(3) opium poppy and poppy straw;

(4) coca leaves and any salt, compound, derivative or preparation of coca leaves and any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

(m) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. "Opiate" does not include, unless specifically designated as controlled under K.S.A. 65-4102, and amendments thereto, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). "Opiate" does include its racemic and levorotatory forms.

(n) "Opium poppy" means the plant of the species Papaver somniferum l. except its seeds.

(o) "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, association or any other legal entity.

(p) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(q) "Possession" means having joint or exclusive control over an item with knowledge of and intent to have such control or knowingly keeping some item in a place where the person has some measure of access and right of control.

(r) "School property" means property upon which is located a structure used by a unified school district or an accredited nonpublic school for student instruction or attendance or extracurricular activities of pupils enrolled in kindergarten or any of the grades one through 12. This definition shall not be construed as requiring that school be in session or that classes are actually being held at the time of the offense or that children must be present within the structure or on the property during the time of any alleged criminal act. If the structure or property meets the above definition, the actual use of that structure or property at the time alleged shall not be a defense to the crime charged or the sentence imposed.

(s) "Simulated controlled substance" means any product which identifies itself by a common name or slang term associated with a controlled substance and which indicates on its label or accompanying promotional material that the product simulates the effect of a controlled

substance.

Sec. 2. K.S.A. 2016 Supp. 65-4101 is hereby amended to read as follows: 65-4101. As used in this act: (a) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:

(1) A practitioner or pursuant to the lawful direction of a practitioner; or

(2) the patient or research subject at the direction and in the presence of the practitioner.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser. It does not include a common carrier, public warehouseman or employee of the carrier or warehouseman.

(c) "Application service provider" means an entity that sells electronic prescription or pharmacy prescription applications as a hosted service where the entity controls access to the application and maintains the software and records on its server.

(d) "Board" means the state board of pharmacy.

(e) "Bureau" means the bureau of narcotics and dangerous drugs, United States department of justice, or its successor agency.

(f) "Controlled substance" means any drug, substance or immediate precursor included in any of the schedules designated in K.S.A. 65-4105, 65-4107, 65-4109, 65-4111 and 65-4113, and amendments thereto.

(g) (1) "Controlled substance analog" means a substance that is intended for human consumption, and *at least one of the following*:

(A) The chemical structure of ~~which~~ *the substance* is substantially similar to the chemical structure of a controlled substance listed in or added to the schedules designated in K.S.A. 65-4105 or 65-4107, and amendments thereto;

(B) ~~which~~ *the substance* has a stimulant, depressant or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant or hallucinogenic effect on the central nervous system of a controlled substance included in the schedules designated in K.S.A. 65-4105 or 65-4107, and amendments thereto; or

(C) with respect to a particular individual, ~~which~~ such individual represents or intends *the substance* to have a stimulant, depressant or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant or hallucinogenic effect on the central nervous system of a controlled substance included in the schedules designated in K.S.A. 65-4105 or 65-4107, and amendments thereto.

(2) "Controlled substance analog" does not include:

(A) A controlled substance;

(B) a substance for which there is an approved new drug application; or

(C) a substance with respect to which an exemption is in effect for investigational use by a particular person under section 505 of the federal food, drug and cosmetic act, 21 U.S.C. § 355, to the extent conduct with respect to the substance is permitted by the exemption.

(h) "Counterfeit substance" means a controlled substance which, or 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 who in fact manufactured, distributed or dispensed the substance.

(i) "Cultivate" means the planting or promotion of growth of five or more plants which contain or can produce controlled substances.

(j) "DEA" means the U.S. department of justice, drug enforcement administration.

(k) "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.

(l) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the packaging, labeling or compounding necessary to prepare the substance for that delivery, or pursuant to the prescription of a mid-level practitioner.

(m) "Dispenser" means a practitioner or pharmacist who dispenses, or a physician assistant who has authority to dispense prescription-only drugs in accordance with K.S.A. 65-28a08(b), and amendments thereto.

(n) "Distribute" means to deliver other than by administering or dispensing a controlled substance.

(o) "Distributor" means a person who distributes.

(p) "Drug" means: (1) Substances recognized as drugs in the official United States ~~pharmacopoeia~~ *pharmacopeia*, official homeopathic pharmacopoeia of the United States or official national formulary or any supplement to any of them; (2) substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human or animals; (3) substances (other than food) intended to affect the structure or any function of the body of human or animals; and (4) substances intended for use as a component of any article specified in paragraph (1), (2) or (3). It does not include devices or their components, parts or accessories.

(q) "Immediate precursor" means a substance which the board has found to be and by rule and regulation designates as being 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 manufacture.

(r) "Electronic prescription" means an electronically prepared prescription that is authorized and transmitted from the prescriber to the pharmacy by means of electronic transmission.

(s) "Electronic prescription application" means software that is used to create electronic prescriptions and that is intended to be installed on the prescriber's computers and servers where access and records are controlled by the prescriber.

(t) "Electronic signature" means a confidential personalized digital key, code, number or other method for secure electronic data transmissions which identifies a particular person as the source of the message, authenticates the signatory of the message and indicates the person's approval of the information contained in the transmission.

(u) "Electronic transmission" means the transmission of an electronic prescription, formatted as an electronic data file, from a prescriber's electronic prescription application to a pharmacy's computer, where the data file is imported into the pharmacy prescription application.

(v) "Electronically prepared prescription" means a prescription that is generated using an electronic prescription application.

(w) "Facsimile transmission" or "fax transmission" means the transmission of a digital image of a prescription from the prescriber or the prescriber's agent to the pharmacy. "Facsimile transmission" includes, but is not limited to, transmission of a written prescription between the prescriber's fax machine and the pharmacy's fax machine; transmission of an electronically prepared prescription from the prescriber's electronic prescription application to the pharmacy's fax machine, computer or printer; or transmission of an electronically prepared prescription from the prescriber's fax machine to the pharmacy's fax machine, computer or printer.

(x) "Intermediary" means any technology system that receives and transmits an electronic prescription between the prescriber and the pharmacy.

(y) "Isomer" means all enantiomers and diastereomers.

(z) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance either directly or indirectly or by extraction from substances of natural origin or 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, except that this term does not include the preparation or compounding of a controlled substance by an individual for the individual's own lawful use or the preparation, compounding, packaging or labeling of a controlled

substance:

(1) By a practitioner or the practitioner's agent pursuant to a lawful order of a practitioner as an incident to the practitioner's administering or dispensing of a controlled substance in the course of the practitioner's professional practice; or

(2) by a practitioner or by the practitioner's authorized agent under such practitioner's supervision for the purpose of or as an incident to research, teaching or chemical analysis or by a pharmacist or medical care facility as an incident to dispensing of a controlled substance.

(aa) "Marijuana" means all parts of all varieties of the plant Cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, except the resin extracted therefrom, fiber, oil, or cake or the sterilized seed of the plant which is incapable of germination.

(bb) "Medical care facility" shall have the meaning ascribed to that term in K.S.A. 65-425, and amendments thereto.

(cc) "Mid-level practitioner" means a certified nurse-midwife engaging in the independent practice of midwifery under the independent practice of midwifery act, an advanced practice registered nurse issued a license pursuant to K.S.A. 65-1131, and amendments thereto, who has authority to prescribe drugs pursuant to a written protocol with a responsible physician under K.S.A. 65-1130, and amendments thereto, or a physician assistant licensed under the physician assistant licensure act who has authority to prescribe drugs pursuant to a written agreement with a supervising physician under K.S.A. 65-28a08, and amendments thereto.

(dd) "Narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(1) Opium and opiate and any salt, compound, derivative or preparation of opium or opiate;

(2) any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (1) but not including the isoquinoline alkaloids of opium;

(3) opium poppy and poppy straw;

(4) coca leaves and any salt, compound, derivative or preparation of coca leaves, and any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of these

substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

(ee) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under K.S.A. 65-4102, and amendments thereto, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

(ff) "Opium poppy" means the plant of the species Papaver somniferum l. except its seeds.

(gg) "Person" means an individual, corporation, government, or governmental subdivision or agency, business trust, estate, trust, partnership or association or any other legal entity.

(hh) "Pharmacist" means any natural person licensed under K.S.A. 65-1625 et seq., and amendments thereto, to practice pharmacy.

(ii) "Pharmacist intern" means: (1) A student currently enrolled in an accredited pharmacy program; (2) a graduate of an accredited pharmacy program serving such person's internship; or (3) a graduate of a pharmacy program located outside of the United States which is not accredited and who had successfully passed equivalency examinations approved by the board.

(jj) "Pharmacy prescription application" means software that is used to process prescription information, is installed on a pharmacy's computers and servers, and is controlled by the pharmacy.

(kk) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(ll) "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist, or scientific investigator or other person authorized by law to use a controlled substance in teaching or chemical analysis or to conduct research with respect to a controlled substance.

(mm) "Prescriber" means a practitioner or a mid-level practitioner.

(nn) "Production" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance.

(oo) "Readily retrievable" means that records kept by automatic data processing applications or other electronic or mechanized recordkeeping systems can be separated out from all other records within a reasonable time not to exceed 48 hours of a request from the board or other authorized agent or that hard-copy records are kept on which certain items are asterisked, redlined or in some other manner visually identifiable apart from other items appearing on the records.

(pp) "Ultimate user" means a person who lawfully possesses a

controlled substance for such person's own use or for the use of a member of such person's household or for administering to an animal owned by such person or by a member of such person's household.

Sec. 3. K.S.A. 2016 Supp. 65-4102 is hereby amended to read as follows: 65-4102. (a) The board shall administer this act and may adopt rules and regulations relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this state. All rules and regulations of the board shall be adopted in conformance with article 4 of chapter 77 of the Kansas Statutes Annotated*, and amendments thereto,* and the procedures prescribed by this act.

(b) Annually, the board shall submit to the speaker of the house of representatives and the president of the senate a report on substances proposed by the board for scheduling, rescheduling or deletion by the legislature with respect to any one of the schedules as set forth in this act, and reasons for the proposal shall be submitted by the board therewith. In making a determination regarding the proposal to schedule, reschedule or delete a substance, the board shall consider the following:

(1) The actual or relative potential for abuse;

(2) the scientific evidence of its pharmacological effect, if known;

(3) the state of current scientific knowledge regarding the substance;

(4) the history and current pattern of abuse;

(5) the scope, duration and significance of abuse;

(6) the risk to the public health;

(7) the potential of the substance to produce psychological or physiological dependence liability; and

(8) whether the substance is an immediate precursor of a substance already controlled under this article.

(c) The board shall not include any nonnarcotic substance within a schedule if such substance may be lawfully sold over the counter without a prescription under the federal food, drug and cosmetic act.

(d) Authority to control under this section does not extend to distilled spirits, wine, malt beverages or tobacco.

(e) Upon receipt of notice under K.S.A. 2016 Supp. 21-5715, and amendments thereto, *or upon the board's finding of an imminent hazard to the public safety,* the board shall initiate scheduling of the controlled substance analog *or a new drug, as defined by K.S.A. 65-656, and amendments thereto,* on an emergency basis pursuant to this subsection. The scheduling of a substance under this subsection expires ~~one year~~ *on July 1 of the following calendar year* after the adoption of the scheduling rule. With respect to the finding of an imminent hazard to the public safety, the board shall consider whether the substance has been scheduled on a temporary basis under federal law or factors set forth in subsections (b)(4), (5) and (6), and may also consider clandestine importation, manufacture or

distribution, and if available, information concerning the other factors set forth in subsection (b). A rule may not be adopted under this subsection until the board initiates a rulemaking proceeding under subsection (a) with respect to the substance. A rule adopted under this subsection lapses upon the conclusion of the rulemaking proceeding initiated under subsection (a) with respect to the substance.

Sec. 4. K.S.A. 2016 Supp. 21-5701, 65-4101 and 65-4102 are hereby repealed.

Sec. 5. This act shall take effect and be in force from and after its publication in the Kansas register.