Session of 2017

HOUSE BILL No. 2107

By Committee on Health and Human Services

1-19

AN ACT concerning public health; relating to the pharmacy act of the state of Kansas; pertaining to biological products; amending K.S.A. 65-669, 65-1660 and 65-7007 and K.S.A. 2016 Supp. 65-1626, 65-1637, 65-1637b, 65-1643, 65-2837a and 65-4202 and repealing the existing sections.

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

Sec. 1. K.S.A. 65-669 is hereby amended to read as follows: 65-669. A drug or device shall be deemed to be misbranded:

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing:

(1) The name and place of business of the manufacturer, the packer or the distributor, except that in the case of a prescription drug it shall bear the name and place of business of the person responsible for the production of the finished dosage form of the drug, the packer and the distributor; except that nothing in ~~clause (1) of~~ this paragraph shall be construed to apply to wholesalers and the requirement of ~~clause (1)~~ *this paragraph* shall be satisfied by stating such information on the label of the drug and filing a statement with such information with the secretary which shall be made available by the secretary on request to local, public and private health agencies, poison control centers, licentiates of the healing arts, the state board of pharmacy, consumers and others to promote the purposes of this act; in no event, however, shall the label contain less information than required under federal law; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under ~~clause (2) of~~ this paragraph reasonable variations shall be permitted and exemptions as to small packages shall be allowed, in accordance with regulations prescribed by the secretary, or issued under the federal act.

(c) If any word, statement, or other information required by or under authority of this act to appear on the label or labeling is not prominently placed thereon with such conspicuousness ~~(~~*,* as compared with other words, statements, designs or devices, in the labeling~~)~~*,* and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of narcotic or

hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of such substance, which derivative has been by the secretary after investigation, found to be, and by regulations under this act, or by regulations issued pursuant to 21 U.S.C. § 352(d), designated as, habit forming, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "warning-may be habit forming."

(e) (1) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name ~~(~~*,* except the applicable systematic chemical name or the chemical formula~~), (i)~~*; (A)* The established name ~~(~~as defined in ~~subparagraph~~ *paragraph* (2)~~)~~ *of this subsection* of the drug, if such there be; and ~~(ii)~~ *(B)* in case it is fabricated from two or more ingredients, the established name of each active ingredient, including the kind and quantity of proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein. The requirements for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs. To the extent that compliance with the requirements of ~~clause (ii)~~ of this ~~subparagraph~~ *paragraph* is impracticable, exemptions shall be allowed under regulations promulgated by the secretary, or under the federal act.

(2) As used in this ~~paragraph~~ *subsection* (e), the term "established name," with respect to a drug or ingredient thereof, means*:*

(A) The applicable official name designated pursuant to 21 U.S.C. *§* 358~~, or~~*;*

(B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium*;* or

(C) if neither ~~clause~~ *subparagraph* (A) nor ~~clause~~ *subparagraph* (B) of this ~~subparagraph~~ *paragraph* applies, then the common or usual name, if any, of such drug or of such ingredient. Where ~~clause~~ *subparagraph* (B) of this ~~subparagraph~~ *paragraph* applies to an article recognized in the United States ~~pharmacopoeia~~ *pharmacopeia* and in the homeopathic pharmacopoeia under different official titles, the official title used in the United States ~~pharmacopoeia~~ *pharmacopeia* shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the homeopathic pharmacopoeia shall apply.

(f) Unless its labeling bears*:*

(1) Adequate directions for use; and

(2) such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

(3) Where any requirement of ~~clause~~ *paragraph* (1) *or (2)* of this ~~paragraph~~ *subsection*, as applied to any drug or device, is not necessary for the protection of the public health, the secretary shall promulgate regulations exempting such drug or device from such requirements. Articles exempted under regulations issued under 21 U.S.C. § 352(f) may also be exempt.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the secretary, or if consent is obtained under the federal act. Whenever a drug is recognized in both the United States ~~pharmacopoeia~~ *pharmacopeia* and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States ~~pharmacopoeia~~ *pharmacopeia* with respect to the packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States, and not to those of the United States ~~pharmacopoeia~~ *pharmacopeia*. In the event of inconsistency between the requirements of this ~~paragraph~~ *subsection* and those of ~~paragraph~~ *subsection* (e) as to the name by which the drug or its ingredients shall be designated, the requirements of ~~paragraph~~ *subsection* (e) shall prevail.

(h) If it has been found by the secretary or under the federal act to be a drug liable to deterioration, unless it is packed in such form and manner, and its label bears a statement of such precautions, as the regulations adopted by the secretary require as necessary for the protection of public health. No such regulations shall be established for any drug recognized in an official compendium until the secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; ~~or~~ (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended, or suggested in the labeling thereof.

(k) If it is, or purports to be, or is represented as a drug composed

wholly or partly of insulin, unless*:* (1) It is from a batch with respect to which a certificate or release has been issued pursuant to 21 U.S.C. § 356~~,~~*;* and (2) such certificate or release is in effect with respect to such drug.

(l) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless*:* (1) It is from a batch with respect to which a certificate or release has been issued pursuant to 21 U.S.C. § 357~~,~~*;* and (2) such certificate or release is in effect with respect to such drug. This ~~paragraph~~ *subsection* shall not apply to any drug or class of drugs exempted by regulations promulgated under 21 U.S.C. § 357(c) or (d). For the purpose of this subsection the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution ~~(~~*,* including the chemically synthesized equivalent of any such substance~~)~~.

(m) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of K.S.A. 65-667*, and amendments thereto,* or of the federal act.

(n) In the case of any prescription drug distributed or offered for sale in this state, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of*:* (1) The established name, as defined in subsection (e) (2) of this section~~,~~*;* (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under 21 U.S.C. § 352(e)~~,~~*;* and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations issued under the federal act.

(o) If a trademark, trade name or other identifying mark, imprint or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.

(p) Drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed shall be exempt from any labeling or packaging requirements of this act if such drugs and devices are being delivered, manufactured, processed, labeled, repacked or otherwise held in compliance with regulations issued by the secretary or under the federal act.

(q) A drug intended for use by ~~man which~~ *humans that:*

~~(A)~~ *(1)* Is a habit-forming drug to which K.S.A. 65-668*, and*

amendments thereto, applies; or

~~(B)~~ *(2)* because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

~~(C)~~ *(3)* is limited by an approved application under 21 U.S.C. § 355 or K.S.A. 65-669a*, and amendments thereto,* to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only*:*

~~(i)~~ *(A)* Upon a written prescription of a practitioner licensed by law to administer such drug or upon the written prescription of a mid-level practitioner as defined in ~~subsection (ii) of~~ K.S.A. 65-1626*,* and amendments thereto~~,~~*;* or

~~(ii)~~ *(B)* upon an oral prescription of such practitioner or mid-level practitioner which is reduced promptly to writing and filed by the pharmacist~~,~~*;* or

~~(iii)~~ *(C)* by refilling, any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the ~~pharmacist.~~

The act of dispensing a drug contrary to the provisions of this ~~paragraph~~ *subsection* shall be deemed to be an act which results in a drug being misbranded while held for sale.

(r) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug or by filling or refilling a written or oral prescription of a mid-level practitioner as defined in ~~subsection (ii) of~~ K.S.A. 65-1626*,* and amendments thereto*,* shall be exempt from the requirements of this section, except subsections (a), (i) (2) and (3), (k), and (l), and the packaging requirements of subsections (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of ~~paragraph~~ *subsection* (q) of this section.

(s) The secretary may, by regulation, remove drugs subject to subsection (d) of this section and K.S.A. 65-669a*, and amendments thereto,* from the requirements of ~~paragraph~~ *subsection* (q) of this section when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the federal act by regulations issued thereunder may also, by *rules and* regulations

issued by the secretary, be removed from the requirements of ~~paragraph~~ *subsection* (q) of this section.

(t) A drug which is subject to ~~paragraph~~ *subsection* (q) of this section shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "caution: federal law prohibits dispensing without prescription," or "caution: state law prohibits dispensing without prescription." A drug to which ~~paragraph~~ *subsection* (q) of this section does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(u) Nothing in this section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications of narcotic drugs or marijuana as defined in the applicable federal and state laws relating to narcotic drugs and marijuana.

Sec. 2. K.S.A. 2016 Supp. 65-1626 is hereby amended to read as follows: 65-1626. For the purposes of this act:

(a) "Administer" means the direct application of a drug, 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;

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

(3) a pharmacist as authorized in K.S.A. 65-1635a, and amendments thereto.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser but shall not include a common carrier, public warehouseman or employee of the carrier or warehouseman when acting in the usual and lawful course of the carrier's or warehouseman's business.

(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) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in section 1504 of the internal revenue code, complies with any one of the following: (1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and (2) the wholesale

distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

(e) *"Biological product" means the same as that term is defined in 42 U.S.C. § 262(i), as in effect on July 1, 2017.*

(f) "Board" means the state board of pharmacy created by K.S.A. 74-1603, and amendments thereto.

~~(f)~~ *(g)* "Brand exchange," *in the case of a drug product prescribed,* means the dispensing of a different drug product of the same dosage form and strength and of the same generic name as the brand name drug product prescribed*, and in the case of a biological product prescribed, means the dispensing of a biological product determined by the federal food and drug administration to be interchangeable with the biological product prescribed*.

~~(g)~~ *(h)* "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler or distributor.

~~(h)~~ *(i)* "Chain pharmacy warehouse" means a permanent physical location for drugs or devices, or both, that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs or devices to chain pharmacies that have the same ownership or control. Chain pharmacy warehouses must be registered as wholesale distributors.

~~(i)~~ *(j)* "Co-licensee" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug and the national drug code on the drug product label shall be used to determine the identity of the drug manufacturer.

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

~~(k)~~ *(l)* "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of any drug whether or not an agency relationship exists.

~~(l)~~ *(m)* "Direct supervision" means the process by which the responsible pharmacist shall observe and direct the activities of a pharmacy student or pharmacy technician to a sufficient degree to assure that all such activities are performed accurately, safely and without risk or harm to patients, and complete the final check before dispensing.

~~(m)~~ *(n)* "Dispense" means to deliver prescription medication to the ultimate user or research subject by or pursuant to the lawful order of a practitioner or pursuant to the prescription of a mid-level practitioner.

~~(n)~~ *(o)* "Dispenser" means a practitioner or pharmacist who dispenses prescription medication, or a physician assistant who has authority to dispense prescription-only drugs in accordance with K.S.A. 65-28a08~~(b)~~,

and amendments thereto.

~~(o)~~ *(p)* "Distribute" means to deliver, other than by administering or dispensing, any drug.

~~(p)~~ *(q)* "Distributor" means a person who distributes a drug.

~~(q)~~ *(r)* "Drop shipment" means the sale, by a manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of the manufacturer's prescription drug, to a wholesale distributor whereby the wholesale distributor takes title but not possession of such prescription drug and the wholesale distributor invoices the pharmacy, the chain pharmacy warehouse, or other designated person authorized by law to dispense or administer such prescription drug, and the pharmacy, the chain pharmacy warehouse, or other designated person authorized by law to dispense or administer such prescription drug receives delivery of the prescription drug directly from the manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of such prescription drug. Drop shipment shall be part of the "normal distribution channel."

~~(r)~~ *(s)* "Drug" means: (1) Articles recognized in the official United States ~~pharmacopoeia~~ *pharmacopeia*, or other such official compendiums of the United States, or official national formulary, or any supplement of any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human or other animals; (3) articles, other than food, intended to affect the structure or any function of the body of human or other animals; and (4) articles intended for use as a component of any articles specified in paragraph (1), (2) or (3); but does not include devices or their components, parts or accessories, except that the term "drug" shall not include amygdalin (laetrile) or any livestock remedy, if such livestock remedy had been registered in accordance with the provisions of article 5 of chapter 47 of the Kansas Statutes Annotated, prior to its repeal.

~~(s)~~ *(t)* "Durable medical equipment" means technologically sophisticated medical devices that may be used in a residence, including the following: (1) Oxygen and oxygen delivery system; (2) ventilators; (3) respiratory disease management devices; (4) continuous positive airway pressure (CPAP) devices; (5) electronic and computerized wheelchairs and seating systems; (6) apnea monitors; (7) transcutaneous electrical nerve stimulator (TENS) units; (8) low air loss cutaneous pressure management devices; (9) sequential compression devices; (10) feeding pumps; (11) home phototherapy devices; (12) infusion delivery devices; (13) distribution of medical gases to end users for human consumption; (14) hospital beds; (15) nebulizers; or (16) other similar equipment determined by the board in rules and regulations adopted by the board.

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

~~(u)~~ *(v)* "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.

~~(v)~~ *(w)* "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.

~~(w)~~ *(x)* "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.

~~(x)~~ *(y)* "Electronically prepared prescription" means a prescription that is generated using an electronic prescription application.

~~(y)~~ *(z)* "Exclusive distributor" means any entity that: (1) Contracts with a manufacturer to provide or coordinate warehousing, wholesale distribution or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug; (2) is registered as a wholesale distributor under the pharmacy act of the state of Kansas; and (3) to be considered part of the normal distribution channel, must be an authorized distributor of record.

~~(z)~~ *(aa)* "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.

~~(aa)~~ *(bb)* "Generic name" means the established chemical name or official name of a drug or drug product.

~~(bb)~~ *(cc)* (1) "Institutional drug room" means any location where prescription-only drugs are stored and from which prescription-only drugs are administered or dispensed and which is maintained or operated for the purpose of providing the drug needs of:

(A) Inmates of a jail or correctional institution or facility;

(B) residents of a juvenile detention facility, as defined by the revised Kansas code for care of children and the revised Kansas juvenile justice code;

(C) students of a public or private university or college, a community college or any other institution of higher learning which is located in Kansas;

(D) employees of a business or other employer; or

(E) persons receiving inpatient hospice services.

(2) "Institutional drug room" does not include:

(A) Any registered pharmacy;

(B) any office of a practitioner; or

(C) a location where no prescription-only drugs are dispensed and no prescription-only drugs other than individual prescriptions are stored or administered.

~~(ee)~~ *(dd) "Interchangeable biological product" means a biological product that the federal food and drug administration has:*

(1) Licensed and determined meets the standards for "interchangeability" as that term is defined in 42 U.S.C. § 262(k), as of July 1, 2017; or

(2) has determined to be therapeutically equivalent as set forth in the latest edition or supplement of the food and drug administration approved drug products with therapeutic equivalence evaluations.

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

~~(dd)~~ *(ff)* "Intracompany transaction" means any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership or control of a corporate entity, or any transaction or transfer between co-licensees of a co-licensed product.

~~(ee)~~ *(gg)* "Medical care facility" shall have the meaning provided in K.S.A. 65-425, and amendments thereto, except that the term shall also include facilities licensed under the provisions of K.S.A. 75-3307b, and amendments thereto, except community mental health centers and facilities for people with intellectual disability.

~~(ff)~~ *(hh)* "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a drug 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 drug or labeling or relabeling of its container, except that this term shall not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug by:

(1) A practitioner or a practitioner's authorized agent incident to such practitioner's administering or dispensing of a drug in the course of the practitioner's professional practice;

(2) a practitioner, by a practitioner's authorized agent or under a practitioner's supervision for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale; or

(3) a pharmacist or the pharmacist's authorized agent acting under the direct supervision of the pharmacist for the purpose of, or incident to, the dispensing of a drug by the pharmacist.

~~(gg)~~ *(ii)* "Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs and devices.

~~(hh)~~ *(jj)* "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 pursuant to 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.

~~(ii)~~ *(kk)* "Normal distribution channel" means a chain of custody for a prescription-only drug that goes from a manufacturer of the prescription-only drug, from that manufacturer to that manufacturer's co-licensed partner, from that manufacturer to that manufacturer's third-party logistics provider or from that manufacturer to that manufacturer's exclusive distributor, directly or by drop shipment, to:

(1) A pharmacy to a patient or to other designated persons authorized by law to dispense or administer such drug to a patient;

(2) a wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(3) a wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or

(4) a chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient.

~~(jj)~~ *(ll)* "Person" means individual, corporation, government, governmental subdivision or agency, partnership, association or any other legal entity.

~~(kk)~~ *(mm)* "Pharmacist" means any natural person licensed under this

act to practice pharmacy.

~~(ll)~~ *(nn)* "Pharmacist-in-charge" means the pharmacist who is responsible to the board for a registered establishment's compliance with the laws and regulations of this state pertaining to the practice of pharmacy, manufacturing of drugs and the distribution of drugs. The pharmacist-in-charge shall supervise such establishment on a full-time or a part-time basis and perform such other duties relating to supervision of a registered establishment as may be prescribed by the board by rules and regulations. Nothing in this definition shall relieve other pharmacists or persons from their responsibility to comply with state and federal laws and regulations.

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

~~(nn)~~ *(pp)* "Pharmacy," "drugstore" or "apothecary" means premises, laboratory, area or other place: (1) Where drugs are offered for sale where the profession of pharmacy is practiced and where prescriptions are compounded and dispensed; or (2) which has displayed upon it or within it the words "pharmacist," "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of these words or combinations of these words or words of similar import either in English or any sign containing any of these words; or (3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited. As used in this subsection, premises refers only to the portion of any building or structure leased, used or controlled by the licensee in the conduct of the business registered by the board at the address for which the registration was issued.

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

~~(pp)~~ *(rr)* "Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, may perform packaging, manipulative, repetitive or other nondiscretionary tasks related to the processing of a prescription or medication order and who assists the pharmacist in the performance of pharmacy related duties, but who does not perform duties restricted to a pharmacist.

~~(qq)~~ *(ss)* "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 prescription-only drug in teaching or chemical analysis or to conduct research with respect

to a prescription-only drug.

~~(rr)~~ *(tt)* "Preceptor" means a licensed pharmacist who possesses at least two years' experience as a pharmacist and who supervises students obtaining the pharmaceutical experience required by law as a condition to taking the examination for licensure as a pharmacist.

~~(ss)~~ *(uu)* "Prescriber" means a practitioner or a mid-level practitioner.

~~(tt)~~ *(vv)* "Prescription" or "prescription order" means: (1) An order to be filled by a pharmacist for prescription medication issued and signed by a prescriber in the authorized course of such prescriber's professional practice; or (2) an order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such prescriber, regardless of whether the communication is oral, electronic, facsimile or in printed form.

~~(uu)~~ *(ww)* "Prescription medication" means any drug, including label and container according to context, which is dispensed pursuant to a prescription order.

~~(vv)~~ *(xx)* "Prescription-only drug" means any drug whether intended for use by human or animal, required by federal or state law, including 21 U.S.C. § 353, to be dispensed only pursuant to a written or oral prescription or order of a practitioner or is restricted to use by practitioners only.

~~(ww)~~ *(yy)* "Probation" means the practice or operation under a temporary license, registration or permit or a conditional license, registration or permit of a business or profession for which a license, registration or permit is granted by the board under the provisions of the pharmacy act of the state of Kansas requiring certain actions to be accomplished or certain actions not to occur before a regular license, registration or permit is issued.

~~(xx)~~ *(zz)* "Professional incompetency" means:

(1) One or more instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes gross negligence, as determined by the board;

(2) repeated instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes ordinary negligence, as determined by the board; or

(3) a pattern of pharmacy practice or other behavior which demonstrates a manifest incapacity or incompetence to practice pharmacy.

~~(yy)~~ *(aaa)* "Readily retrievable" means that records kept by automatic data processing applications or other electronic or mechanized record-keeping 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.

~~(zz)~~ *(bbb)* "Retail dealer" means a person selling at retail nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a prescription-only drug; or (3) a drug intended for human use by hypodermic injection.

~~(aaa)~~ *(ccc)* "Secretary" means the executive secretary of the board.

~~(bbb)~~ *(ddd)* "Third party logistics provider" means an entity that: (1) Provides or coordinates warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition; (2) is registered as a wholesale distributor under the pharmacy act of the state of Kansas; and (3) to be considered part of the normal distribution channel, must also be an authorized distributor of record.

~~(ccc)~~ *(eee)* "Unprofessional conduct" means:

(1) Fraud in securing a registration or permit;

(2) intentional adulteration or mislabeling of any drug, medicine, chemical or poison;

(3) causing any drug, medicine, chemical or poison to be adulterated or mislabeled, knowing the same to be adulterated or mislabeled;

(4) intentionally falsifying or altering records or prescriptions;

(5) unlawful possession of drugs and unlawful diversion of drugs to others;

(6) willful betrayal of confidential information under K.S.A. 65-1654, and amendments thereto;

(7) conduct likely to deceive, defraud or harm the public;

(8) making a false or misleading statement regarding the licensee's professional practice or the efficacy or value of a drug;

(9) commission of any act of sexual abuse, misconduct or exploitation related to the licensee's professional practice; or

(10) performing unnecessary tests, examinations or services which have no legitimate pharmaceutical purpose.

~~(ddd)~~ *(fff)* "Vaccination protocol" means a written protocol, agreed to by a pharmacist and a person licensed to practice medicine and surgery by the state board of healing arts, which establishes procedures and recordkeeping and reporting requirements for administering a vaccine by the pharmacist for a period of time specified therein, not to exceed two years.

~~(eee)~~ *(ggg)* "Valid prescription order" means a prescription that is issued for a legitimate medical purpose by an individual prescriber licensed by law to administer and prescribe drugs and acting in the usual

course of such prescriber's professional practice. A prescription issued solely on the basis of an internet-based questionnaire or consultation without an appropriate prescriber-patient relationship is not a valid prescription order.

~~(fff)~~ *(hhh)* "Veterinary medical teaching hospital pharmacy" means any location where prescription-only drugs are stored as part of an accredited college of veterinary medicine and from which prescription-only drugs are distributed for use in treatment of or administration to a nonhuman.

~~(ggg)~~ *(iii)* "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs or devices in or into the state, including, but not limited to, manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees, exclusive distributors, third party logistics providers, chain pharmacy warehouses that conduct wholesale distributions, and wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distributions. Wholesale distributor shall not include persons engaged in the sale of durable medical equipment to consumers or patients.

~~(hhh)~~ *(jjj)* "Wholesale distribution" means the distribution of prescription drugs or devices by wholesale distributors to persons other than consumers or patients, and includes the transfer of prescription drugs by a pharmacy to another pharmacy if the total number of units of transferred drugs during a twelve-month period does not exceed 5% of the total number of all units dispensed by the pharmacy during the immediately preceding twelve-month period. Wholesale distribution does not include:

(1) The sale, purchase or trade of a prescription drug or device, an offer to sell, purchase or trade a prescription drug or device or the dispensing of a prescription drug or device pursuant to a prescription;

(2) the sale, purchase or trade of a prescription drug or device or an offer to sell, purchase or trade a prescription drug or device for emergency medical reasons;

(3) intracompany transactions, as defined in this section, unless in violation of own use provisions;

(4) the sale, purchase or trade of a prescription drug or device or an offer to sell, purchase or trade a prescription drug or device among hospitals, chain pharmacy warehouses, pharmacies or other health care entities that are under common control;

(5) the sale, purchase or trade of a prescription drug or device or the offer to sell, purchase or trade a prescription drug or device by a charitable organization described in 503(c)(3) of the internal revenue code of 1954 to

a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(6) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a prescription drug or device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;

(7) the transfer of prescription drugs or devices between pharmacies pursuant to a centralized prescription processing agreement;

(8) the sale, purchase or trade of blood and blood components intended for transfusion;

(9) the return of recalled, expired, damaged or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy, chain pharmacy warehouse or charitable institution in accordance with the board's rules and regulations;

(10) the sale, transfer, merger or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's rules and regulations;

(11) the distribution of drug samples by manufacturers' and authorized distributors' representatives;

(12) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use; or

(13) the sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned or recalled prescription drugs to the original manufacturer, originating wholesale distributor or to a third party returns processor in accordance with the board's rules and regulations.

Sec. 3. K.S.A. 2016 Supp. 65-1637 is hereby amended to read as follows: 65-1637. In every store, shop or other place defined in this act as a "pharmacy" there shall be a pharmacist in charge and, except as otherwise provided by law, the compounding and dispensing of prescriptions shall be limited to pharmacists only. Except as otherwise provided by the pharmacy act of this state, when a pharmacist is not in attendance at a pharmacy, the premises shall be enclosed and secured. Prescription orders may be written, oral, telephonic or by electronic transmission unless prohibited by law. Blank forms for written prescription orders may have two signature lines. If there are two lines, one signature line shall state: "dispense as written" and the other signature line shall state: "brand exchange permissible." Prescriptions shall only be filled or refilled in accordance with the following requirements:

(a) All prescriptions shall be filled in strict conformity with any

directions of the prescriber, except *that*:

(1) ~~That~~ A pharmacist may provide up to three-month supply of a prescription drug that is not a controlled substance or psychotherapeutic drug when a practitioner has written a drug order to be filled with a smaller supply but included sufficient numbers of refills for a three-month supply;~~ and~~

(2) ~~that~~ a pharmacist who receives a prescription order for a brand name drug product may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

(A) The prescriber, in the case of a prescription signed by the prescriber and written on a blank form containing two signature lines, signs the signature line following the statement "dispense as written,"

(B) the prescriber, in the case of a prescription signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" on the prescription,

(C) the prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated, or

(D) the federal food and drug administration has determined that a drug product of the same generic name is not bioequivalent to the prescribed brand name prescription medication*; and*

(3) a pharmacist who received a prescription order for a biological product may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

(A) The prescriber, in the case of a prescription signed by a prescriber and written on a blank form containing two signature lines, signs the signature line following the statement "dispense as written";

(B) the prescriber, in the case of a prescription signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" on the prescription;

(C) the prescriber, in the case of a prescription other than the one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated; or

(D) the federal food and drug administration has not determined the biological product to be interchangeable with the prescribed biological product.

(b) *A pharmacist who selects an interchangeable biological product shall, prior to dispensing an interchangeable biological product, inform the patient or the patient's representative that an interchangeable biological product will be substituted for the biological product prescribed*.

(c) Prescription orders shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original

prescription to be dispensed by the pharmacist. This record, if telephoned by other than the physician shall bear the name of the person so telephoning. Nothing in this paragraph shall be construed as altering or affecting in any way laws of this state or any federal act requiring a written prescription order.

~~(c)~~ *(d)* (1) Except as provided in paragraph (2), no prescription shall be refilled unless authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

(2) A pharmacist may refill a prescription order issued on or after the effective date of this act for any prescription drug *or biological product* except a drug listed on schedule II of the uniform controlled substances act or a narcotic drug listed on any schedule of the uniform controlled substances act without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional judgment, continuation of the medication is necessary for the patient's health, safety and welfare. Such prescription refill shall only be in an amount judged by the pharmacist to be sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this paragraph be more than a seven day supply or one package of the drug. However, if the prescriber states on a prescription that there shall be no emergency refilling of that prescription, then the pharmacist shall not dispense any emergency medication pursuant to that prescription. A pharmacist who refills a prescription order under this ~~subsection (c)(2)~~ *paragraph* shall contact the prescriber of the prescription order on the next business day subsequent to the refill or as soon thereafter as possible. No pharmacist shall be required to refill any prescription order under this ~~subsection (c)(2)~~ *paragraph*. A prescriber shall not be subject to liability for any damages resulting from the refilling of a prescription order by a pharmacist under this ~~subsection (c)(2)~~ *paragraph* unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions by the prescriber.

~~(d)~~ *(e)* If any prescription order contains a provision that the prescription may be refilled a specific number of times within or during any particular period, such prescription shall not be refilled except in strict conformity with such requirements.

~~(e)~~ *(f)* If a prescription order contains a statement that during any particular time the prescription may be refilled at will, there shall be no limitation as to the number of times that such prescription may be refilled except that it may not be refilled after the expiration of the time specified or one year after the prescription was originally issued, whichever occurs first.

~~(f)~~ *(g)* Any pharmacist who exercises brand exchange and dispenses a

less expensive drug *or interchangeable biological* product shall not charge the purchaser more than the regular and customary retail price for the dispensed drug *or biological product*.

Nothing contained in this section shall be construed as preventing a pharmacist from refusing to fill or refill any prescription if in the pharmacist's professional judgment and discretion such pharmacist is of the opinion that it should not be filled or refilled.

(h) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:

(1) An inter-operable electronic medical records system;

(2) an electronic prescribing technology;

(3) a pharmacy benefits management system; or

(4) a pharmacy record.

(i) Entry into an electronic records system as described in subsection (h) shall be presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission or other prevailing means, provided that communication shall not be required where:

(1) There is no federal food and drug administration approved interchangeable biological product for the product prescribed; or

(2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(j) The pharmacist shall maintain a record of the biological product dispensed for at least five years.

(k) The board shall maintain a link on its website to the current list of all biological products that the federal food and drug administration has determined to be interchangeable biological products.

Sec. 4. K.S.A. 2016 Supp. 65-1637b is hereby amended to read as follows: 65-1637b. (a) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of any prescription order consistent with federal and state laws and rules and regulations. A pharmacist shall not dispense a prescription drug if the pharmacist, in the exercise of professional judgment, determines that the prescription is not a valid prescription order.

(b) The prescriber may authorize an agent to transmit to the pharmacy a prescription order orally, by facsimile transmission or by electronic transmission provided that the first and last names of the transmitting agent are included in the order.

(c) (1) A new written or electronically prepared and transmitted prescription order shall be manually or electronically signed by the prescriber. If transmitted by the prescriber's agent, the first and last names of the transmitting agent shall be included in the order.

(2) If the prescription is for a controlled substance and is written or printed from an electronic prescription application, the prescription shall be manually signed by the prescriber prior to delivery of the prescription to the patient or prior to facsimile transmission of the prescription to the pharmacy.

(3) An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to electronic transmission. An electronically prepared and transmitted prescription which is printed following electronic transmission shall be clearly labeled as a copy, not valid for dispensing.

(4) In consultation with industry, the state board of pharmacy shall conduct a study on the issues of electronic transmission of prior authorizations and step therapy protocols. ~~The report on the results of such study shall be completed and submitted to the legislature no later than January 15, 2013.~~

(5) The board is hereby authorized to conduct pilot projects related to any new technology implementation when deemed necessary and practicable, except that no state moneys shall be expended for such purpose.

(d) An authorization to refill a prescription order or to renew or continue an existing drug therapy may be transmitted to a pharmacist through oral communication, in writing, by facsimile transmission or by electronic transmission initiated by or directed by the prescriber.

(1) If the transmission is completed by the prescriber's agent, and the first and last names of the transmitting agent are included in the order, the prescriber's signature is not required on the fax or alternate electronic transmission.

(2) If the refill order or renewal order differs in any manner from the original order, such as a change of the drug strength, dosage form or directions for use, the prescriber shall sign the order as provided by paragraph (1).

(e) Regardless of the means of transmission to a pharmacy, only a pharmacist or a pharmacist intern shall be authorized to receive a new prescription order from a prescriber or transmitting agent. A pharmacist, a pharmacist intern or a registered pharmacy technician may receive a refill or renewal order from a prescriber or transmitting agent if such registered pharmacy technician's supervising pharmacist has authorized that function.

(f) A refill is one or more dispensings of a prescription drug or device that results in the patient's receipt of the quantity authorized by the

prescriber for a single fill as indicated on the prescription order. A prescription for a schedule III, IV or V controlled substance may authorize no more than five refills within six months following the date on which the prescription is issued.

(g) Prescriptions shall only be filled or refilled in accordance with the following requirements:

(1) All prescriptions shall be filled in strict conformity with any directions of the prescriber, except that a pharmacist who receives a prescription order for a brand name drug product may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

(A) The prescriber, in the case of a prescription electronically signed by the prescriber, includes the statement "dispense as written" on the prescription;

(B) the prescriber, in the case of a written prescription signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" on the prescription;

(C) the prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated; or

(D) the federal food and drug administration has determined that a drug product of the same generic name is not bioequivalent to the prescribed brand name prescription medication.

(2) All prescriptions shall be filled in strict conformity with any directions of the prescriber, except that a pharmacist who receives a prescription order for a biological product may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

(A) The prescriber, in the case of a prescription signed by the prescriber and written on a blank form containing two signature lines, signs the signature line following the statement "dispense as written";

(B) the prescriber, in the case of a prescription signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" on the prescription;

(C) the prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated; or

(D) the federal food and drug administration has not determined the biological product to be interchangeable with the prescribed biological product.

(h) If a prescription order contains a statement that during any particular time the prescription may be refilled at will, there shall be no limitation as to the number of times that such prescription may be refilled except that it may not be refilled after the expiration of the time specified

or one year after the prescription was originally issued, whichever occurs first.

(i) Prescription orders shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be dispensed by the pharmacist. This record, if telephoned by other than the prescriber, shall bear the full name of the person so telephoning. Nothing in this section shall be construed as altering or affecting in any way laws of this state or any federal act requiring a written prescription order.

(j) (1) Except as provided in paragraph (2), no prescription shall be refilled unless authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

(2) A pharmacist may refill a prescription order issued on or after the effective date of this act for any prescription drug except a drug listed on schedule II of the uniform controlled substances act or a narcotic drug listed on any schedule of the uniform controlled substances act without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional judgment, continuation of the medication is necessary for the patient's health, safety and welfare. Such prescription refill shall only be in an amount judged by the pharmacist to be sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this paragraph be more than a seven day supply or one package of the drug. However, if the prescriber states on a prescription that there shall be no emergency refilling of that prescription, then the pharmacist shall not dispense any emergency medication pursuant to that prescription. A pharmacist who refills a prescription order under this ~~subsection (j)(2)~~ *paragraph* shall contact the prescriber of the prescription order on the next business day subsequent to the refill or as soon thereafter as possible. No pharmacist shall be required to refill any prescription order under this ~~subsection (j)(2)~~ *paragraph*. A prescriber shall not be subject to liability for any damages resulting from the refilling of a prescription order by a pharmacist under this ~~subsection (j)(2)~~ *paragraph* unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions by the prescriber.

(k) If any prescription order contains a provision that the prescription may be refilled a specific number of times within or during any particular period, such prescription shall not be refilled except in strict conformity with such requirements.

(l) Any pharmacist who exercises brand exchange and dispenses a less expensive drug *or biological* product shall not charge the purchaser more than the regular and customary retail price for the dispensed drug *or*

biological product.

(m) Nothing contained in this section shall be construed as preventing a pharmacist from refusing to fill or refill any prescription if in the pharmacist's professional judgment and discretion such pharmacist is of the opinion that it should not be filled or refilled.

Sec. 5. K.S.A. 2016 Supp. 65-1643 is hereby amended to read as follows: 65-1643. It shall be unlawful:

(a) For any person to operate, maintain, open or establish any pharmacy within this state without first having obtained a registration from the board. Each application for registration of a pharmacy shall indicate the person or persons desiring the registration, including the pharmacist in charge, as well as the location, including the street name and number, and such other information as may be required by the board to establish the identity and exact location of the pharmacy. The issuance of a registration for any pharmacy shall also have the effect of permitting such pharmacy to operate as a retail dealer without requiring such pharmacy to obtain a retail dealer's permit. On evidence satisfactory to the board: (1) That the pharmacy for which the registration is sought will be conducted in full compliance with the law and the rules and regulations of the board; (2) that the location and appointments of the pharmacy are such that it can be operated and maintained without endangering the public health or safety; and (3) that the pharmacy will be under the supervision of a pharmacist, a registration shall be issued to such persons as the board shall deem qualified to conduct such a pharmacy.

(b) For any person to manufacture within this state any drugs except under the personal and immediate supervision of a pharmacist or such other person or persons as may be approved by the board after an investigation and a determination by the board that such person or persons is qualified by scientific or technical training or experience to perform such duties of supervision as may be necessary to protect the public health and safety; and no person shall manufacture any such drugs without first obtaining a registration so to do from the board. Such registration shall be subject to such rules and regulations with respect to requirements, sanitation and equipment, as the board may from time to time adopt for the protection of public health and safety.

(c) For any person to distribute at wholesale any drugs without first obtaining a registration so to do from the board.

(d) For any person to sell or offer for sale at public auction or private sale in a place where public auctions are conducted, any drugs without first having obtained a registration from the board so to do, and it shall be necessary to obtain the permission of the board in every instance where any of the products covered by this section are to be sold or offered for sale.

(e) For any person to in any manner distribute or dispense samples of any drugs without first having obtained a permit from the board so to do, and it shall be necessary to obtain permission from the board in every instance where the samples are to be distributed or dispensed. Nothing in this subsection shall be held to regulate or in any manner interfere with the furnishing of samples of drugs to duly licensed practitioners, to mid-level practitioners, to pharmacists or to medical care facilities.

(f) Except as otherwise provided in this subsection ~~(f)~~, for any person operating a store or place of business to sell, offer for sale or distribute any drugs to the public without first having obtained a registration or permit from the board authorizing such person so to do. No retail dealer who sells 12 or fewer different nonprescription drug products shall be required to obtain a retail dealer's permit under the pharmacy act of the state of Kansas or to pay a retail dealer new permit or permit renewal fee under such act. It shall be lawful for a retail dealer who is the holder of a valid retail dealer's permit issued by the board or for a retail dealer who sells 12 or fewer different nonprescription drug products to sell and distribute nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a prescription-only drug; or (3) a drug product intended for human use by hypodermic injection; but such a retail dealer shall not be authorized to display any of the words listed in subsection ~~(dd)~~ *(ff)* of K.S.A. 65-1626, and amendments thereto, for the designation of a pharmacy or drugstore.

(g) For any person to sell any drugs manufactured and sold only in the state of Kansas, unless the label and directions on such drugs shall first have been approved by the board.

(h) For any person to operate an institutional drug room without first having obtained a registration to do so from the board. Such registration shall be subject to the provisions of K.S.A. 65-1637a, and amendments thereto and any rules and regulations adopted pursuant thereto.

(i) For any person to operate a veterinary medical teaching hospital pharmacy without first having obtained a registration to do so from the board. Such registration shall be subject to the provisions of K.S.A. 65-1662, and amendments thereto and any rules and regulations adopted pursuant thereto.

(j) For any person to sell or distribute in a pharmacy a controlled substance designated in ~~subsection (e) or (f) of~~ K.S.A. 65-4113, and amendments thereto, unless:

(1) (A) Such controlled substance is sold or distributed by a licensed pharmacist, a registered pharmacy technician or a pharmacy intern or clerk

supervised by a licensed pharmacist;

(B) any person purchasing, receiving or otherwise acquiring any such controlled substance produces a photo identification showing the date of birth of the person and signs a log and enters in the log, or allows the seller to enter in the log, such person's address and the date and time of sale or allows the seller to enter such information into an electronic logging system pursuant to K.S.A. 2016 Supp. 65-16,102, and amendments thereto. The log or database required by the board shall be available for inspection during regular business hours to the board of pharmacy and any law enforcement officer;

(C) the seller determines that the name entered in the log corresponds to the name provided on such identification and that the date and time entered are correct; and

(D) the seller enters in the log the name of the controlled substance and the quantity sold; or

(2) there is a lawful prescription.

(k) For any pharmacy to allow customers to have direct access to any controlled substance designated in ~~subsection (e) or (f) of~~ K.S.A. 65-4113, and amendments thereto. Such controlled substance shall be placed behind the counter or stored in a locked cabinet that is located in an area of the pharmacy to which customers do not have direct access.

(l) A seller who in good faith releases information in a log pursuant to subsection (j) to any law enforcement officer is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton or willful misconduct.

(m) For any person to sell or lease or offer for sale or lease durable medical equipment without first obtaining a registration from the board, in accordance with rules and regulations adopted by the board, except that this subsection shall not apply to:

(1) Sales not made in the regular course of the person's business; or

(2) sales by charitable organizations exempt from federal income taxation pursuant to the internal revenue code of 1986, as amended.

Sec. 6. K.S.A. 65-1660 is hereby amended to read as follows: 65-1660. (a) Except as otherwise provided in this section, the provisions of the pharmacy act of the state of Kansas shall not apply to dialysates, devices or drugs which are designated by the board for the purposes of this section relating to treatment of a person with chronic kidney failure receiving dialysis and which are prescribed or ordered by a physician or a mid-level practitioner for administration or delivery to a person with chronic kidney failure if:

(1) The wholesale distributor is registered with the board and lawfully holds the drug or device; and

(2) the wholesale distributor*:* (A) Delivers the drug or device to: (i) A

person with chronic kidney failure for self-administration at the person's home or specified address; (ii) a physician for administration or delivery to a person with chronic kidney failure; or (iii) a medicare approved renal dialysis facility for administering or delivering to a person with chronic kidney failure; and (B) has sufficient and qualified supervision to adequately protect the public health.

(b) The wholesale distributor pursuant to subsection (a) shall be supervised by a pharmacist consultant pursuant to rules and regulations adopted by the board.

(c) The board shall adopt such rules or regulations as are necessary to effectuate the provisions of this section.

(d) As used in this section, "physician" means a person licensed to practice medicine and surgery; "mid-level practitioner" means mid-level practitioner as such term is defined in ~~subsection (ii) of~~ K.S.A. 65-1626, and amendments thereto.

(e) This section shall be part of and supplemental to the pharmacy act of the state of Kansas.

Sec. 7. K.S.A. 2016 Supp. 65-2837a is hereby amended to read as follows: 65-2837a. (a) It shall be unlawful for any person licensed to practice medicine and surgery to prescribe, order, dispense, administer, sell, supply or give or for a mid-level practitioner as defined in K.S.A. 65-1626~~(ii)~~, and amendments thereto, to prescribe, administer, supply or give any amphetamine or sympathomimetic amine designated in schedule II, III or IV under the uniform controlled substances act, except as provided in this section. Failure to comply with this section by a licensee shall constitute unprofessional conduct under K.S.A. 65-2837, and amendments thereto.

(b) When any licensee prescribes, orders, dispenses, administers, sells, supplies or gives or when any mid-level practitioner as defined in K.S.A. 65-1626~~(ii)~~, and amendments thereto, prescribes, administers, sells, supplies or gives any amphetamine or sympathomimetic amine designated in schedule II, III or IV under the uniform controlled substances act, the patient's medical record shall adequately document the purpose for which the drug is being given. Such purpose shall be restricted to one or more of the following:

(1) The treatment of narcolepsy.

(2) The treatment of drug-induced brain dysfunction.

(3) The treatment of attention-deficit/hyperactivity disorder.

(4) The differential diagnostic psychiatric evaluation of depression.

(5) The treatment of depression shown by adequate medical records and documentation to be unresponsive to other forms of treatment.

(6) The clinical investigation of the effects of such drugs or compounds, in which case, before the investigation is begun, the licensee

shall, in addition to other requirements of applicable laws, apply for and obtain approval of the investigation from the board of healing arts.

(7) The treatment of obesity with controlled substances, as may be defined by rules and regulations adopted by the board of healing arts.

(8) The treatment of binge eating disorder.

(9) The treatment of any other disorder or disease for which such drugs or compounds have been found to be safe and effective by competent scientific research which findings have been generally accepted by the scientific community, in which case, the licensee before prescribing, ordering, dispensing, administering, selling, supplying or giving the drug or compound for a particular condition, or the licensee before authorizing a mid-level practitioner to prescribe the drug or compound for a particular condition, shall obtain a determination from the board of healing arts that the drug or compound can be used for that particular condition.

Sec. 8. K.S.A. 2016 Supp. 65-4202 is hereby amended to read as follows: 65-4202. As used in this act: (a) "Board" means the state board of nursing.

(b) The "practice of mental health technology" means the performance, under the direction of a physician licensed to practice medicine and surgery or registered professional nurse, of services in caring for and treatment of the mentally ill, emotionally disturbed, or people with intellectual disability for compensation or personal profit, which services:

(1) Involve responsible nursing and therapeutic procedures for patients with mental illness or intellectual disability requiring interpersonal and technical skills in the observations and recognition of symptoms and reactions of such patients, the accurate recording of such symptoms and reactions and the carrying out of treatments and medications as prescribed by a licensed physician or a mid-level practitioner as defined in ~~subsection (ii) of~~ K.S.A. 65-1626, and amendments thereto; ~~and~~

(2) require an application of techniques and procedures that involve understanding of cause and effect and the safeguarding of life and health of the patient and others; and

(3) require the performance of duties that are necessary to facilitate rehabilitation of the patient or are necessary in the physical, therapeutic and psychiatric care of the patient and require close work with persons licensed to practice medicine and surgery, psychiatrists, psychologists, rehabilitation therapists, social workers, registered nurses, and other professional personnel.

(c) A "licensed mental health technician" means a person who lawfully practices mental health technology as defined in this act.

(d) An "approved course in mental health technology" means a program of training and study including a basic curriculum which shall be prescribed and approved by the board in accordance with the standards

prescribed herein, the successful completion of which shall be required before licensure as a mental health technician, except as hereinafter provided.

Sec. 9. K.S.A. 65-7007 is hereby amended to read as follows: 65-7007. (a) Each regulated chemical distributor and retailer shall submit to the bureau:

(1) Any regulated transaction involving an extraordinary quantity of a regulated chemical, an uncommon method of payment or delivery, or any other circumstance that may indicate that the regulated chemical will be used in violation of this act.

(2) Any proposed regulated transaction with a person whose description or other identifying characteristic the bureau has previously furnished to the regulated chemical distributor or retailer.

(3) Any unusual or excessive loss or disappearance of a regulated chemical under the control of the regulated chemical distributor or retailer. The regulated person responsible for reporting a loss in-transit is the distributor.

(b) Each report submitted pursuant to subsection (a), whenever possible shall be made orally to the bureau at the earliest practicable opportunity after the regulated chemical distributor or retailer becomes aware of the circumstances involved and as much in advance of the conclusion of the transaction as possible. Written reports of these transactions shall subsequently be filed within 15 days after the regulated chemical distributor or retailer becomes aware of the circumstances of the event. A transaction may not be completed with a person whose description or identifying characteristics have previously been furnished to the regulated distributor by the bureau unless the transaction is approved by the bureau.

(c) This section shall not apply to any of the following:

(1) Any pharmacist, pharmacy or other authorized person who sells or furnishes a substance listed in ~~subsection (1) of~~ K.S.A. 65-7003, and amendments thereto, upon the prescription or order of a practitioner as defined under ~~subsection (x) of~~ K.S.A. 65-1626, and amendments thereto;

(2) any practitioner as defined under ~~subsection (x) of~~ K.S.A. 65-1626, and amendments thereto, who administers, dispenses or furnishes a substance listed in ~~subsection (1) of~~ K.S.A. 65-7003, and amendments thereto, to such patients within the scope of a practitioner's professional practice. Such administration or dispensing shall be in the patient record;

(3) ~~an~~ *any* sale, transfer, furnishing or receipt of any drug which contains any substance listed in ~~subsection (1) of~~ K.S.A. 65-7003, and amendments thereto, and which is lawfully sold, transferred or furnished over-the-counter without a prescription pursuant to the federal food, drug and cosmetic act or regulations adopted thereunder; and

(4) a regulated chemical retailer who only sells or distributes regulated chemicals that are nonprescription, over-the-counter medicines with less than three grams of base ingredient in the package in the following manner:

(A) Blister packs of not more than two dosage units per blister;

(B) liquid cold or cough medicines;

(C) liquid cold or cough gel capsules; and

(D) nasal drops or sprays.

Sec. 10. K.S.A. 65-669, 65-1660 and 65-7007 and K.S.A. 2016 Supp. 65-1626, 65-1637, 65-1637b, 65-1643, 65-2837a and 65-4202 are hereby repealed.

Sec. 11. This act shall take effect and be in force from and after its publication in the statute book.