Session of 2012

SENATE BILL No. 328

By Committee on Public Health and Welfare

1-24

AN ACT concerning prescription of drugs; relating to electronic prescription; amending K.S.A. 65-4123 and K.S.A. 2011 Supp. 65-1626 , 65-1637 and 65-4101 and repealing the existing sections.

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

Section 1. K.S.A. 2011 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.

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

~~(e)~~ *(f)* "Brand exchange" 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.

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

~~(g)~~ *(h)* "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.

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

~~(i)~~ *(k)* "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.

~~(j)~~ *(l)* "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.

~~(k)~~ *(m)* "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.

~~(l)~~ *(n)* "Dispenser" means a practitioner or pharmacist who dispenses prescription medication.

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

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

~~(o)~~ *(q)* "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."

~~(p)~~ *(r)* "Drug" means: (1) Articles recognized in the official United States pharmacopoeia, 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 man or other animals; (3) articles, other than food, intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any articles specified in clause (1), (2) or (3) of this subsection; 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.

~~(q)~~ *(s)* "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; (16) other similar equipment determined by the board in rules and regulations adopted by the board.

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

(u) "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 practitioner.

(v) "Electronic signature" means a confidential personalized digital key, code, number or other method for secure electronic data transmissions which identified 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) "Electronic transmission" means the transmission of an electronic prescription, formatted as an electronic data file, from a practitioner's electronic prescription application to a pharmacy's computer, where the data file is imported into the pharmacy prescription application.

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

~~(r)~~ *(y)* "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.

~~(s) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.~~

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

~~(u)~~ *(bb)* (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.

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

(dd) "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.

~~(w)~~ *(ee)* "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 the mentally retarded.

~~(x)~~ *(ff)* "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.

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

~~(z)~~ *(hh) "Mid-level practitioner" means 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 protocol with a responsible physician under K.S.A. 65-28a08, and amendments thereto.

(ii) "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.

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

~~(bb)~~ *(kk)* "Pharmacist" means any natural person licensed under this act to practice pharmacy.

~~(cc)~~ *(ll)* "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) "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.

~~(dd)~~ *(nn)* "Pharmacy," "drug store" 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.

~~(ee) "Pharmacy student" means an individual, registered with the board of pharmacy, enrolled in a accredited school of pharmacy.~~

(oo) "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.

~~(ff)~~ *(pp)* "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.

~~(gg)~~ *(qq)* "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.

~~(hh)~~ *(rr)* "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.

~~(ii) "Prescription" means, according to the context, either a prescription order or a prescription medication.~~

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

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

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

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

~~(ll) "Prescription order" means: (1) An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner or a mid-level practitioner in the authorized course of professional practice; or (2) an order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such practitioner or mid-level practitioner.~~

~~(mm)~~ *(ww)* "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.

~~(nn)~~ *(xx)* "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.

~~(oo)~~ *(yy) "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) "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.

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

~~(qq)~~ *(bbb)* "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.

~~(rr)~~*(ccc)* "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.

~~(ss) "Mid-level practitioner" means 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 protocol with a responsible physician under K.S.A. 65-28a08, and amendments thereto.~~

~~(tt)~~*(ddd)* "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.

~~(uu)~~*(eee)* "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.

~~(vv)~~ *(fff)* "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.

~~(ww)~~ *(ggg)* "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. 2. K.S.A. 2011 Supp. 65-1637 is hereby amended to read as follows: 65-1637. (a) 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 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:~~

~~(1) 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," or~~

~~(2) 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, or~~

~~(3) 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~~

~~(4) 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.~~

~~(b) 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) (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 (c)(2) 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). 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) unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions

~~by the prescriber.~~

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

~~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~~

(b) 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.

New Sec. 3. (a) A valid prescription order shall be based on a valid patient-prescriber relationship. 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. In exercising professional judgment, the prescriber and the pharmacist shall take adequate measures to guard against the diversion of prescription drugs and controlled substances through prescription forgeries.

(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 and title 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 and title 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.

(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 and title 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, a pharmacist intern or a certified pharmacy technician shall be authorized to receive a new prescription order from a prescriber or transmitting agent. In addition to a pharmacist, a pharmacist intern and a certified pharmacy technician, 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) The pharmacist shall ensure that the prescription order, regardless of means of transmission, has been issued for a legitimate medical purpose by an authorized prescriber acting in the usual course of the prescriber's professional practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an internet-based questionnaire, an internet-based consultation or a telephonic consultation and without a valid preexisting patient-practitioner relationship.

(g) 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.

(1) A prescription for a prescription drug or device that is not a controlled substance may authorize no more than 12 refills within 18 months following the date on which the prescription is issued.

(2) 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.

(h) 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 manually or electronically signed by the prescriber and prepared on a form containing two signature lines, signs the signature line following the statement "dispense as written";

(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.

(i) 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.

(j) 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 section shall be construed as altering or affecting in any way laws of this state or any federal act requiring a written prescription order.

(k) (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 (k)(2) 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 (k)(2). 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 (k)(2) unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions by the prescriber.

(l) 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.

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

(n) 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. 4. K.S.A. 2011 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.

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

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

~~(e)~~ *(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:

(A) The chemical structure of which 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 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 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.

~~(f)~~ *(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.

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

(j) "DEA" mean 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.

~~(h)~~ *(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.

~~(i)~~ *(m)* "Dispenser" means a practitioner or pharmacist who dispenses.

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

~~(k)~~ *(o)* "Distributor" means a person who distributes.

~~(l)~~ *(p)* "Drug" means:

(1) Substances recognized as drugs in the official United States pharmacopoeia, 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 clause (1), (2) or (3) of this subsection. It does not include devices or their components, parts or accessories.

~~(m)~~ *(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.

~~(n)~~ *(r) "Electronic prescription" means an electronically prepared prescription that is authorized and transmitted form 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 precriber's computers and servers where access and records are controlled by the practitioner.

(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 practitioner'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.

~~(o)~~ *(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.

~~(p)~~ *(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 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 protocol with a responsible 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 clause (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.

~~(q)~~ *(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.

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

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

~~(t)~~ *(hh) "Pharmacist" means any natural person licensed under K.S.A. 65-1625, et seq., 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.

~~(u) "Pharmacist" means an individual currently licensed by the board to practice the profession of pharmacy in this state.~~

~~(v)~~ *(ll)* "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist licensed under the optometry law as a therapeutic licensee or diagnostic and therapeutic licensee, 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.

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

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

~~(x)~~ *(oo) "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.*

(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.

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

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

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

~~(bb) (1) "Controlled substance analog" means a substance that is intended for human consumption, and:~~

~~(A) The chemical structure of which 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 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 individual represents or intends 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.~~

~~(ee) "Mid-level practitioner" means 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 protocol with a responsible physician under K.S.A. 65-28a08, and amendments thereto.~~

Sec. 5. K.S.A. 65-4123 is hereby amended to read as follows: 65-4123. (a) Except as otherwise provided in K.S.A. 65-4117, and amendments thereto, or in this subsection (a), no schedule I controlled substance may be dispensed. The board by rules and regulations may designate in accordance with the provisions of this subsection (a) a schedule I controlled substance as a schedule I designated prescription substance. ~~A schedule I controlled substance designated as a schedule I designated prescription substance may be dispensed only upon the written prescription of a practitioner. Prior to designating a schedule I controlled substance as a schedule I designated prescription substance, the board shall find: (1) That the schedule I controlled substance has an accepted medical use in treatment in the United States; (2) that the public health will benefit by the designation of the substance as a schedule I designated prescription substance; and (3) that the substance may be sold lawfully under federal law pursuant to a prescription. No prescription for a schedule I designated prescription substance may be refilled.~~

(b) Except when dispensed by a practitioner, other than a pharmacy,

to an ultimate user, no controlled substance in schedule II may be dispensed without the written *or electronic* prescription of a practitioner or a mid-level practitioner. In emergency situations, as defined by rules and regulations of the board, schedule II drugs may be dispensed upon oral prescription of a practitioner or a mid-level practitioner reduced promptly to writing *or transmitted electronically* and filed by the pharmacy. No prescription for a schedule II substance may be refilled.

(c) Except when dispensed by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV which is a prescription drug shall not be dispensed without ~~a written or oral prescription of a practitioner or a mid-level practitioner~~ *either a paper prescription manually signed by a practitioner, a facsimile of a manually signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that has been digitally signed by a practitioner with a digital certificate, or an oral prescription made by an individual practitioner and promptly reduced to writing*. The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times.

(d) A controlled substance shall not be distributed or dispensed other than for a medical purpose. ~~Prescriptions shall be retained in conformity with the requirements of K.S.A. 65-4121 and amendments thereto.~~ *Electronic prescriptions shall be retained electronically for five years from the date of their creation or receipt. The records must be readily retrievable from all other records and easily rendered into a format a person can read. Paper, oral and facsimile prescriptions shall be maintained as a hard copy for five years at the registered location.*

Sec. 6. K.S.A. 65-4123 and K.S.A. 2011 Supp. 65-1626, 65-1637 and 65-4101 are hereby repealed.

Sec. 7. This act shall take effect and be in force from and after its publication in the statute book.