Session of 2019

HOUSE BILL No. 2082

By Committee on Health and Human Services

1-24

AN ACT concerning health and healthcare; relating to the practice of pharmacy; amending K.S.A. 65-1626 and repealing the existing section.

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

New Section 1. (a) A licensed pharmacist may administer a drug to a patient pursuant to a prescription order, unless the prescription order includes the words "not to be administered by a pharmacist," or words of like effect.

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

Sec. 2. K.S.A. 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 *or section 1*, and amendments thereto.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, repackager, wholesale distributor, third-party logistics provider or dispenser but does 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) "Automated dispensing system" means a robotic or mechanical system controlled by a computer that: (1) Performs operations or activities, other than compounding or administration, relative to the storage, packaging, labeling, dispensing or distribution of drugs; (2) collects, controls and maintains all transaction information; and (3) operates in

accordance with the board's rules and regulations.

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

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

(g) "Brand exchange," in the case of a drug 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 an interchangeable biological product.

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

(i) "Co-licensed partner" means a person or pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer or an affiliate of the manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a product.

(j) "Common carrier" means any person who undertakes, whether directly or by any other arrangement, to transport property, including drugs, for compensation.

(k) "Compounding" means the combining of components into a compounded preparation under either of the following conditions:

(1) As the result of a practitioner's prescription drug order or initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice to meet the specialized medical need of an individual patient of the practitioner that cannot be filled by an FDA-approved drug; or

(2) for the purpose of, or incidental to, research, teaching or chemical analysis, and not for sale or dispensing.

Compounding includes the preparation of drugs or devices in anticipation of receiving prescription drug orders based on routine, regularly observed prescribing patterns.

Compounding does not include reconstituting any oral or topical drug according to the FDA-approved labeling for the drug or preparing any sterile or nonsterile preparation that is essentially a copy of a commercially available product.

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

(m) "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.

(n) "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.

(o) "Dispense" or "dispensing" 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.

(p) "Dispenser" means:

(1) 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; or

(2) a retail pharmacy, hospital pharmacy or group of pharmacies under common ownership and control that do not act as a wholesale distributor, or affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.

(q) "Distribute" or "distribution" means to deliver, offer to deliver, sell, offer to sell, purchase, trade, transfer, broker, give away, handle, store or receive, other than by administering or dispensing, any product, but does not include dispensing a product pursuant to a prescription executed in accordance with 21 U.S.C. § 353 or the dispensing of a product approved under 21 U.S.C. § 360b.

(r) "Distributor" means a person or entity that distributes a drug.

(s) "Drop shipment" means the sale, by a manufacturer, repackager or 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 dispenser, and the dispenser receives delivery of the prescription drug directly from the manufacturer, repackager, third-party logistics provider or exclusive distributor, of such prescription drug.

(t) "Drug" means: (1) Articles recognized in the official United States pharmacopeia, or other such official compendiums of the United States, or official national formulary, or any supplement to 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.

(u) "Durable medical equipment" means equipment that: (1) Provides therapeutic benefits or enables an individual to perform certain tasks that the individual is unable to otherwise undertake due to certain medical conditions or illnesses; (2) is primarily and customarily used to serve a medical purpose; (3) generally is not useful to a person in the absence of an illness or injury; (4) can withstand repeated use; (5) is appropriate for use in the home, long-term care facility or medical care facility, but may be transported to other locations to allow the individual to complete instrumental activities of daily living that are more complex tasks required for independent living; and (6) may include devices and medical supplies or other similar equipment determined by the board in rules and regulations adopted by the board.

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

(w) "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.

(x) "Electronic signature" means a confidential personalized digital key, code, number or other method for secure electronic data transmissions that 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.

(y) "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.

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

(aa) "Exclusive distributor" means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor or dispenser.

(bb) "FDA" means the U.S. department of health and human services, food and drug administration.

(cc) "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.

(dd) "Generic name" means the established chemical name or official name of a drug or drug product.

(ee) "Health care entity" means any person that provides diagnostic, medical, surgical or dental treatment or rehabilitative care but does not include any retail pharmacy or wholesale distributor.

(ff) (1) "Institutional drug room" means any location where prescription-only drugs are stored and from which prescription-only drugs are administered or dispensed and that 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 that 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.

(gg) "Interchangeable biological product" means a biological product that the FDA has:

(1) Licensed and determined meets the standards for "interchangeability" as defined in 42 U.S.C. § 262(k), as in effect on January 1, 2017; or

(2) determined to be therapeutically equivalent as set forth in the latest edition or supplement to the FDA's approved drug products with therapeutic equivalence evaluations.

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

(ii) "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-licensed partners.

(jj) "Label" means a display of written, printed or graphic matter upon the immediate container of any drug.

(kk) "Labeling" means the process of preparing and affixing a label to any drug container, exclusive of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug.

(ll) "Long-term care facility" means "nursing facility," as defined in K.S.A. 39-923, and amendments thereto.

(mm) "Medical care facility" means the same as defined in K.S.A. 65-425, and amendments thereto, except that the term also includes facilities licensed under the provisions of K.S.A. 2018 Supp. 39-2001 et seq., and amendments thereto, except community mental health centers and facilities for people with intellectual disability.

(nn) "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 or biological synthesis or by a combination of extraction and chemical or biological synthesis or the packaging or repackaging of the drug or labeling or relabeling of its container, except that this term does 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.

(oo) "Manufacturer" means:

(1) A person that holds an application approved under section 505 of the federal food, drug and cosmetic act or a license issued under section 351 of the federal public health service act for such drug or, if such drug is not the subject of an approved application or license, the person who manufactured the drug;

(2) a co-licensed partner of the person described in paragraph (1) that obtains the drug directly from a person described in paragraph (1) or (3); or

(3) an affiliate of a person described in paragraph (1) or (2) that receives the product directly from a person described in paragraph (1) or (2).

(pp) *"Medication order" means an order by a prescriber for a registered patient of a Kansas licensed medical care facility.*

(qq) "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.

~~(qq)~~*(rr)* "Nonresident pharmacy" means a pharmacy located outside of Kansas.

~~(rr)~~*(ss)* "Outsourcing facility" or "virtual outsourcing facility" means a facility at one geographic location or address that is engaged in the compounding of sterile drugs and has registered with the FDA as an outsourcing facility pursuant to 21 U.S.C. § 353b.

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

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

~~(uu)~~*(vv)* "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.

~~(vv)~~*(ww)* "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 that is not accredited and who has successfully passed equivalency examinations approved by the board.

~~(ww)~~*(xx)* "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; (2) that 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.

~~(xx)~~*(yy)* "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.

~~(yy)~~*(zz)* "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.

~~(zz)~~*(aaa)* "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.

~~(aaa)~~*(bbb)* "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.

~~(bbb)~~*(ccc)* "Prescriber" means a practitioner or a mid-level practitioner.

~~(ccc)~~*(ddd)* "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.

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

~~(eee)~~*(fff)* "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.

~~(fff)~~*(ggg)* "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.

~~(ggg)~~*(hhh)* "Product" means the same as defined by part H of the federal drug supply chain security act, 21 U.S.C. § 351 et seq. and 21 U.S.C. § 360eee.

~~(hhh)~~*(iii)* "Professional incompetency" means:

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

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

~~(iii)~~*(jjj)* "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.

~~(jjj)~~*(lll)* "Repackage" means changing the container, wrapper, quantity or label of a drug to further the distribution of the drug.

~~(lll)~~*(mmm)* "Repackager" means a person who owns or operates a facility that repackages.

~~(mmm)~~*(nnn)* "Retail dealer" means a person selling at retail nonprescription drugs that 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.

~~(nnn)~~*(ooo)* "Return" means providing product to the authorized immediate trading partner from whom such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

~~(ooo)~~*(ppp)* "Returns processor" or "reverse logistics provider" means a person who owns or operates an establishment that disposes of or otherwise processes saleable or nonsaleable products received from an authorized trading partner such that the product may be processed for

credit to the purchaser, manufacturer or seller or disposed of for no further distribution.

~~(ppp)~~*(qqq)* "Secretary" means the executive secretary of the board.

~~(qqq)~~*(rrr)* "Third-party logistics provider" means an entity that provides or coordinates warehousing or other logistic services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser, but does not take ownership of the product or have responsibility to direct the sale or disposition of the product.

~~(rrr)~~*(sss)* "Trading partner" means:

(1) A manufacturer, repackager, wholesale distributor or dispenser from whom a manufacturer, repackager, wholesale distributor or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor or dispenser transfers direct ownership of a product; or

(2) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor or dispenser transfers direct possession of a product.

~~(sss)~~*(ttt)* "Transaction" means the transfer of product between persons in which a change of ownership occurs.

~~(ttt)~~*(uuu)* "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 that have no legitimate pharmaceutical purpose.

~~(uuu)~~*(vvv)* "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, that 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.

~~(vvv)~~*(www)* "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.

~~(www)~~*(xxx)* "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.

~~(xxx)~~*(yyy)* "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs, other than a manufacturer, co-licensed partner, third-party logistics provider or repackager.

~~(yyy)~~*(zzz)* "Wholesale distribution" means the distribution or receipt of prescription drugs to or by persons other than consumers or patients, in which a change of ownership occurs. Wholesale distribution does not include:

(1) The dispensing of a prescription drug pursuant to a prescription;

(2) the distribution of a prescription drug or an offer to distribute a prescription drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the public health service act, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(3) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(4) the distribution of a prescription drug or an offer to distribute a prescription drug among hospitals or other health care entities under common control;

(5) the distribution of a prescription drug or the offer to distribute a prescription drug 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 dispenser, hospital or other health care entity for use by such dispenser, hospital or other health care entity;

(7) the distribution of a drug by the manufacturer of such drug;

(8) the receipt or transfer of a drug by an authorized third-party logistics provider, provided that such third-party logistics provider does not take ownership of the drug;

(9) the transport of a drug by a common carrier, provided that the common carrier does not take ownership of the drug;

(10) the distribution of a drug or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e) of the federal food, drug and cosmetic act;

(11) saleable drug returns when conducted by a dispenser;

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

(13) the distribution of a collection of finished medical devices, including a product or biological product in accordance with 21 U.S.C. § 353(e)(4)(M);

(14) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes, including sodium, chloride and potassium, or calories, including dextrose and amino acids;

(15) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(16) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) the distribution of medical gas;

(18) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments;

(19) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating under the direction of a hospital or other health care entity, to a repackager described in section 581(16)(B) and registered under section 510 of the food, drug and cosmetic act for the purpose of repackaging the drug for use by that hospital or other health care entity, or other health care entities under common control, if ownership of the drug remains with the hospital or other health care entity at all times; or

(20) the sale or transfer from a retail pharmacy 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. 65-1626 is hereby repealed.

Sec. 4. This act shall take effect and be in force from and after its publication in the statute book.