Session of 2022

SENATE BILL No. 454

By Committee on Public Health and Welfare

2-8

AN ACT concerning health professions and practices; relating to advanced practice registered nurses; licensure thereof; authorizing the prescribing of drugs without a supervising physician; requiring malpractice insurance coverage; rules and regulations; amending K.S.A. 65-1130 and K.S.A. 2021 Supp. 65-1626 and 65-4101 and repealing the existing sections.

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

Section 1. K.S.A. 65-1130 is hereby amended to read as follows: 65-1130. (a) No professional nurse shall announce or represent to the public that such person is an advanced practice registered nurse unless such professional nurse has complied with requirements established by the board and holds a valid license as an advanced practice registered nurse in accordance with the provisions of this section.

(b) *(1)* The board shall establish standards and requirements for any professional nurse who desires to obtain licensure as an advanced practice registered nurse. Such standards and requirements shall include, but not be limited to, standards and requirements relating to the education of advanced practice registered nurses. The board may give such examinations and secure such assistance as it deems necessary to determine the qualifications of applicants.

(2) (A) On and after July 1, 2023, an applicant for initial licensure as an advanced practice registered nurse shall have a current advanced practice registered nurse certification in such applicant's specific role and population focus that has been granted by a national certifying organization recognized by the board and whose certification standards are approved by the board as equal to or greater than the corresponding standards established by the board; and

(B) an advanced practice registered nurse whose initial licensure is prior to July 1, 2023, may submit evidence of such certification to the board upon renewal.

(c) The board shall adopt rules and regulations *consistent with the Kansas nurse practice act* applicable to advanced practice registered nurses ~~which~~ *that*:

(1) Establish roles and identify titles and abbreviations of advanced

practice registered nurses ~~which~~ *that* are consistent with nursing practice specialties recognized by the nursing profession.

(2) Establish education and qualifications necessary for licensure for each role of advanced practice registered nurse established by the board at a level adequate to assure the competent performance by advanced practice registered nurses of functions and procedures which advanced practice registered nurses are authorized to perform. Advanced practice registered nursing is based on knowledge and skills acquired in basic nursing education, licensure as a registered nurse and graduation from or completion of a master's or higher degree in one of the advanced practice registered nurse roles approved by the board of nursing.

(3) Define the role of advanced practice registered nurses and establish limitations and restrictions on such role. The board shall adopt a definition of the role under this paragraph ~~which~~ *that* is consistent with the education and qualifications required to obtain a license as an advanced practice registered nurse~~, which~~ *that* protects the public from persons performing functions and procedures as advanced practice registered nurses for which they lack adequate education and qualifications and ~~which~~ *that* authorizes advanced practice registered nurses to perform acts generally recognized by the profession of nursing as capable of being performed, in a manner consistent with the public health and safety, by persons with postbasic education in nursing. In defining such role the board shall consider:

(A) The education required for a licensure as an advanced practice registered nurse;

(B) the type of nursing practice and preparation in specialized advanced practice skills involved in each role of advanced practice registered nurse established by the board;

(C) the scope and limitations of advanced practice nursing prescribed by national advanced practice organizations; and

(D) acts recognized by the nursing profession as appropriate to be performed by persons with postbasic education in nursing.

(d) *(1)* An advanced practice registered nurse may prescribe ~~drugs pursuant to a written protocol as authorized by a responsible physician. Each written protocol shall contain a precise and detailed medical plan of care for each classification of disease or injury for which the advanced practice registered nurse is authorized to prescribe and shall specify all drugs which may be prescribed by the advanced practice registered nurse. Any written~~ *durable medical equipment and prescribe, procure and administer any drug in accordance with the uniform controlled substances act, consistent with such licensee's specific role and population focus.*

(2) A prescription order shall include the name, address and telephone number of the ~~responsible physician~~ *advanced practice registered nurse*.

~~The~~ *An* advanced practice registered nurse may not dispense drugs~~,~~ but may request, receive and sign for professional samples and may distribute professional samples to patients~~ pursuant to a written protocol as authorized by a responsible physician~~.

(3) In order to prescribe controlled substances, the advanced practice registered nurse shall:

~~(1)~~ *(A)* Register with the federal drug enforcement administration; and

~~(2) notify the board of the name and address of the responsible physician or physicians. In no case shall the scope of authority of the advanced practice registered nurse exceed the normal and customary practice of the responsible physician~~

(B) comply with federal drug enforcement administration requirements related to controlled substances.

(4) An advanced practice registered nurse certified in the role of registered nurse anesthetist while functioning as a registered nurse anesthetist under K.S.A. 65-1151 through 65-1164, and amendments thereto, shall be subject to the provisions of K.S.A. 65-1151 through 65-1164, and amendments thereto, with respect to drugs and anesthetic agents and shall not be subject to the provisions of this subsection.~~ For the purposes of this subsection, "responsible physician" means a person licensed to practice medicine and surgery in Kansas who has accepted responsibility for the protocol and the actions of the advanced practice registered nurse when prescribing drugs.~~

(5) An advanced practice registered nurse shall maintain malpractice insurance coverage as a condition of rendering professional clinical services as an advanced practice registered nurse in this state and shall provide proof of insurance at the time of licensure and renewal of license. The requirements of this subsection shall not apply to an advanced practice registered nurse who:

(i) Practices solely in employment for which the advanced practice registered nurse is covered under the federal tort claims act or the Kansas tort claims act;

(ii) practices solely as a charitable healthcare provider under K.S.A. 75-6102, and amendments thereto; or

(iii) is serving on active duty in the armed forces of the United States.

(e) As used in this section, "drug" means those articles and substances defined as drugs in K.S.A. 65-1626 and 65-4101, and amendments thereto.

(f) A person registered to practice as an advanced registered nurse practitioner in the state of Kansas immediately prior to the effective date of this act shall be deemed to be licensed to practice as an advanced practice registered nurse under this act and such person shall not be required to file an original application for licensure under this act. Any application for

registration filed which has not been granted prior to the effective date of this act shall be processed as an application for licensure under this act.

(g) An advanced practice registered nurse certified in the role of certified nurse-midwife and engaging in the independent practice of midwifery under the independent practice of midwifery act with respect to prescribing drugs shall be subject to the provisions of the independent practice of midwifery act and shall not be subject to the provisions of this section.

Sec. 2. K.S.A. 2021 Supp. 65-1626 is hereby amended to read as follows: 65-1626. As used in the pharmacy act of the state of Kansas:

(a) "Address" means, with respect to prescriptions, the physical address where a patient resides, including street address, city and state.

(b) "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,* or K.S.A. 2021 Supp. 65-16,129, and amendments thereto.

(c) "Agent" means an authorized person who acts on behalf of or at the direction of amanufacturer, 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.

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

(A) 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

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

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

(3) Compounding does not include reconstituting any mixed drug according to the FDA-approved labeling for the drug.

(l) "Current good manufacturing practices" or "CGMP" means the requirements for ensuring that drugs and drug products are consistently manufactured, repackaged, produced, stored and dispensed in accordance with 21 C.F.R. §§ 207, 210 and 211.

(m) "DEA" means the United States department of justice, drug enforcement administration.

(n) "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.

(o) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component part or accessory that:

(1) (A) Is recognized in the official national formulary, or the United States pharmacopoeia, or any supplement thereof;

(B) is intended for use in the diagnosis of disease or other conditions;

(C) is used for the cure, mitigation, treatment or prevention of disease in human or other animals; or

(D) is intended to affect the structure or any function of the body of human or other animals; and

(2) (A) does not achieve its primary intended purposes through

chemical action within or on the body of human or other animals; and

(B) is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

(p) "Direct supervision" means the process by which the responsible pharmacist shall observe and direct the activities of a pharmacist intern or pharmacy technician, be readily and immediately available at all time activities are performed, provide personal assistance, direction and approval throughout the time the activities are performed and complete the final check before dispensing.

(q) "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, including, but not limited to, delivering prescription medication to a patient by mail, common carrier, personal delivery or third-party delivery to any location requested by the patient.

(r) "Dispenser" means:

(1) A practitioner or pharmacist who dispenses prescription drugs or devices 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.

(s) "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.

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

(u) "Diversion" means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.

(v) "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.

(w) "Drug" means *articles*:

(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~~ *does* 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.

(x) "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.

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

(z) "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.

(aa) "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.

(bb) "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.

(cc) "Electronically prepared prescription" means a prescription that

is generated using an electronic prescription application.

(dd) "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.

(ee) "FDA" means the United States department of health and human services, food and drug administration.

(ff) "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.

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

(hh) "~~Health care~~*Healthcare* 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.

(ii) (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 correctional facility or juvenile detention facility, as defined in K.S.A. 38-2302, and amendments thereto;

(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.

(jj) "Interchangeable biological product" means a biological product that the FDA has identified in the "purple book: lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations" as meeting the standards for

"interchangeability" as defined in 42 U.S.C. § 262(k), as in effect on January 1, 2017.

(kk) "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.

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

(mm) "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.

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

(oo) "Medical care facility" means the same as defined in K.S.A. 65-425, and amendments thereto, ~~except that the term~~ *and* also includes psychiatric hospitals and psychiatric residential treatment facilities as defined by K.S.A. 39-2002, and amendments thereto.

(pp) "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.

(qq) "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).

(rr) "Medication order" means a written or oral order by a prescriber or the prescriber's authorized agent for administration of a drug or device to a patient in a Kansas licensed medical care facility or in a Kansas licensed nursing facility or nursing facility for mental health, as such terms are defined by K.S.A. 39-923, and amendments thereto.

(ss) "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.

(tt) "Nonresident pharmacy" means a pharmacy located outside of Kansas.

(uu) "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.

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

(ww) "Pharmacist" means any natural person licensed under this act to practice pharmacy.

(xx) "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.

(yy) "Pharmacist intern" or "intern" means:

(1) A student currently enrolled in and in good standing with 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.

(zz) "Pharmacy," "drugstore" or "apothecary" means premises, laboratory, area or other place, including any electronic medium:

(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 in any language or on any sign containing any of these words as used in the context of health, medical or pharmaceutical care or services; or

(3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited in the context of health, medical or pharmaceutical care or services. 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.

(aaa) "Pharmacy prescription application" means software that is used to process prescription information and is either installed on a pharmacy's computers or servers and is controlled by the pharmacy or is maintained on the servers of an entity that sells electronic pharmacy prescription applications as a hosted service where the entity controls access to the application and maintains the software and records on its server.

(bbb) "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.

(ccc) "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.

(ddd) "Preceptor" means a licensed pharmacist who possesses at least two years' experience as a pharmacist and who supervises and is responsible for the actions of pharmacist interns obtaining pharmaceutical experience.

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

(fff) "Prescription" or "prescription order" means the front and back of a lawful written, electronic or facsimile order from a prescriber or an oral order from a prescriber or the prescriber's authorized agent that communicates the prescriber's instructions for a prescription drug or device to be dispensed.

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

(hhh) "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.

(iii) "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.

(jjj) "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.

(lll) "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.

(mmm) "Readily retrievable" or "readily available" means that records kept in hard copy or by automatic data processing applications or other electronic or mechanized record-keeping systems can be separated out from all other records quickly and easily during an inspection or investigation, or within a reasonable time not to exceed 48 hours of a written request from the board or other authorized agent.

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

(ooo) "Repackager" means a person who owns or operates a facility that repackages.

(ppp) "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.

(qqq) "Reverse distributor" 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.

(rrr) "Secretary" means the executive secretary of the board.

(sss) "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.

(ttt) "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.

(uuu) "Transaction" means the transfer of product between persons in which a change of ownership occurs.

(vvv) "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.

(www) "Vaccination protocol" means a written protocol, agreed to and signed 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.

(xxx) "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.

(yyy) "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.

(zzz) "Virtual manufacturer" means an entity that engages in the manufacture of a drug or device for which it:

(1) Owns the new drug application or abbreviated new drug application number, if a prescription drug;

(2) owns the unique device identification number, as available, for a prescription device;

(3) contracts with a contract manufacturing organization for the physical manufacture of the drug or device;

(4) is not involved in the physical manufacture of the drug or device; and

(5) does not store or take physical possession of the drug or device.

(aaaa) "Virtual wholesale distributor" means a wholesale distributor that sells, brokers or transfers a drug or device but never physically possesses the product.

(bbbb) "Wholesale distributor" means any person engaged in wholesale distribution or reverse distribution of drugs or devices, other than a manufacturer, co-licensed partner or third-party logistics provider.

(cccc) "Wholesale distribution" means the distribution or receipt of drugs or devices 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 drug or device pursuant to a prescription;

(2) the distribution of a drug or device or an offer to distribute a drug or device 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 or device shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(3) intracompany distribution;

(4) the distribution of a drug or device, or an offer to distribute a drug or device, among hospitals or other ~~health care~~ *healthcare* entities under common control;

(5) the distribution of a drug or device, or the offer to distribute a drug or device, by a charitable organization described in section 501(c)(3) of the internal revenue code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

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

(7) 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 reverse distributor registered in accordance with the board's rules and regulations.

Sec. 3. K.S.A. 2021 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~~ *"Agent"* does not include a common carrier, public warehouseman or employee of the carrier or warehouseman.

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

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

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

(f) "Controlled substance" means any drug, substance or immediate precursor included in any of the schedules designated in K.S.A. 65-4105,

65-4107, 65-4109, 65-4111 and 65-4113, and amendments thereto.

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

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

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

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

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

(A) A controlled substance;

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

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

(h) "Counterfeit substance" means a controlled substance that, or the container or labeling of which, without authorization bears the trademark, trade name or other identifying mark, imprint, number or device or any likeness thereof of a manufacturer, distributor or dispenser other than the person who in fact manufactured, distributed or dispensed the substance.

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

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

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

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

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

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

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

(p) "Drug" means *substances*:

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

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

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

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

(q) "Immediate precursor" means a substance that 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 that is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

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

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

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

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

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

(w) "Facsimile transmission" or "fax transmission" means the transmission of a digital image of a prescription from the prescriber or the

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

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

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

(z) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance either directly or indirectly or by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance by an individual for the individual's own lawful use or the preparation, compounding, packaging or labeling of a controlled substance:

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

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

(aa) "Marijuana" means all parts of all varieties of the plant Cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin. It does not include:

(1) 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 that is incapable of germination;

(2) any substance listed in schedules II through V of the uniform controlled substances act;

(3) cannabidiol (other trade name: 2-[(3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol); or

(4) industrial hemp as defined in K.S.A. 2021 Supp. 2-3901, and amendments thereto, when cultivated, produced, possessed or used for activities authorized by the commercial industrial hemp act.

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

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

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

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

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

(3) opium poppy and poppy straw;

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

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

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

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

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

(ii) "Pharmacist intern" means:

(1) A student currently enrolled in an accredited pharmacy program;

(2) a graduate of an accredited pharmacy program serving such person's internship; or

(3) a graduate of a pharmacy program located outside of the United States that is not accredited and who had successfully passed equivalency examinations approved by the board.

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

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

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

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

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

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

(pp) "Ultimate user" means a person who lawfully possesses a controlled substance for such person's own use or for the use of a member of such person's household or for administering to an animal owned by such person or by a member of such person's household.

Sec. 4. K.S.A. 65-1130 and K.S.A. 2021 Supp. 65-1626 and 65-4101 are hereby repealed.

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