

2021 Kansas Statutes

65-1626. Pharmacy act; definitions. 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 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 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.
- (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: (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.

(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 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 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 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.

History: L. 1953, ch. 290, § 3; L. 1975, ch. 319, § 2; L. 1977, ch. 217, § 1; L. 1978, ch. 242, § 1; L.

1978, ch. 243, § 1; L. 1979, ch. 193, § 1; L. 1982, ch. 182, § 138; L. 1986, ch. 235, § 1; L. 1986, ch. 231, § 9; L. 1986, ch. 236, § 1; L. 1987, ch. 235, § 5; L. 1987, ch. 236, § 1; L. 1988, ch. 297, § 2; L. 1989, ch. 193, § 1; L. 1989, ch. 192, § 2; L. 1989, ch. 192, § 3; L. 1991, ch. 272, § 10; L. 1996, ch. 229, § 118; L. 1997, ch. 112, § 1; L. 1999, ch. 38, § 1; L. 1999, ch. 149, § 6; L. 2000, ch. 89, § 1; L. 2000, ch. 159, § 10; L. 2001, ch. 31, § 1; L. 2002, ch. 25, § 2; L. 2003, ch. 124, § 8; L. 2006, ch. 169, § 117; L. 2007, ch. 177, § 30; L. 2011, ch. 114, § 55; L. 2012, ch. 107, § 1; L. 2012, ch. 166, § 11; L. 2014, ch. 131, § 4; L. 2015, ch. 46, § 2; L. 2016, ch. 92, § 99; L. 2017, ch. 34, § 1; L. 2019, ch. 52, § 7; L. 2021, ch. 106, § 6; June 3.