{As Amended by Senate Committee of the Whole}

Session of 2017

Senate Substitute for HOUSE BILL No. 2055

By Committee on Public Health and Welfare

3-24

AN ACT concerning the state board of pharmacy; relating to powers, duties and functions thereof; biological products; amending K.S.A. 65-669, 65-1633, 65-1635, 65-1648, 65-1660 and 65-7007 and K.S.A. 2016 Supp. 65-1626, 65-1627, 65-1636, 65-1637, 65-1642, 65-1643, 65-1645, 65-1655, 65-1663, 65-1669, 65-1676, 65-2837a and 65-4202 and repealing the existing sections; also repealing K.S.A. 2016 Supp. 65-1637b and 65-1651a.

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

Section 1. K.S.A. 2016 Supp. 65-1626 is hereby amended to read as follows: 65-1626. For the purposes of this act:

(a) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:

(1) A practitioner or pursuant to the lawful direction of a practitioner;

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

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

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, *repackager, wholesale* distributor*, third-party logistics provider* or dispenser but ~~shall~~ *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) ~~"Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in section 1504 of the internal revenue code, complies with any one of the following: (1) The wholesale~~

~~distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and (2) the wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis~~*"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.

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

~~(f)~~*(g)* "Brand exchange," *in the case of a drug 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*.

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

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

(i) "~~Co-licensee~~*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 ~~prescription drug and the national drug code on the drug product label shall be used to determine the identity of the drug manufacturer~~ *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.

~~(k)~~*(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.

~~(l)~~ *(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.

~~(m)~~ *(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.

~~(n)~~ *(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.

~~(o)~~ *(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 ~~drug~~ *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*.

~~(p)~~ *(r)* "Distributor" means a person ~~who~~ *or entity that* distributes a drug.

~~(q)~~ *(s)* "Drop shipment" means the sale, by a manufacturer, ~~that manufacturer's co-licensee, that manufacturer's third party logistics~~

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

~~(r)~~ *(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 ~~of~~ *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.

~~(s)~~ *(u)* "Durable medical equipment" means ~~technologically sophisticated medical devices that may be used in a residence, including~~ the following *equipment that*: (1) ~~Oxygen and oxygen delivery system~~ *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) ~~ventilators~~ *is primarily and customarily used to serve a medical purpose*; (3) ~~respiratory disease management devices~~ *generally is not useful to a person in the absence of an illness or injury*; (4) ~~continuous positive airway pressure (CPAP) devices~~ *can withstand repeated use*; (5) ~~electronic and computerized wheelchairs and seating systems~~*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) ~~apnea monitors; (7) transcutaneous electrical nerve stimulator (TENS) units; (8) low air loss cutaneous pressure management devices; (9) sequential compression devices; (10) feeding pumps; (11) home phototherapy devices; (12) infusion delivery devices; (13) distribution of~~

~~medical gases to end users for human consumption; (14) hospital beds; (15) nebulizers; or (16)~~ *may include devices and medical supplies or* other similar equipment determined by the board in rules and regulations adopted by the board.

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

~~(u)~~ *(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.

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

~~(w)~~ *(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.

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

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

~~(z)~~ *(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.

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

~~(bb)~~ *(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 ~~which~~ *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 ~~which~~ *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.

~~(cc)~~ *(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.

~~(dd)~~ *(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-licensees of a co-licensed product~~ *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.

~~(cc)~~ *(mm)* "Medical care facility" ~~shall have the meaning provided~~ *means the same as defined* in K.S.A. 65-425, and amendments thereto, except that the term ~~shall~~ also ~~include~~ *includes* facilities licensed under the provisions of K.S.A. ~~75-3307b~~ *2016 Supp. 39-2001 et seq.*, and amendments thereto, except community mental health centers and facilities for people with intellectual disability.

~~(ff)~~ *(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 ~~and includes any~~ *or the* packaging or repackaging of the drug or labeling or relabeling of its container, except that this term ~~shall~~ *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.

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

(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).

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

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

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

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

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

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

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

(rr) "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.

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

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

~~(ll)~~ *(uu)* "Pharmacist-in-charge" means the pharmacist who is responsible to the board for a registered establishment's compliance with

the laws and regulations of this state pertaining to the practice of pharmacy, manufacturing of drugs and the distribution of drugs. The pharmacist-in-charge shall supervise such establishment on a full-time or a part-time basis and perform such other duties relating to supervision of a registered establishment as may be prescribed by the board by rules and regulations. Nothing in this definition shall relieve other pharmacists or persons from their responsibility to comply with state and federal laws and regulations.

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

~~(nn)~~ *(ww)* "Pharmacy," "drugstore" or "apothecary" means premises, laboratory, area or other place: (1) Where drugs are offered for sale where the profession of pharmacy is practiced and where prescriptions are compounded and dispensed; ~~or~~ (2) ~~which~~ *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.

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

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

~~(qq)~~ *(zz)* "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist or scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug.

~~(rr)~~ *(aaa)* "Preceptor" means a licensed pharmacist who possesses at least two years' experience as a pharmacist and who supervises students

obtaining the pharmaceutical experience required by law as a condition to taking the examination for licensure as a pharmacist.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Fraud in securing a registration or permit;

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

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

(4) intentionally falsifying or altering records or prescriptions;

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

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

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

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

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

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

~~(ddd)~~ *(uuu)* "Vaccination protocol" means a written protocol, agreed to by a pharmacist and a person licensed to practice medicine and surgery by the state board of healing arts, ~~which~~ *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.

~~(eee)~~ *(vvv)* "Valid prescription order" means a prescription that is issued for a legitimate medical purpose by an individual prescriber licensed by law to administer and prescribe drugs and acting in the usual course of such prescriber's professional practice. A prescription issued solely on the basis of an internet-based questionnaire or consultation without an appropriate prescriber-patient relationship is not a valid prescription order.

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

~~(ggg)~~ *(xxx)* "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs ~~or devices in or into the state, including, but not limited to, manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees,~~

~~exclusive distributors, third party logistics providers, chain pharmacy warehouses that conduct wholesale distributions, and wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distributions. Wholesale distributor shall not include persons engaged in the sale of durable medical equipment to consumers or patients~~*, other than a manufacturer, co-licensed partner, third-party logistics provider or repackager.*

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

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

(2) the ~~sale, purchase or trade~~ *distribution* of a prescription drug ~~or device~~ or an offer to ~~sell, purchase or trade~~ *distribute* a prescription 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 shortage not caused by a public health emergency shall not constitute an emergency medical reason*;

(3) intracompany ~~transactions, as defined in this section, unless in violation of own use provisions~~ *distribution of any drug between members of an affiliate or within a manufacturer*;

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

(5) the ~~sale, purchase or trade~~ *distribution* of a prescription drug ~~or device~~ or the offer to ~~sell, purchase or trade~~ *distribute* a prescription drug ~~or device~~ by a charitable organization described in 503(c)(3) of the internal revenue code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

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

(7) ~~the transfer of prescription drugs or devices between pharmacies pursuant to a centralized prescription processing agreement~~ *the distribution of a drug by the manufacturer of such drug*;

(8) ~~the sale, purchase or trade of blood and blood components intended for transfusion~~ *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 return of recalled, expired, damaged or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy, chain pharmacy warehouse or charitable institution in accordance with the board's rules and regulations~~ *the transport of a drug by a common carrier, provided that the common carrier does not take ownership of the drug*;

(10) ~~the sale, transfer, merger or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's rules and regulations~~ *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) ~~the distribution of drug samples by manufacturers' and authorized distributors' representatives~~ *saleable drug returns when conducted by a dispenser*;

(12) the ~~sale~~ *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

~~(13)~~*(20)* the sale or transfer from a retail pharmacy ~~or chain pharmacy warehouse~~ of expired, damaged, returned or recalled prescription drugs to the original manufacturer, originating wholesale distributor or to a third-party returns processor in accordance with the board's rules and regulations.

Sec. 2. K.S.A. 2016 Supp. 65-1627 is hereby amended to read as follows: 65-1627. (a) The board may revoke, suspend, place in a probationary status or deny ~~a~~ *an application or* renewal of any license of any pharmacist upon a finding that:

(1) The ~~license was obtained by~~ *licensee has obtained, renewed or reinstated, or attempted to obtain, renew or reinstate, a license by false or* fraudulent means*, including misrepresentation of a material fact*;

(2) the licensee has been convicted of a *misdemeanor involving moral turpitude or gross immorality or any* felony and the licensee fails to show that the licensee has been sufficiently rehabilitated to warrant the public trust;

(3) the licensee is found by the board to be guilty of unprofessional conduct or professional incompetency;

(4) the licensee is addicted to the liquor or drug habit to such a degree as to render the licensee unfit to practice the profession of pharmacy;

(5) the licensee has violated a provision of the federal or state food, drug and cosmetic act, the uniform controlled substances act of the state of Kansas, or any rule and regulation adopted under any such act;

(6) the licensee is found by the board to have filled a prescription not in strict accordance with the directions of the practitioner or a mid-level practitioner;

(7) the licensee is found to be mentally or physically incapacitated to such a degree as to render the licensee unfit to practice the profession of pharmacy;

(8) the licensee has violated any of the provisions of the pharmacy act of the state of Kansas or any rule and regulation adopted by the board pursuant to the provisions of such pharmacy act;

(9) the licensee has failed to comply with the *continuing education* requirements of the board ~~relating to the continuing education of pharmacists~~ *for license renewal*;

(10) the licensee as a pharmacist in charge or consultant pharmacist under the provisions of ~~subsection (c) or (d) of~~ K.S.A. 65-1648*(c) or (d)*, and amendments thereto, has failed to comply with the requirements of

~~subsection (c) or (d) of~~ K.S.A. 65-1648*(c) or (d)*, and amendments thereto;

(11) the licensee has knowingly submitted a misleading, deceptive, untrue or fraudulent misrepresentation on a claim form, bill or statement;

(12) the licensee has had a license to practice pharmacy revoked, suspended or limited, has been censured or has had other disciplinary action taken, or voluntarily surrendered the license after formal proceedings have been commenced, or has had an application for license denied, by the proper licensing authority of another state, territory, District of Columbia or other country, a certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof;

(13) the licensee has self-administered any controlled substance without a practitioner's prescription order or a mid-level practitioner's prescription order; or

(14) the licensee has assisted suicide in violation of K.S.A. 21-3406, prior to its repeal, or K.S.A. 2016 Supp. 21-5407, and amendments thereto, as established by any of the following:

(A) A copy of the record of criminal conviction or plea of guilty for a felony in violation of K.S.A. 21-3406, prior to its repeal, or K.S.A. 2016 Supp. 21-5407, and amendments thereto.

(B) A copy of the record of a judgment of contempt of court for violating an injunction issued under K.S.A. 60-4404, and amendments thereto.

(C) A copy of the record of a judgment assessing damages under K.S.A. 60-4405, and amendments thereto;~~ or~~

(15) the licensee has failed to furnish the board, its investigators or its representatives any information legally requested by the board*;*

(16) the licensee has violated or failed to comply with any lawful order or directive of the board; or

(17) the licensee has violated any of the provisions of the prescription monitoring program act of the state of Kansas or any rule and regulation of the board pursuant to the provisions of the prescription monitoring program act.

(b) In determining whether or not the licensee has violated subsection (a)(3), (a)(4), (a)(7) or (a)(13), the board upon reasonable suspicion of such violation has authority to compel a licensee to submit to mental or physical examination or drug screen, or any combination thereof, by such persons as the board may designate. To determine whether reasonable suspicion of such violation exists, the investigative information shall be presented to the board as a whole. Information submitted to the board as a whole and all reports, findings and other records shall be confidential and not subject to discovery by or release to any person or entity. The licensee shall submit to the board a release of information authorizing the board to obtain a report of such examination or drug screen, or both. A person

affected by this subsection shall be offered, at reasonable intervals, an opportunity to demonstrate that such person can resume the competent practice of pharmacy with reasonable skill and safety to patients. For the purpose of this subsection, every person licensed to practice pharmacy and who shall accept the privilege to practice pharmacy in this state by so practicing or by the making and filing of a renewal application to practice pharmacy in this state shall be deemed to have consented to submit to a mental or physical examination or a drug screen, or any combination thereof, when directed in writing by the board and further to have waived all objections to the admissibility of the testimony, drug screen or examination report of the person conducting such examination or drug screen, or both, at any proceeding or hearing before the board on the ground that such testimony or examination or drug screen report constitutes a privileged communication. In any proceeding by the board pursuant to the provisions of this subsection, the record of such board proceedings involving the mental and physical examination or drug screen, or any combination thereof, shall not be used in any other administrative or judicial proceeding.

(c) The board may temporarily suspend or temporarily limit the license of any licensee in accordance with the emergency adjudicative proceedings under the Kansas administrative procedure act if the board determines that there is cause to believe that grounds exist for disciplinary action under subsection (a) against the licensee and that the licensee's continuation in practice would constitute an imminent danger to the public health and safety.

(d) The board may suspend, revoke, place in a probationary status or deny a renewal of any retail dealer's permit issued by the board when information in possession of the board discloses that such operations for which the permit was issued are not being conducted according to law or the rules and regulations of the board. When the board determines that action under this subsection requires the immediate protection of the public interest, the board shall conduct an emergency proceeding in accordance with K.S.A. 77-536, and amendments thereto, under the Kansas administrative procedure act.

(e) The board may revoke, suspend, place in a probationary status or deny a renewal of the registration of a pharmacy upon a finding that:

(1) Such pharmacy has been operated in such manner that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith;

(2) the owner or any pharmacist employed at such pharmacy is convicted, subsequent to such owner's acquisition of or such employee's employment at such pharmacy, of a violation of the pharmacy act or uniform controlled substances act of the state of Kansas, or the federal or

state food, drug and cosmetic act;

(3) the owner or any pharmacist employed by such pharmacy has fraudulently claimed money for pharmaceutical services; or

(4) the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country, a certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof. When the board determines that action under this subsection requires the immediate protection of the public interest, the board shall conduct an emergency proceeding in accordance with K.S.A. 77-536, and amendments thereto, under the Kansas administrative procedure act.

(f) A registration to manufacture *or repackage* drugs, to ~~distribute at~~ *operate as a* wholesale ~~a drug~~ *distributor*, to sell durable medical equipment *or to operate as a third-party logistics provider,* or a registration for the place of business where any such operation is conducted*,* may be suspended, revoked, placed in a probationary status or the renewal of such registration may be denied by the board upon a finding that the registrant or the registrant's agent:

(1) Has materially falsified any application filed pursuant to or required by the pharmacy act of the state of Kansas;

(2) has been convicted of a felony under any federal or state law relating to the manufacture or distribution of drugs;

(3) has had any federal registration for the manufacture or distribution of drugs suspended or revoked;

(4) has refused to permit the board or its duly authorized agents to inspect the registrant's establishment in accordance with the provisions of K.S.A. 65-1629, and amendments thereto;

(5) has failed to keep, ~~or~~ has failed to file with the board or has falsified records required to be kept or filed by the provisions of the pharmacy act of the state of Kansas or by the board's rules and regulations; or

(6) has violated the pharmacy act of the state of Kansas or rules and regulations adopted by the state board of pharmacy under the pharmacy act of the state of Kansas ~~or,~~ has violated the uniform controlled substances act or rules and regulations adopted by the state board of pharmacy under the uniform controlled substances act *or has violated a provision of the federal drug supply chain security act or any rule or regulation adopted under such act*. When the board determines that action under this subsection requires the immediate protection of the public interest, the board shall conduct an emergency proceeding in accordance with K.S.A. 77-536, and amendments thereto, under the Kansas administrative

procedure act.

(g) Orders under this section, and proceedings thereon, shall be subject to the provisions of the Kansas administrative procedure act.

Sec. 3. K.S.A. 65-1633 is hereby amended to read as follows: 65-1633. Every pharmacist who changes residential address *or email address* shall within 30 days thereof ~~by letter~~ notify the ~~executive~~ secretary ~~of the board~~ of such change *on a form prescribed and furnished by the board*, and upon receipt of the notice the ~~executive~~ secretary shall make the proper alterations in the record kept for that purpose.

Sec. 4. K.S.A. 65-1635 is hereby amended to read as follows: 65-1635. (a) Nothing contained in the pharmacy act of the state of Kansas shall prohibit any duly licensed practitioner from purchasing and keeping drugs, from compounding prescriptions or from administering, supplying or dispensing to such practitioner's patients such drugs as may be fit, proper and necessary. Except as provided in subsection (b) or (c), such drugs shall be dispensed by such practitioner and shall comply with the Kansas food, drug and cosmetic act and be subject to inspection as provided by law.

(b) Nothing contained in the pharmacy act of the state of Kansas shall be construed to prohibit any nurse or other person, acting under the direction of a duly licensed practitioner, from administering drugs to a patient.

(c) Nothing contained in the pharmacy act of the state of Kansas shall be construed to prohibit any registered nurse, acting under the supervision of a person who is licensed to practice medicine and surgery as of July 1, 1982, from dispensing drugs to patients of such person so long as the principal office of such person is, and as of July 1, 1982, was, located in a city not having a registered pharmacy within its boundaries. For the purposes of this subsection (c), "supervision" means guidance and direction of the dispensing of drugs by the person licensed to practice medicine and surgery who shall be physically present in the general location at which the drugs are being dispensed.

(d) Nothing contained in the pharmacy act of the state of Kansas shall be construed to prohibit a duly registered ~~wholesaler~~ *wholesale distributor* from distributing a prescription-only drug pursuant to a veterinarian practitioner's written prescription or order~~,~~ where a valid veterinarian-client-patient relationship, VCPR, as defined in K.S.A. 47-816, and amendments thereto, exists, to the layman responsible for the control of the animal.

(e) Nothing contained in the pharmacy act of the state of Kansas shall require an in-person examination or encounter between a person licensed to practice medicine and surgery and the patient prior to a pharmacist filling or refilling any prescription.

Sec. 5. K.S.A. 2016 Supp. 65-1636 is hereby amended to read as follows: 65-1636. (a) Except as otherwise provided in this act, the sale and ~~distribution~~ *dispensing* of drugs shall be limited to pharmacies operating under registrations as required by this act, and the actual sale or ~~distribution~~ *dispensing* of drugs shall be made by a pharmacist or other persons acting under the immediate personal direction and supervision of the pharmacist.

(b) The donation, acceptance, transfer, distribution or dispensing of any drug in compliance with the provisions of the utilization of unused medications act and any rules and regulations promulgated thereunder shall not constitute a violation of this section.

Sec. 6. K.S.A. 2016 Supp. 65-1637 is hereby amended to read as follows: 65-1637. ~~In every store, shop or other place defined in this act as a "pharmacy" there shall be a pharmacist in charge and, except as otherwise provided by law, the compounding and dispensing of prescriptions shall be limited to pharmacists only. Except as otherwise provided by the pharmacy act of this state, when a pharmacist is not in attendance at a pharmacy, the premises shall be enclosed and secured. Prescription orders may be written, oral, telephonic or by electronic transmission unless prohibited by law. Blank forms for written prescription orders may have two signature lines. If there are two lines, one signature line shall state: "Dispense as written" and the other signature line shall state: "Brand exchange permissible." Prescriptions shall only be filled or refilled in accordance with the following requirements:~~

~~(a) All prescriptions shall be filled in strict conformity with any directions of the prescriber, except:~~

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

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

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

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

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

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

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

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

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

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

~~(e) If a prescription order contains a statement that during any particular time the prescription may be refilled at will, there shall be no~~

~~limitation as to the number of times that such prescription may be refilled except that it may not be refilled after the expiration of the time specified or one year after the prescription was originally issued, whichever occurs first.~~

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

~~Nothing contained in this section shall be construed as preventing a pharmacist from refusing to fill or refill any prescription if in the pharmacist's professional judgment and discretion such pharmacist is of the opinion that it should not be filled or refilled.~~ *(a) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of any prescription order consistent with federal and state laws and rules and regulations.* ***{Except as provided in K.S.A. 65-1635(e), and amendments thereto, and as may otherwise be provided by law,}*** *a pharmacist shall not dispense a prescription drug if the pharmacist, in the exercise of professional judgment, determines that the prescription is not a valid prescription order.*

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

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

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

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

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

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

electronic transmission initiated by or directed by the prescriber.

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

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

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

(f) A refill is one or more dispensings of a prescription drug or device that results in the patient's receipt of the quantity authorized by the prescriber for a single fill as indicated on the prescription order.

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

(g) All prescriptions shall be filled or refilled in strict conformity with any directions of the prescriber, except that:

(1) A pharmacist who receives a prescription order for a brand name drug product, excluding a biological product, may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

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

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

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

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

(2) a pharmacist may provide up to a three-month supply of a prescription drug that is not a controlled substance or psychotherapeutic drug when a practitioner has written a drug order to be filled with a

smaller supply but included sufficient numbers of refills for a three-month supply; or

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

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

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

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

(D) the biological product is not an interchangeable biological product for the prescribed biological product.

(h) A pharmacist who selects an interchangeable biological product shall inform the patient or the patient's representative that an interchangeable biological product has been substituted for the prescribed biological product.

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

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

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

(2) A pharmacist may refill a prescription order issued on or after the effective date of this act for any prescription drug, except a drug listed on schedule II of the uniform controlled substances act or a narcotic drug listed on any schedule of the uniform controlled substances act, without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional

judgment, continuation of the medication is necessary for the patient's health, safety and welfare. Such prescription refill shall only be in an amount judged by the pharmacist to be sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this paragraph be more than a seven-day supply or one package of the drug. However, if the prescriber states on a prescription that there shall be no emergency refilling of that prescription, then the pharmacist shall not dispense any emergency medication pursuant to that prescription. A pharmacist who refills a prescription order under this paragraph shall contact the prescriber of the prescription order on the next business day subsequent to the refill or as soon thereafter as possible. No pharmacist shall be required to refill any prescription order under this paragraph. A prescriber shall not be subject to liability for any damages resulting from the refilling of a prescription order by a pharmacist under this paragraph unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions by the prescriber.

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

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

(n) ***{Except as provided in K.S.A. 65-1635(e), and amendments thereto, and as may otherwise be provided by law,}*** *nothing contained in this section shall be construed as preventing a pharmacist from refusing to fill or refill any prescription if, in the pharmacist's professional judgment and discretion, such pharmacist is of the opinion that it should not be filled or refilled.*

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

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

(2) an electronic prescribing technology;

(3) a pharmacy benefits management system; or

(4) a pharmacy record.

(p) Entry into an electronic records system as described in subsection (o) shall be presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission or other

prevailing means, provided that communication shall not be required where:

(1) There is no FDA-approved interchangeable biological product for the product prescribed; or

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

(q) A pharmacist shall maintain a record of any biological product dispensed for at least five years.

(r) The board shall maintain a link on its website to the current lists of all biological products that the FDA has determined to be interchangeable biological products.

New Sec. 7. (a) An automated dispensing system shall be under the supervision of a pharmacist licensed in Kansas, who may be retained on a part-time basis and who shall be responsible for recordkeeping and storage of all drugs and verifying and documenting each prescription drug prepared or dispensed by such system.

(b) The board shall adopt such rules and regulations relating to automated dispensing systems as necessary for proper control and operation.

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

Sec. 8. K.S.A. 2016 Supp. 65-1642 is hereby amended to read as follows: 65-1642. (a) Each pharmacy shall be equipped with proper pharmaceutical utensils, in order that prescriptions can be properly filled and United States ~~pharmacopoeia~~ *pharmacopeia* and national formulary preparations properly compounded, and with proper sanitary appliances ~~which~~ *that* shall be kept in a clean and orderly manner. The board shall prescribe the minimum of such professional and technical equipment which a pharmacy shall at all times possess.

(b) Each pharmacy shall keep a suitable book or file ~~which~~ *that* records every prescription order filled at the pharmacy and a medication profile record system as provided under subsection (d). The book or file of prescription orders shall be kept for a period of not less than five years. The book or file of prescription orders shall at all times be open to inspection by members of the board, the secretary of health and environment, the duly authorized agents or employees of such board or secretary and other proper authorities.

(c) (1) A medication profile record system shall be maintained in all pharmacies for persons for whom prescriptions are dispensed. The following information shall be recorded: (A) The name and address of the patient for whom the medication is intended; (B) the prescriber's name, the original date the prescription is dispensed and the number or designation identifying the prescription; (C) the name, strength and quantity of the

drug dispensed and the name of the dispensing pharmacist; and (D) drug allergies and sensitivities.

(2) Upon receipt of a prescription order, the pharmacist shall examine the patient's medication profile record before dispensing the medication to determine the possibility of a harmful drug interaction or reaction to medication. Upon recognizing a potential harmful drug interaction or reaction to the medication, the pharmacist shall take appropriate action to avoid or minimize the problem ~~which~~ *that* shall, if necessary, include consultation with the prescriber with documentation of actions taken on the prescription record.

(3) A medication profile record shall be maintained for a period of not less than five years from the date of the last entry in the record.

(4) All prescription drug orders communicated by way of electronic transmission shall conform to federal and state laws and the provisions of the board's rules and regulations.

(d) No registration shall be issued or continued for the conduct of a pharmacy until or unless the provisions of this section have been complied with.

(e) Each pharmacy shall comply with the requirements of the federal drug supply chain security act, 21 U.S.C. § 351 et seq.

Sec. 9. K.S.A. 2016 Supp. 65-1643 is hereby amended to read as follows: 65-1643. It shall be unlawful:

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

(b) For any person to ~~manufacture within this state any drugs except under the personal and immediate supervision of a pharmacist or such other person or persons as may be approved by the board after an investigation and a determination by the board that such person or persons~~

~~is qualified by scientific or technical training or experience to perform such duties of supervision as may be necessary to protect the public health and safety; and no person shall manufacture any such drugs without first obtaining a registration so to do from the board. Such registration shall be subject to such rules and regulations with respect to requirements, sanitation and equipment, as the board may from time to time adopt for the protection of public health and safety~~ *violate the federal drug supply chain security act, 21 U.S.C. § 351 et seq*.

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

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

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

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

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

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

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

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

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

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

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

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

(2) there is a lawful prescription.

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

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

(m) For any person to sell or lease or offer for sale or lease durable

medical equipment without first obtaining a registration from the board, in accordance with rules and regulations adopted by the board, except that this subsection shall not apply to:

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

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

(n) For any person to operate as an outsourcing facility within this state, or operate as an outsourcing facility outside of Kansas and ship, mail or deliver drugs into this state, without having first obtained a registration from the board.

(o) For any person to operate an automated dispensing system within this state without having first obtained a registration from the board.

Sec. 10. K.S.A. 2016 Supp. 65-1645 is hereby amended to read as follows: 65-1645. (a) Application for registrations or permits under K.S.A. 65-1643, and amendments thereto, shall be made on a form prescribed and furnished by the board. Applications for registration ~~to distribute at wholesale any drugs~~ shall contain such information as may be required by the board in accordance with the provisions of K.S.A. 65-1655, and amendments thereto*, and sections 13 and 14, and amendments thereto*. The application shall be accompanied by the fee prescribed by the board under the provisions of this section. When such application and fees are received by the ~~executive~~ secretary ~~of the board~~ on or before the due date, such application shall have the effect of temporarily renewing the applicant's registration or permit until actual issuance or denial of the renewal. However, if at the time of filing a proceeding is pending before the board ~~which~~ *that* may result in the suspension, probation, revocation or denial of the applicant's registration or permit, the board may declare, by emergency order, that such application for renewal shall not have the effect of temporarily renewing such applicant's registration or permit. Separate applications shall be made and separate registrations or permits issued for each separate place at which is carried on any of the operations for which a registration or permit is required by K.S.A. 65-1643, and amendments thereto.

(b) The nonrefundable fees required for the issuing of the licenses, registrations or permits under the pharmacy act of the state of Kansas shall be fixed by the board as herein provided, subject to the following:

(1) Pharmacy, new registration not more than $150, renewal not more than $125;

(2) pharmacist, new license by examination not more than $350;

(3) pharmacist, reinstatement application fee not more than $250;

(4) pharmacist, biennial renewal fee not more than $200;

(5) pharmacist, evaluation fee not more than $250;

(6) pharmacist, reciprocal licensure fee not more than $250;

(7) pharmacist, penalty fee, not more than $500;

(8) manufacturer, new registration not more than $500, renewal not more than $400;

(9) ~~wholesaler~~*wholesale distributor*, new registration not more than $500, renewal not more than $400, except that a ~~wholesaler~~ *wholesale distributor* dealing exclusively in nonprescription drugs, the manufacturing, distributing or dispensing of which does not require registration under the uniform controlled substances act, shall be assessed a fee for registration and re-registration not to exceed $50;

(10) special auction not more than $50;

(11) samples distribution not more than $50, renewal not more than $50;

(12) institutional drug room, new registration not more than $40, renewal not more than $35;

(13) retail dealer selling more than 12 different nonprescription drug products, new permit not more than $12, renewal not more than $12;

(14) certification of grades for each applicant for examination and registration not more than $25;

(15) veterinary medical teaching hospital pharmacy, new registration not more than $40, renewal not more than $35; ~~or~~

(16) durable medical equipment registration fee, not more than $300, renewal not more than $300*;*

(17) third-party logistics provider, new registration not more than $500, renewal not more than $400, except that a third-party logistics provider exclusively providing nonprescription drugs, the manufacturing, distributing or dispensing of which does not require registration under the uniform controlled substances act, shall be assessed a fee for registration and re-registration not to exceed $50;

(18) outsourcing facility, new registration not more than $500, renewal not more than $400;

(19) repackager, new registration not more than $500, renewal not more than $400; or

(20) automated dispensing system registration fee, not more than $40, renewal not more than $35.

(c) For the purpose of fixing fees, the board may establish classes of retail dealers' permits for retail dealers selling more than 12 different nonprescription drug products, and the board may fix a different fee for each such class of permit.

(d) The board shall determine annually the amount necessary to carry out and enforce the provisions of this act for the next ensuing fiscal year and shall fix by rules and regulations the fees authorized for such year at the sum deemed necessary for such purposes. The fees fixed by the board under this section immediately prior to the effective date of this act shall

continue in effect until different fees are fixed by the board by rules and regulations as provided under this section.

(e) The board may deny renewal of any registration or permit required by K.S.A. 65-1643, and amendments thereto, on any ground ~~which~~ *that* would authorize the board to suspend, revoke or place on probation a registration or permit previously granted pursuant to the provisions of K.S.A. 65-1643, and amendments thereto. Registrations and permits issued under the provisions of K.S.A. 65-1643 and 65-1644, and amendments thereto, shall be conspicuously displayed in the place for which the registration or permit was granted. Such registrations or permits shall not be transferable. All such registrations and permits shall expire every year. The expiration date shall be established by rules and regulations adopted by the board. All registrations and permits shall be renewed annually. Notice of renewal of registrations and permits shall be ~~mailed~~ *sent* by the board to each registrant or permittee at least 30 days prior to expiration of the registration or permit. If application for renewal is not made prior to expiration, the existing registration or permit shall lapse and become null and void on the date of its expiration, and no new registration or permit shall be granted except upon payment of the required renewal fee plus a penalty equal to the renewal fee. Failure of any registrant or permittee to receive such notice of renewal shall not relieve the registrant or permittee from the penalty hereby imposed if the renewal is not made as prescribed.

(f) In each case in which a license of a pharmacist is issued or renewed for a period of time less than two years, the board shall prorate to the nearest whole month the license or renewal fee established pursuant to this section.

(g) The board may require that fees paid for any examination under the pharmacy act of the state of Kansas be paid directly to the examination service by the person taking the examination.

Sec. 11. K.S.A. 65-1648 is hereby amended to read as follows: 65-1648. (a) Any medical care facility pharmacy registered by the board may keep drugs in such facility and may supply drugs to its inpatients and outpatients. Distribution and control of prescription medications in a medical care facility pharmacy shall be under the supervision of a pharmacist in charge. A designated registered nurse or nurses or a licensed physician assistant approved by the pharmacist in charge and under the supervision of the pharmacist in charge shall be in charge of the distribution and control of drugs of a medical care facility pharmacy when a pharmacist is not on the premises. Drugs supplied to outpatients when a pharmacist is not on the premises shall be limited to the quantity necessary until a prescription can be filled.

(b) Nothing contained in this act shall be construed as prohibiting an

adult care home ~~which~~ *that* utilizes the services of a pharmacist, from maintaining an emergency medication kit approved by the adult care home's medical staff composed of a duly licensed practitioner and a pharmacist. The emergency medication kit shall be used only in emergency cases under the supervision and direction of a duly licensed practitioner, and a pharmacist shall have supervisory responsibility of maintaining said emergency medication kit.

(c) Every adult care home ~~which~~ *that* maintains an emergency medication kit under subsection (b) shall comply with the following requirements:

(1) Drugs in an emergency medication kit shall be maintained under the control of the pharmacist in charge of the pharmacy from which the kit came until administered to the patient upon the proper order of a practitioner.

(2) Drugs contained within the emergency medication kit may include controlled substances, but in such case a pharmaceutical services committee shall be responsible for specifically limiting the type and quantity of controlled substance to be placed in each emergency kit.

(3) Administration of controlled substances contained within the emergency medication kit shall be in compliance with the provisions of the uniform controlled substances act.

(4) The consultant pharmacist of the adult care home shall be responsible for developing procedures, proper control and accountability for the emergency medication kit and shall maintain complete and accurate records of the controlled substances, if any, placed in the emergency kit. Periodic physical inventory of the kit shall be required.

(d) (1) The ~~state~~ department of health and environment, any county, city-county or multicounty health department, indigent health care clinic, federally qualified health center and any private not-for-profit family planning clinic, when registered by the board, may keep drugs for the purpose of distributing drugs to patients being treated by that health department, indigent health care clinic, federally qualified health center or family planning clinic. Distribution and control of prescription medications in a health department, indigent health care clinic, federally qualified health center or family planning clinic shall be under the supervision of a pharmacist in charge. A designated registered nurse or nurses or a licensed physician assistant approved by the pharmacist in charge shall be in charge of distribution and control of drugs in the health department, indigent health care clinic, federally qualified health center or family planning clinic under the supervision of the pharmacist in charge when a pharmacist is not on the premises. Drugs supplied to patients when a pharmacist is not on the premises shall be limited to the quantity necessary to complete a course of treatment as ordered by the practitioner

supervising such treatment.

(2) The board shall adopt rules and regulations relating to specific drugs to be used, to recordkeeping and to storage of drugs by a health department, indigent health care clinic, federally qualified health center or family planning clinic as are necessary for proper control of drugs.

(3) Any medical care facility pharmacy registered by the board shall comply with the applicable requirements of the federal drug supply chain security act, 21 U.S.C. § 351 et seq.

Sec. 12. K.S.A. 2016 Supp. 65-1655 is hereby amended to read as follows: 65-1655. (a) The board shall require an applicant for registration ~~to distribute at~~ *as a* wholesale ~~any drugs~~ *distributor* under K.S.A. 65-1643, and amendments thereto, or an applicant for renewal of such a registration, to provide the following information:

(1) The name, full business address and telephone number of the applicant;

(2) all trade or business names used by the applicant;

(3) addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling and distribution of prescription drugs;

(4) the type of ownership or operation of the applicant;

(5) the name of the owner or operator, or both, of the applicant, including:

(A) If a person, the name of the person;

(B) if a partnership, the name of each partner~~,~~ and the name of the partnership;

(C) if a corporation, the name and title of each corporate officer and director, the corporate names and the name of the state of incorporation;

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

(6) such other information as the board deems appropriate.

Changes in any information in this subsection ~~(a)~~ shall be submitted to the board as required by ~~such~~ *the* board.

(b) In reviewing the qualifications for applicants for initial registration or renewal of registration ~~to distribute at~~ *as a* wholesale ~~any drugs~~ *distributor*, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

(2) any felony convictions of the applicant under federal or state laws;

(3) the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) the furnishing by the applicant of false or fraudulent material in

any application made in connection with drug manufacturing or distribution;

(5) suspension or revocation by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) compliance with registration requirements under previously granted registrations, if any;

(7) compliance with requirements to maintain or make available to the board or to federal state or local law enforcement officials those records required by federal food, drug and cosmetic act~~,~~ and rules and regulations adopted pursuant thereto; and

(8) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(c) After consideration of the qualifications for applicants for registration ~~to distribute at~~ *as a* wholesale ~~any drugs~~ *distributor*, the board may deny an initial application for registration or application for renewal of a registration if the board determines that the granting of such registration would not be in the public interest. The authority of the board under this subsection to deny a registration ~~to distribute at~~ *as a* wholesale ~~any drugs~~ *distributor* shall be in addition to the authority of the board under ~~subsection (e) of~~ K.S.A. 65-1627*(e)*, and amendments thereto, or ~~subsection (e) of~~ K.S.A. 65-1645*(e)*, and amendments thereto.

(d) The board by rules and regulations shall require that personnel employed by persons registered ~~to distribute at~~ *as a* wholesale ~~any drugs~~ *distributor* have appropriate education or experience, or both, to assume responsibility for positions related to compliance with state registration requirements.

(e) The board by rules and regulations may implement this section to conform to any requirements of the federal ~~prescription drug marketing act of 1987~~ *drug supply chain security act* ~~(~~*,* 21 U.S.C. § ~~321~~ *351* et seq.~~)~~*,* in effect on the effective date of this act.

(f) Each facility that engages in wholesale distribution must undergo an inspection by the board or a third party recognized by the board to inspect ~~and accredit~~ wholesale distributors for the purpose of inspecting the wholesale distribution operations prior to initial registration and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three years. ~~The board shall have the authority to waive registration requirements for wholesale distributors that are accredited by an accrediting agency approved by the board.~~ The board shall adopt rules and regulations to establish standards and requirements for the issuance and maintenance of a wholesale distributor registration, including inspections of wholesale distributor facilities domiciled in the

state.

(1) Individual or third party inspectors must demonstrate to the board that they have received training or demonstrate familiarity with the inspection standards. Evidence such as a letter of certification from a training program, notice from the inspector's employing third party organization or other means recognized by the board shall be accepted as meeting the requirement.

(2) The board may register a wholesale distributor that is licensed or registered under the laws of another state if:

(A) The requirements of that state are deemed by the board to be substantially equivalent; or

(B) the applicant is inspected ~~and accredited~~ by a third party recognized and approved by the board.

(g) A person licensed or approved by the ~~federal food and drug administration~~ *FDA* to engage in ~~the manufacture of drugs or devices engaged in~~ wholesale distribution need only satisfy the minimum federal requirements for licensure provided in ~~federal food and drug administration~~ *FDA* regulations 21 C.F.R. Part 205 to provide wholesale distribution services.

(h) The board by rule and regulation shall establish standards and requirements for the issuance and maintenance of a wholesale distributor registration, including, but not limited to, requirements regarding the following:

(1) An application and renewal fee;

(2) a surety bond;

(3) registration and periodic inspections;

(4) certification of a designated representative;

(5) designation of a registered agent;

(6) storage of drugs and devices;

(7) handling, transportation and shipment of drugs and devices;

(8) security;

(9) examination of drugs and devices and treatment of those found to be unacceptable as defined by the board;

(10) due diligence regarding other ~~wholesale distributors~~ *trading partners*;

(11) creation and maintenance of records, including transaction records; ~~and~~

(12) procedures for operation*; and*

(13) procedures for compliance with the requirements of the federal drug supply chain security act, 21 U.S.C. § 351 et seq.

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

New Sec. 13. (a) The board shall require an applicant for registration

to operate as a third-party logistics provider under K.S.A. 65-1643, and amendments thereto, or an applicant for renewal of such a registration, to provide the following information:

(1) The name, full business address and telephone number of the applicant;

(2) all trade or business names used by the applicant;

(3) addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling and distribution of prescription drugs;

(4) the type of ownership or operation of the applicant;

(5) the name of the owner or operator, or both, of the applicant, including:

(A) If a person, the name of the person;

(B) if a partnership, the name of each partner, and the name of the partnership;

(C) if a corporation, the name and title of each corporate officer and director, the corporate names and the name of the state of incorporation;

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

(6) such other information as the board deems appropriate.

Changes in any information in this subsection shall be submitted to the board as required by the board.

(b) In reviewing the qualifications for applicants for initial registration or renewal of registration to operate as a third-party logistics provider, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

(2) any felony convictions of the applicant under federal or state laws;

(3) the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) suspension or revocation by any federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) compliance with registration requirements under previously granted registrations, if any;

(7) compliance with requirements to maintain or make available to the board or to federal state or local law enforcement officials those

records required by the federal food, drug and cosmetic act, and rules and regulations adopted pursuant thereto; and

(8) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(c) After consideration of the qualifications for applicants for registration to operate as a third-party logistics provider, the board may deny an initial application for registration or application for renewal of a registration if the board determines that the granting of such registration would not be in the public interest. The authority of the board under this subsection to deny a registration to operate a third-party logistics provider shall be in addition to the authority of the board under K.S.A. 65-1627(e) or 65-1645(e), and amendments thereto.

(d) The board by rules and regulations shall require that personnel employed by persons registered to operate as a third-party logistics provider have appropriate education or experience, or both, to assume responsibility for positions related to compliance with state registration requirements.

(e) The board by rules and regulations may implement this section to conform to any requirements of the federal drug supply chain security act, 21 U.S.C. § 351 et seq., in effect on the effective date of this act.

(f) Each facility that operates as a third-party logistics provider must undergo an inspection by the board or a third party recognized by the board to inspect third-party logistics provider operations prior to initial registration and periodically thereafter in accordance with a schedule to be determined by the board, but not less than once every three years. The board shall adopt rules and regulations to establish standards and requirements for the issuance and maintenance of a third-party logistics provider registration, including inspections of third-party logistics provider facilities domiciled in the state.

(1) Individual or third-party inspectors must demonstrate to the board that they have received training or demonstrate familiarity with the inspection standards. Evidence, such as a letter of certification from a training program, notice from the inspector's employing third-party organization or other means recognized by the board shall be accepted as meeting the requirement.

(2) The board may register a third-party logistics provider that is licensed or registered under the laws of another state if:

(A) The requirements of that state are deemed by the board to be substantially equivalent; or

(B) the applicant is inspected by a third party recognized and approved by the board.

(g) A person licensed or approved by the FDA to engage in third-party logistics need only satisfy the minimum federal requirements for

licensure provided in FDA regulations 21 C.F.R. part 205 to provide third-party logistics services.

(h) The board by rules and regulations shall establish standards and requirements for the issuance and maintenance of a third-party logistics provider registration, including, but not limited to, requirements regarding the following:

(1) An application and renewal fee;

(2) a surety bond;

(3) registration and periodic inspections;

(4) certification of a designated representative;

(5) designation of a registered agent;

(6) storage of drugs and devices;

(7) handling, transportation and shipment of drugs and devices;

(8) security;

(9) examination of drugs and devices and treatment of those found to be unacceptable as defined by the board;

(10) due diligence regarding other trading partners;

(11) creation and maintenance of records, including transaction records;

(12) procedures for operation; and

(13) procedures for compliance with the requirements of the federal drug supply chain security act, 21 U.S.C. § 351 et seq.

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

New Sec. 14. (a) The board shall require an applicant for registration as an outsourcing facility under K.S.A. 65-1643, and amendments thereto, or an applicant for renewal of such a registration, to provide the following information:

(1) The name, full business address and telephone number of the applicant;

(2) all trade or business names used by the applicant;

(3) the type of ownership or operation of the applicant;

(4) the name of the owner or operator, or both, of the applicant, including:

(A) If a person, the name of the person;

(B) if a partnership, the name of each partner, and the name of the partnership;

(C) if a corporation, the name and title of each corporate officer and director, the corporate names and the name of the state of incorporation;

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(5) a copy of the valid FDA registration as an outsourcing facility as required by 21 U.S.C. § 353b;

(6) the name and license number of the pharmacist who is designated as the pharmacist-in-charge of the outsourcing facility;

(7) a copy of a current inspection report resulting from an FDA inspection that indicates compliance with the requirements of the federal food, drug and cosmetic act, including guidance documents and current good manufacturing practices established by the FDA, or if no FDA inspection has been conducted within the prior two-year period, the outsourcing facility must undergo an inspection pursuant to subsection (e); and

(8) such other information as the board deems appropriate.

Changes in any information in this subsection shall be submitted to the board as required by the board.

(b) In reviewing the qualifications for applicants for initial registration or renewal of registration as an outsourcing facility, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

(2) any felony convictions of the applicant under federal or state laws;

(3) the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) suspension or revocation by any federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) compliance with registration requirements under previously granted registrations, if any;

(7) compliance with requirements to maintain or make available to the board or to federal state or local law enforcement officials those records required by the federal food, drug and cosmetic act, and rules and regulations adopted pursuant thereto; and

(8) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(c) After consideration of the qualifications for applicants for registration as an outsourcing facility, the board may deny an initial application for registration or application for renewal of a registration if the board determines that the granting of such registration would not be in the public interest. The authority of the board under this subsection to deny a registration to operate as an outsourcing facility shall be in addition to

the authority of the board under K.S.A. 65-1627(e) or 65-1645(e), and amendments thereto.

(d) The board by rules and regulations shall require that personnel employed by persons registered as an outsourcing facility have appropriate education or experience, or both, to assume responsibility for positions related to compliance with state registration requirements.

(e) Each outsourcing facility must undergo an inspection by the board or a third party recognized by the board for the purpose of inspecting operations prior to initial registration and periodically thereafter in accordance with a schedule to be determined by the board, but not less than once every three years. The board shall adopt rules and regulations to establish standards and requirements for the issuance and maintenance of an outsourcing facility registration, including inspections of facilities domiciled in the state.

(f) The board by rules and regulations shall establish standards and requirements for the issuance and maintenance of an outsourcing facility registration, including, but not limited to, requirements regarding the following:

(1) An application and renewal fee;

(2) a surety bond;

(3) registration and periodic inspections;

(4) certification of a designated representative;

(5) designation of a registered agent;

(6) storage of drugs and devices;

(7) handling, transportation and shipment of drugs and devices;

(8) security;

(9) examination of drugs and devices and treatment of those found to be unacceptable as defined by the board;

(10) due diligence regarding other trading partners;

(11) creation and maintenance of records, including transaction records; and

(12) procedures for operation.

(g) Notwithstanding any other provision, no outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it is also registered as a pharmacy in this state and meets all other applicable requirements of federal and state law.

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

Sec. 15. K.S.A. 2016 Supp. 65-1663 is hereby amended to read as follows: 65-1663. (a) It shall be unlawful for any person to function as a pharmacy technician in this state unless such person is registered with the board as a pharmacy technician. *Every person registered as a pharmacy technician shall have graduated from an accredited high school or its*

equivalent, obtained a graduate equivalent diploma (GED) or be enrolled and in good standing in a high school education program. Every person registered as a pharmacy technician shall pass one or more examinations identified and approved by the board within the period or periods of time specified by the board after becoming registered. The board shall adopt rules and regulations identifying the required examinations, when they must be passed and establishing the criteria for the required examinations and passing scores. The board may include as a required examination any national pharmacy technician certification examination. *The board shall adopt rules and regulations restricting the tasks a pharmacy technician may perform prior to passing any required examinations.*

(b) All applications for registration shall be made on a form to be prescribed and furnished by the board. Each application for registration shall be accompanied by a registration fee fixed by the board by rule and regulation not to exceed $50.

(c) The board shall take into consideration any felony conviction of an applicant, but such conviction shall not automatically operate as a bar to registration.

(d) Except as otherwise provided in this subsection, each pharmacy technician registration issued by the board shall expire every two years. The expiration date shall be established by rules and regulations adopted by the board. To provide for a system of biennial renewal of pharmacy technician registrations, the board may provide by rules and regulations that registrations issued or renewed may expire less than two years from the date of issuance or renewal. Each applicant for renewal of a pharmacy technician registration shall be made on a form prescribed and furnished by the board and shall be accompanied by a renewal fee fixed by the board by rule and regulation not to exceed $25. Pharmacy technician registration renewal fees may be prorated for registration periods which are less than biennial in accordance with rules and regulations of the board. Except as otherwise provided in this subsection, the application for registration renewal, when accompanied by the renewal fee and evidence satisfactory to the board that the person has successfully complied with the rules and regulations of the board establishing the requirements for a program of continuing pharmacy technician education and received by the ~~executive~~ secretary ~~of the board~~ on or before the date of expiration of the registration, shall have the effect of temporarily renewing the applicant's registration until actual issuance or denial of the renewal registration. If at the time of filing a proceeding is pending before the board which may result in the suspension, probation, revocation or denial of the applicant's registration, the board may by emergency order declare that the application for renewal shall not have the effect of temporarily renewing such applicant's registration. If the renewal fee is not paid prior to the expiration

date of the renewal year, the registration is void.

(e) *Continuing pharmacy technician education requirements shall be fixed by the board at not more than 20 clock hours biennially of a program of continuing education approved by the board. Continuing education hours may be prorated for licensure periods that are less than biennial in accordance with rules and regulations of the board.*

(f) (1) The board may limit, suspend or revoke a registration or deny an application for issuance or renewal of any registration as a pharmacy technician on any ground, which would authorize the board to take action against the license of a pharmacist under K.S.A. 65-1627, and amendments thereto.

(2) The board may require a physical or mental examination, or both, of a person applying for or registered as a pharmacy technician.

(3) The board may temporarily suspend or temporarily limit the registration of any pharmacy technician in accordance with the emergency adjudicative proceedings under the Kansas administrative procedure act if the board determines that there is cause to believe that grounds exist for disciplinary action under this section against the registrant and that the registrant's continuation of pharmacy technician functions would constitute an imminent danger to the public health and safety.

(4) Proceedings under this section shall be subject to the Kansas administrative procedure act.

~~(f)~~*(g)* Every registered pharmacy technician, within 30 days of obtaining new employment *or ceasing employment as a pharmacy technician*, shall ~~furnish~~ *notify* the ~~board's executive~~ secretary ~~notice~~ of the name and address of the new employer *or cessation of employment.*

(h) Every pharmacy technician who changes their residential address, email address or legal name shall, within 30 days thereof, notify the secretary of such change on a form prescribed and furnished by the board.

~~(g)~~*(i)* Each pharmacy shall at all times maintain a list of the names of pharmacy technicians employed by the pharmacy. A pharmacy technician shall work under the direct supervision and control of a pharmacist*, and while on duty, shall wear a name badge or similar identification with the pharmacy technician's name and designation as a pharmacy technician*. It shall be the responsibility of the supervising pharmacist to determine that the pharmacy technician is in compliance with the applicable rules and regulations of the board, and the supervising pharmacist shall be responsible for the acts and omissions of the pharmacy technician in the performance of the pharmacy technician's duties. The ratio of pharmacy technicians to pharmacists in the prescription area of a pharmacy shall be prescribed by the board by rule and regulation. Any change in the ratio of pharmacy technicians to pharmacists in the prescription area of the

pharmacy must be adopted by a vote of no less than six members of the board.

~~(h)~~*(j)* ~~A person holding a~~*Every registered* pharmacy technician ~~registration~~ shall display ~~such~~ *the current* registration in that part of the place of business in which such person is engaged in pharmacy technician activities.

(k) Every pharmacy technician registered after July 1, 2017, shall be required to pass a certified pharmacy technician examination approved by the board.

~~(i)~~*(l)* The board shall adopt such rules and regulations as are necessary to ensure that pharmacy technicians are adequately trained as to the nature and scope of their lawful duties.

~~(j)~~*(m)* The board may adopt rules and regulations as may be necessary to carry out the purposes and enforce the provisions of this act.

~~(k)~~*(n)* This section shall be part of and supplemental to the pharmacy act of the state of Kansas.

Sec. 16. K.S.A. 2016 Supp. 65-1676 is hereby amended to read as follows: 65-1676. (a) It shall be unlawful for any person to function as a pharmacist intern in this state unless such person is registered with the board as a pharmacist intern.

(b) All applications for registration shall be made on a form to be prescribed and furnished by the board. Each application for registration shall be accompanied by a registration fee fixed by the board by rule and regulation not to exceed $25.

(c) Each pharmacist intern registration issued by the board shall expire six years from the date of issuance.

(d) (1) The board may limit, suspend or revoke a registration or deny an application for issuance or renewal of any registration as a pharmacist intern on any ground that would authorize the board to take action against the license of a pharmacist under K.S.A. 65-1627, and amendments thereto.

(2) The board may temporarily suspend or temporarily limit the registration of any pharmacist intern in accordance with the emergency adjudicative proceedings under the Kansas administrative procedure act, if the board determines that there is cause to believe that grounds exist for disciplinary action under this section against the registrant and that the registrant's continuation of pharmacist intern functions would constitute an imminent danger to the public health and safety.

(3) Proceedings under this section shall be subject to the Kansas administrative procedure act.

(e) Every registered pharmacist intern, within 30 days of obtaining new employment, shall furnish the ~~board's executive~~ secretary notice of the name and address of the new employer.

(f) *Every pharmacist intern who changes their residential address, email address or legal name shall, within 30 days thereof, notify the secretary of such change on a form prescribed and furnished by the board.*

(g) Each pharmacy shall at all times maintain a list of the names of pharmacist interns employed by the pharmacy. A pharmacist intern shall work under the direct supervision and control of a pharmacist. It shall be the responsibility of the supervising pharmacist to determine that the pharmacist intern is in compliance with the applicable rules and regulations of the board, and the supervising pharmacist shall be responsible for the acts and omissions of the pharmacist intern in the performance of the pharmacist intern's duties.

~~(g)~~*(h)* A person holding a pharmacist intern registration shall display such registration in that part of the place of business in which such person is engaged in pharmacist intern activities.

~~(h)~~*(i)* The board shall adopt such rules and regulations as are necessary to ensure that pharmacist interns are adequately trained as to the nature and scope of their lawful duties. The board may adopt rules and regulations as may be necessary to carry out the purposes of and enforce the provisions of this section.

~~(i)~~*(j)* This section shall be part of and supplemental to the pharmacy act of the state of Kansas.

New Sec. 17. (a) The board shall adopt rules and regulations governing proper compounding practices and distribution of compounded drugs by pharmacists and pharmacies.

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

Sec. 18. K.S.A. 65-669 is hereby amended to read as follows: 65-669. A drug or device shall be deemed to be misbranded:

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

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

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

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

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

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

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

(2) As used in this ~~paragraph (e)~~ *subsection*, the term "established name," with respect to a drug or ingredient thereof, means*:* (A) The applicable official name designated pursuant to 21 U.S.C. *§* 358~~, or~~*,* (B) if there is no such name and such drug, or such ingredient, is an article

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

(f) Unless its labeling bears*:* (1) Adequate directions for use; and (2) such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form~~,~~ as are necessary for the protection of users. Where any requirement of ~~clause~~ *paragraph* (1) ~~of this paragraph~~, as applied to any drug or device, is not necessary for the protection of the public health, the secretary shall promulgate regulations exempting such drug or device from such requirements. Articles exempted under regulations issued under 21 U.S.C. *§* 352 (f) may also be exempt.

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

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

failed within a reasonable time to prescribe such requirements.

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

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

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

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

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

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

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

(p) Drugs and devices~~ which~~ *that* are, in accordance with the practice

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

(q) A drug intended for use by ~~man which (A)~~ *human that: (1)* Is a habit-forming drug to which K.S.A. 65-668*, and amendments thereto,* applies; or ~~(B)~~ *(2)* because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or ~~(C)~~ *(3)* is limited by an approved application under 21 U.S.C. *§* 355 or K.S.A. 65-669a*, and amendments thereto,* to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only ~~(i)~~*: (A)* Upon a written prescription of a practitioner licensed by law to administer such drug or upon the written prescription of a mid-level practitioner as defined in ~~subsection (ii) of~~ K.S.A. 65-1626*,* and amendments thereto~~, or (ii)~~*; (B)* upon an oral prescription of such practitioner or mid-level practitioner which is reduced promptly to writing and filed by the pharmacist~~,~~*;* or ~~(iii)~~ *(C)* by refilling, any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in a drug being misbranded while held for sale.

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

(s) The secretary may, by regulation, remove drugs subject to subsection (d) ~~of this section~~ and K.S.A. 65-669a*, and amendments thereto,* from the requirements of ~~paragraph~~ *subsection* (q) ~~of this section~~

when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the federal act by regulations issued thereunder may also, by regulations issued by the secretary, be removed from the requirements of ~~paragraph~~ *subsection* (q) ~~of this section~~.

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

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

Sec. 19. K.S.A. 65-1660 is hereby amended to read as follows: 65-1660. (a) Except as otherwise provided in this section, the provisions of the pharmacy act of the state of Kansas shall not apply to dialysates, devices or drugs which are designated by the board for the purposes of this section relating to treatment of a person with chronic kidney failure receiving dialysis and which are prescribed or ordered by a physician or a mid-level practitioner for administration or delivery to a person with chronic kidney failure if:

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

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

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

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

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

and amendments thereto.

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

Sec. 20. K.S.A. 2016 Supp. 65-1669 is hereby amended to read as follows: 65-1669. As used in the utilization of unused medications act:

(a) "Adult care home" has the same meaning as such term is defined in K.S.A. 39-923, and amendments thereto.

(b) "Community mental health center" has the same meaning as such term is defined in K.S.A. ~~75-3307c~~ *2016 Supp. 39-2002*, and amendments thereto.

(c) "Donating entities" means adult care homes, mail service pharmacies, institutional drug rooms and medical care facilities who elect to participate in the program.

(d) "Drug" has the same meaning as such term is defined in K.S.A. 65-1626, and amendments thereto.

(e) "Federally qualified health center" means a center ~~which~~ *that* meets the requirements for federal funding under 42 U.S.C. § 1396d(1) of the public health service act, and amendments thereto, and ~~which~~ *that* has been designated as a "federally qualified health center" by the federal government.

(f) "Indigent health care clinic" has the same meaning as such term is defined in K.S.A. 75-6102, and amendments thereto.

(g) "Institutional drug room" has the meaning as such term is defined in K.S.A. 65-1626~~(bb)~~, and amendments thereto.

(h) "Mail service pharmacy" means a licensed Kansas pharmacy that ships, mails or delivers by any lawful means a lawfully dispensed medication in tamper-resistant packaging to residents of this state or another state.

(i) "Medical care facility" has the same meaning as such term is defined in K.S.A. 65-425, and amendments thereto.

(j) "Medically indigent" has the same meaning as such term is defined in K.S.A. 75-6102, and amendments thereto.

(k) "Medication" means a prescription drug or drug as defined by this section.

(l) "Mid-level practitioner" has the same meaning as such term is defined in K.S.A. 65-1626, and amendments thereto.

(m) "Practitioner" has the same meaning as such term is defined in K.S.A. 65-1626, and amendments thereto.

(n) "Prescription drug" means a drug ~~which~~ *that* may be dispensed only upon prescription of a practitioner or mid-level practitioner authorized by law and ~~which~~ *that* is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the federal food, drug and cosmetic act, 52 Stat. 1040 (1938), 21 U.S.C.A. § 301.

(o) "Qualifying center or clinic" means an indigent health care clinic, federally qualified health center or community mental health center.

(p) "Samples of medications or injectables" means a unit of drug that is not intended to be sold and is intended to promote the sale of the drug.

Sec. 21. K.S.A. 2016 Supp. 65-2837a is hereby amended to read as follows: 65-2837a. (a) It shall be unlawful for any person licensed to practice medicine and surgery to prescribe, order, dispense, administer, sell, supply or give or for a mid-level practitioner as defined in K.S.A. 65-1626~~(ii)~~, and amendments thereto, to prescribe, administer, supply or give any amphetamine or sympathomimetic amine designated in schedule II, III or IV under the uniform controlled substances act, except as provided in this section. Failure to comply with this section by a licensee shall constitute unprofessional conduct under K.S.A. 65-2837, and amendments thereto.

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

(1) The treatment of narcolepsy.

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

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

(4) The differential diagnostic psychiatric evaluation of depression.

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

(6) The clinical investigation of the effects of such drugs or compounds, in which case, before the investigation is begun, the licensee shall, in addition to other requirements of applicable laws, apply for and obtain approval of the investigation from the *state* board of healing arts.

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

(8) The treatment of binge eating disorder.

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

board of healing arts that the drug or compound can be used for that particular condition.

Sec. 22. K.S.A. 2016 Supp. 65-4202 is hereby amended to read as follows: 65-4202. As used in this act: (a) "Board" means the ~~state~~ board of nursing.

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

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

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

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

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

(d) An "approved course in mental health technology" means a program of training and study including a basic curriculum which shall be prescribed and approved by the board in accordance with the standards prescribed herein, the successful completion of which shall be required before licensure as a mental health technician, except as hereinafter provided.

Sec. 23. K.S.A. 65-7007 is hereby amended to read as follows: 65-7007. (a) Each regulated chemical distributor and retailer shall submit to the bureau:

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

(2) Any proposed regulated transaction with a person whose description or other identifying characteristic the bureau has previously

furnished to the regulated chemical distributor or retailer.

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

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

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

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

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

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

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

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

(B) liquid cold or cough medicines;

(C) liquid cold or cough gel capsules; and

(D) nasal drops or sprays.

Sec. 24. K.S.A. 65-669, 65-1633, 65-1635, 65-1648, 65-1660 and 65-7007 and K.S.A. 2016 Supp. 65-1626, 65-1627, 65-1636, 65-1637, 65-1642, 65-1643, 65-1645, 65-1655, 65-1663, 65-1669, 65-1676, 65-2837a and 65-4202 are hereby repealed.

Sec. 25. This act shall take effect and be in force from and after its publication in the Kansas register.