Proposed Amendments for HB 2614 #1
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HOUSE HEALTH & HUMAN SERVICES
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ATTACHMENT 5

Session of 2016

HOUSE BILL No. 2614

By Committee on Health and Human Services

2-4

AN ACT concerning the state board of pharmacy; powers, duties and functions thereof; amending K.S.A. 65-669, 65-1633, 65-1635, 65-1648, 65-1660 and 65-7007 and K.S.A. 2015 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. 2015 Supp. 65-1637b and 65-1651a.

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

Section 1. K.S.A. 2015 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 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 which: (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) "Board" means the state board of pharmacy created by K.S.A. 74-1603, and amendments thereto.

(f) "Brand exchange" means the dispensing of a different drug product of the same dosage form and strength and of the same generic name as the brand name drug product prescribed.

(g) "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)~~ *(h)* "~~Co-licensee~~*Co-licensed partner*" means ~~a pharmaceutical manufacturer~~ that has entered into an agreement with ~~another~~ pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a ~~prescription drug~~ ~~and the national drug code on the drug product label shall be used to determine the identity of the drug manufacturer~~.

any person

a

product

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

(j) "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 incident to, research, teaching, or chemical analysis and not for sale or dispensing.

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

Compounding shall not include reconstituting any oral or topical drug

compounded and dispensed;~~or~~ (2) which has displayed upon it or within it the words "pharmacist," "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of these words or combinations of these words or words of similar import either in English or any sign containing any of these words; or (3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited. As used in this subsection, premises refers only to the portion of any building or structure leased, used or controlled by the licensee in the conduct of the business registered by the board at the address for which the registration was issued.

~~(oo)~~ *(vv)* "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)~~ *(ww)* "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)~~ *(xx)* "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)~~ *(yy)* "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)~~ *(zz)* "Prescriber" means a practitioner or a mid-level practitioner.

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

~~(vv)~~ *(ccc)* "Prescription-only drug" means any drug whether intended for use by~~man~~ *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)~~ *(ddd)* "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)~~ *(eee)* *"Product" ~~means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, including, but not limited to, capsules, tablets and lyophilized products before reconstitution~~* shall have the meaning as defined by part H of the federal drug supply chain security act, 21 U.S.C. § 351 et seq., 21 U.S.C. § 360eee

(fff) "Professional incompetency" means:

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

(2) repeated instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes ordinary negligence, as determined by the board; or

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

~~(yy)~~ *(ggg)* "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.

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

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

~~(zz)~~ *(jjj)* "Retail dealer" means a person selling at retail nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a prescription-only drug; or (3) a drug intended for human use by hypodermic injection.

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

(mmm) "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)~~ *(nnn)* "Secretary" means the executive secretary of the board.

~~(bbb)~~ *(ooo)* "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~~.

(ppp) "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

(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.

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

~~(ccc)~~ *(rrr)* "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

or to whom a manufacturer, repackager, wholesale distributor or dispenser transfers direct ownership of a product

have no legitimate pharmaceutical purpose.

~~(ddd)~~ *(sss)* "Vaccination protocol" means a written protocol, agreed to by a pharmacist and a person licensed to practice medicine and surgery by the state board of healing arts, which establishes procedures and recordkeeping and reporting requirements for administering a vaccine by the pharmacist for a period of time specified therein, not to exceed two years.

~~(eee)~~ *(ttt)* "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)~~ *(uuu)* "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)~~ *(vvv)* "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)~~ *(www)* "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~~. 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~~