Proposed Amendments for HB 2614 #2
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HOUSE HEALTH & HUMAN SERVICES
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ATTACHMENT 6

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~~.

~~(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

(e) "Biological product" means a virus, a therapeutic serum, a toxin, an antitoxin, a vaccine, blood, a blood polypeptide, or an analogous product, arsphenamine or derivative or arphenamine, or any other trivalent organic arsenic compound which is applicable to the prevention, treatment or cure of a disease or condition of humans.

And by redesignating subsections accordingly

~~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. 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 which 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:

(1) 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:

, excluding a biological product,

(A) The prescriber, in the case of a prescription electronically signed