## Kansas Pharmacy Act Amendments; Filling and Refilling Prescriptions; Biological Products; Senate Sub. for HB 2055

**Senate Sub. for HB 2055** makes several amendments to the Kansas Pharmacy Act (Act).

The bill deletes, adds, and modifies definitions to be consistent with federal standards; modifies the requirements for processing prescription orders to prohibit pharmacists from exercising brand exchange for a biological product; inserts provisions to bring the Act into compliance with the federal Drug Supply Chain Security Act (DSCSA) [Title II of the Drug Quality and Security Act, P.L. 113-54]; modifies requirements for wholesale distributors; inserts requirements for an automated dispensing system, a third-party logistics provider, and an outsourcing facility; changes requirements for pharmacy technicians; sets caps on registration fees for third-party logistics providers, outsourcing facilities, repackagers, and automated dispensing systems; and expands the rules and regulations authority for the Board of Pharmacy (Board) in several areas.

The bill consolidates provisions of two statutes (KSA 2016 Supp. 65-1637b into KSA 2016 Supp. 65-1637; KSA 2016 Supp. 65-1637b is repealed). The bill also repeals an outdated statute requiring study results to be presented to the 2007 Legislature.

The bill also amends the Act to allow a pharmacist to exercise brand exchange (substitution) of biological products without prior approval from the prescriber, unless certain conditions exist. The bill requires pharmacists to notify the patient and prescriber of the substitution of a biological product after the exchange has occurred and establishes recording requirements for biological product substitutions. The bill defines "biological product" and "interchangeable biological product" and clarifies the definition of a "brand exchange" to distinguish between a brand exchange for a prescribed drug product and brand exchange for a prescribed biological product, provides for emergency refill of biological products, and addresses allowable charges for brand exchange of biological products.

### *Definitions*

The bill deletes definitions from the Act for "authorized distributor of record," "chain pharmacy warehouse," and "normal distribution channel."

The bill adds definitions to the Act, including the following:

- "Automated dispensing system" means a robotic or mechanical system controlled by a computer that:
    - Performs operations or activities, other than compounding or administration, relative to storage, packaging, labeling, dispensing, or distribution of drugs;
    - Collects, controls, and maintains all transaction information; and
    - Operates in accordance within the Board's rules and regulations;

- "Biological product" means the same as the term is defined in federal law [42 USC §262(i)], as in effect on January 1, 2017;

- "Common carrier" means any person who undertakes to transport property, including drugs, for compensation;

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

    - 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 a drug approved by the Federal Drug and Drug Administration (FDA); or

    - For the purpose of, or incident to, research, teaching, or chemical analysis, and not for sale or dispensing [*Note:* The bill also clarifies what compounding does and does not include, as outlined below in the section on compounding.];

- "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;

- "Interchangeable biological product" means a biological product the FDA has:

    - Licensed and determined to meet the standards for "interchangeability" as the term is defined in federal law [42 USC §262(k)], as of January 1, 2017; or

    - Determined to be therapeutically equivalent as set forth in the latest edition or supplement of the FDA's approved drug products with their therapeutic equivalence evaluations;

- "Nonresident pharmacy" means a pharmacy located outside of Kansas;

- "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 federal law;

- "Product" means the same as the term is defined by Part H of the DSCSA;

- "Repackage" means changing the container, wrapper, quantity, or label of a drug to further the distribution of the drug;

- "Repackager" means a person who owns or operates a facility that repackages;

- "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;

- "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; and

- "Trading partner" means:

    - 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

    - 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.

The bill also adds definitions for "FDA," "label," "labeling," "long-term care facility," and "transaction."

The bill amends definitions in the Act, including the following:

- "Agent" includes an authorized person who acts on behalf of or at the direction of a repackager, wholesale distributor, or third-party logistics provider;

- "Brand exchange" means:

    - In the case of a drug product prescribed, 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, the dispensing of an interchangeable biological product;

- "Co-licensee" changes to "co-licensed partner" and means a person or a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer or an affiliate of the manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a product;

- "Dispenser" includes 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;

- "Distribute" or "distribution" includes a means to offer to deliver, sell, offer to sell, purchase, trade, transfer, broker, give away, handle, store or receive, other than by administering or dispensing, any product but does not include dispensing a product pursuant to a prescription executed in accordance with or approved under federal law;

- "Drop shipment" means the sale, by a manufacturer, repackager, or exclusive distributor, of the manufacturer's prescription drug, to a wholesale distributor whereby the wholesale distributor takes title to but not possession of such prescription drug and the wholesale distributor invoices the dispenser, and the dispenser receives delivery of the prescription drug directly from the manufacturer, repackager, third-party logistics provider, or exclusive distributor, of such prescription drug;

- "Durable medical equipment" removes references to specific types of equipment and means equipment that:

    - 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;

    - Is primarily and customarily used to serve a medical purpose;

    - Is generally not useful to a person in the absence of an illness or injury;

    - Can withstand repeated use;

    - 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, which are more complex tasks required for independent living; and

    - May include devices and medical supplies or other similar equipment determined by the Board in rules and regulations adopted by the Board;

- "Exclusive distributor" means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser;

- "Manufacturer" means: (1) a person that holds an application approved under the federal Food, Drug, and Cosmetic Act or a license issued under 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 (1) that obtains the drug directly from a person described in (1) or (3); or (3) an affiliate of a person described in (1) or (2) that receives the product directly from a person described in (1) or (2);

- "Third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser, but does not take ownership of the product or have responsibility to direct the sale or disposition of the product;

- "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs other than a manufacturer, co-licensed partner, third–party logistics provider, or repackager; and

- "Wholesale distribution" means the distribution or receipt of prescription drugs to or by persons other than consumers or patients in which a change of ownership occurs. The bill also adds activities that are not considered wholesale distribution.

***Pharmacists***

*Licensure*

The Board has authority to revoke, suspend, place in a probationary status, or deny the renewal of any license of any pharmacist upon findings of the Board. The bill expands that authority to an application for licensure and adds to the list of findings in law as follows:

- The 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;

- The licensee has been convicted of a misdemeanor involving moral turpitude or gross immorality;

- The licensee has failed to comply with the continuing education requirements of the Board for license renewal;

- The licensee has violated or failed to comply with any lawful order or directive of the Board; and

- The licensee has violated any of the provisions of the State's Prescription Monitoring Program Act or any rule and regulation of the Board pursuant to the provisions of the Prescription Monitoring Program Act.

*E-mail Requirement*

The bill requires every pharmacist who changes an e-mail address to notify the Secretary of the Board (Secretary) of such change on a form prescribed and furnished by the Board within 30 days.

*In-person Examination or Encounter Not Required*

The bill states nothing in the Act 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.

*Prescription Orders*

The bill consolidates two statutes regarding how a pharmacist receives, fills, and refills prescription orders, omitting outdated provisions, and amends law to prohibit a pharmacist from exercising brand exchange for prescription orders for a biological product.

### *Wholesale Distributors*

Under the bill, it is unlawful for any person to distribute at wholesale any drugs without first registering as a wholesale distributor from the Board. The bill removes the accreditation requirement for wholesale distributors. The authority for the Board to waive registration requirements for accredited wholesale distributors is removed. The bill allows the Board, by rules and regulations, to implement laws related to wholesale distributors to conform with provisions of the DSCSA.

The bill adds a requirement that the Board, by rules and regulations, follow FDA procedures for compliance with the DSCSA with regard to establishing standards and requirements for the issuance and maintenance of a wholesale distributor registration.

### *Automated Dispensing*

The bill requires an automated dispensing system be under the supervision of a pharmacist licensed in Kansas who is responsible for recordkeeping and storage of all drugs and verifying and documenting each prescription drug prepared or dispensed by the system. The Board is required to adopt rules and regulations related to the control and operation of the system. It is unlawful for any person to operate an automated dispensing system within Kansas without first registering with the Board.

### *Registration Requirements*

It is unlawful for a person to operate as a wholesale distributor, a third-party logistics provider, an outsourcing facility in Kansas, or an outsourcing facility outside of Kansas and ship, mail, or deliver drugs into the state without first obtaining a registration from the Board. The bill allows the Board to suspend, revoke, or place in a probationary status the registration or deny the renewal of such registration to manufacture or repackage drugs, operate as a wholesale distributor, operate an outsourcing facility, sell durable medical equipment, or operate as a third-party logistics provider, or a registration for the place of business where any such operation is conducted, upon specific findings. The bill adds to those findings a violation of the DSCSA or any rule or regulation adopted under the DSCSA.

### *Registration Fees*

The bill sets caps on fees for new and renewal registration for wholesale distributors, third-party logistics providers, outsourcing facilities, repackagers, and automated dispensing systems.

### *Compliance with the Federal Drug Supply Chain Security Act*

The bill requires each pharmacy to comply with the DSCSA and makes it unlawful for any person to violate the Act. The bill also requires any medical care facility pharmacy registered by the Board to comply with the DSCSA.

### *Third-party Logistics Provider*

The bill makes it unlawful for any person to operate as a third-party logistics provider without first having obtained a registration from the Board and sets forth requirements for third-party logistics providers, as follows:

- The Board requires a new or renewal applicant for registration to operate a third-party logistics provider to provide certain information including all trade or business names used, contact information, type of ownership or operation of the applicant, name of owner or operator, the classification of the business, and other information as the Board deems appropriate;

- In reviewing the qualifications for applicants, the Board is required to consider certain factors, including criminal convictions of the applicant, the applicant's experience in the manufacture or distribution of prescription drugs, furnishing of false or fraudulent information on any related application, any suspension or revocation of any license or registration related to the manufacture or distribution of drugs currently or previously held by the applicant, compliance of the applicant as it relates to previously granted registrations and as it relates to maintenance and availability of records as required by federal law, and any other factors the Board considers relevant to and consistent with public health and safety;

- After reviewing applications, the Board has the authority to deny any application of a registration if the Board determines the granting of such registration is not in the public interest;

- The Board is required to adopt rules and regulations to implement the third-party logistics provider provisions;

- Each facility that operates as a third-party logistics provider is required to undergo an inspection, by the Board or a third party recognized by the Board, prior to initial registration and not less than once every three years thereafter. Individual and third-party inspectors are allowed to conduct the inspections but are required to meet the standards set forth in the bill;

- Individual or third-party inspectors are required to demonstrate competence to the Board, as set forth in the bill; and

- A person licensed or approved by the FDA to engage in third-party logistics needs to satisfy only the minimum federal requirements for licensure provided in applicable FDA regulations.

***Outsourcing Facility***

The bill makes it unlawful for any person to operate an outsourcing facility without first having obtained a registration from the Board and sets forth requirements for an outsourcing facility, as follows:

- The Board requires a new or renewal applicant for registration to operate an outsourcing facility to provide certain information including all trade or business names used; contact information; the name of the owner or operator, or both; type of ownership or operation of the applicant; the classification of the business; a copy of the valid FDA registration as an outsourcing facility; the name and license number of the pharmacist who is designated as the pharmacist-in-charge of the outsourcing facility; a copy of a current inspection report resulting from an FDA inspection that indicates compliance with federal law; and other information as the Board deems appropriate;

- In reviewing the qualifications for applicants, the Board is required to consider certain factors, including criminal convictions of the applicant; the applicant's experience in the manufacture or distribution of prescription drugs; furnishing of false or fraudulent information on any related application; any suspension or revocation of any license or registration related to the manufacture or distribution of drugs currently or previously held by the applicant; compliance of the applicant as it relates to previously granted registrations and as it relates to maintenance and availability of records as required by federal law; and any other factors the Board considers relevant to and consistent with public health and safety;

- After reviewing applications, the Board has the authority to deny any application for registration if the Board determines the granting of such registration is not in the public interest;

- The Board is required to adopt rules and regulations to set forth the education and experience requirements for personnel employed by an outsourcing facility and to establish standards and requirements for the issuance and maintenance of an outsourcing facility registration, including inspections;

- Each outsourcing facility is required to undergo an inspection prior to initial registration and not less than once every three years thereafter; and

- No outsourcing facility is allowed to distribute or dispense any drug to any person pursuant to a prescription unless it is also registered as a pharmacy in Kansas and meets all other applicable requirements of federal and state law.

***Pharmacy Technicians***

The bill amends the law relating to pharmacy technicians, as follows:

- Every person registered as a pharmacy technician is required to have graduated from an accredited high school, obtained a graduate equivalent diploma, or be enrolled and in good standing in a high school education program;

- The Board is required to adopt rules and regulations restricting the tasks a pharmacy technician may perform prior to passing any required examinations;

- Continuing pharmacy technician education requirements are fixed by the Board at not more than 20 clock hours biennially of a program approved by the Board, with prorating allowed for less than biennial licensure periods in accordance with rules and regulations of the Board;

- Every registered pharmacy technician is required to notify the Secretary within 30 days of ceasing employment as a pharmacy technician;

- Every pharmacy technician who changes residential address, e-mail address, or legal name is required, within 30 days, to notify the Secretary of such change on a form prescribed and furnished by the Board;

- A pharmacy technician, while on duty, is required to wear a name badge with the pharmacy technician's name and designation as a pharmacy technician;

- Every registered pharmacy technician is required to display his or her current registration in the part of the business where such person is engaged in pharmacy technician activities; and

- Every pharmacy technician registered after July 1, 2017, is required to pass a certified pharmacy technician examination approved by the Board.

***Pharmacist Intern***

The bill requires every pharmacist intern who changes residential address, e-mail address, or legal name, within 30 days, to notify the Secretary of such change on a form prescribed and furnished by the Board.

### *Compounding*

The bill requires the Board to adopt rules and regulations governing proper compounding practices and distribution of compounded drugs by pharmacists and pharmacies. 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.

### *Pharmacist Prescription Fill Requirements for Biological Products*

#### *Exception to Prescription Fill in Strict Conformity with Prescriber Directions*

The bill adds an exception to the requirement that prescriptions be filled in strict conformity with any directions of the prescriber to allow a pharmacist to exercise brand exchange for biological products unless certain conditions are present. The bill provides that 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:

- In the case of a prescription signed by a prescriber and written on a blank form containing two signature lines, the prescriber signs the signature line following the statement “dispense as written”;

- In the case of a prescription signed by the prescriber, the prescriber writes in the prescriber’s own handwriting “dispense as written” on the prescription;

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

- The biological product is not an interchangeable biological product for the prescribed biological product.

#### *Emergency Refill of Biological Products*

The bill allows a pharmacist to refill a prescription order issued on or after the effective date of the bill for any biological product without the prescriber’s authorization when all reasonable efforts to contact the prescriber have failed and, in the pharmacist’s professional judgment, continuation of the medication is necessary for the patient’s health, safety, and welfare. The limit on the amount of the refill authorized in this situation and the prohibition on refilling if the prescriber states no emergency refilling is allowed applicable to prescription drugs not otherwise excluded also applies to refills of biological products. As is currently applicable for emergency refills for authorized prescription drugs, in an emergency refill of a biological product, the following apply:

- The pharmacist is required to contact the prescriber on the next business day following the emergency refill or as soon as possible thereafter;

- A pharmacist is not required to do an emergency refill; and

- Absent gross negligence or willful or wanton acts or omissions by a prescriber, the prescriber is not subject to liability for any damages resulting from the emergency refilling of a prescription order by a pharmacist.

***Allowable Charges for Brand Exchange***

The bill expands law prohibiting a pharmacist from charging the purchaser more than the regular and customary retail price for the dispensed drug when exercising brand exchange and dispensing a less expensive drug product to make such prohibition applicable to a brand exchange of an interchangeable biological product.

***Notice and Recording Requirements for Biological Product Substitutions***

*Notice to Patient or Patient's Representative*

A pharmacist who selects an interchangeable biological product is required to inform the patient or the patient's representative that an interchangeable biological product has been substituted for the biological product prescribed.

*Recording and Notice to Prescriber*

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

- An interoperable electronic medical records system;

- An electronic prescribing technology;

- A pharmacy benefits management system; or

- A pharmacy record.

Entry into an electronic records system, as described above, is presumed to provide notice to the prescriber. Otherwise, the pharmacist is required to communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required when:

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

- A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

The pharmacist is required to maintain a record of the biological product dispensed for at least five years.

The Board is required to maintain a link on its website to the current lists of all biological products the FDA has determined to be interchangeable biological products.