

SESSION OF 2017

SUPPLEMENTAL NOTE ON HOUSE BILL NO. 2055

As Recommended by House Committee on
Health and Human Services

Brief*

HB 2055 would amend the Kansas Pharmacy Act (Act) by deleting, adding, and modifying definitions to be consistent with federal standards (the updated definitions are inserted throughout the bill); modifying the requirements for processing prescription orders to prohibit pharmacists from exercising brand exchange for a biological product; inserting 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]; modifying requirements for wholesale distributors; inserting requirements for an automated dispensing system, a third-party logistics provider, and an outsourcing facility; changing requirements for pharmacy technicians; setting caps on registration fees for third-party logistics providers, outsourcing facilities, repackagers, and automated dispensing systems; and expanding the rules and regulations authority for the Board of Pharmacy (Board) in several areas.

Additionally, the bill would consolidate KSA 2016 Supp. 65-1637 and KSA 2016 Supp. 65-1637b, and repeal KSA 2016 Supp. 65-1637b outright. The bill would repeal an outdated statute requiring study results to be presented to the 2007 Legislature. Finally, the bill would make technical amendments.

*Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at <http://www.kslegislature.org>

Definitions

The bill would delete definitions from the Act for “authorized distributor of record,” “chain pharmacy warehouse,” and “normal distribution channel.”

The bill would add definitions to the Act, including:

- “Automated dispensing system” to mean 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” to mean a virus, a therapeutic serum, a toxin, an antitoxin, a vaccine, blood, a blood polypeptide, or an analogous product, arsphenamine, or derivative of [f] ar[s]phenamine, or any other trivalent organic arsenic compound applicable to the prevention, treatment, or cure of a disease or condition of humans;
- “Common carrier” to mean any person who undertakes to transport property, including drugs, for compensation;
- “Compounding” to mean 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 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 would and would not include, as outlined later in the section on compounding.];

- “Health care entity” to mean any person that provides diagnostic, medical, surgical, or dental treatment or rehabilitative care but does not include any retail pharmacy or wholesale distributor;
- “Nonresident pharmacy” to mean a pharmacy located outside of Kansas;
- “Outsourcing facility” or “virtual outsourcing facility” to mean 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” to have the same meaning as defined by Part H of the DSCSA;
- “Repackage” to mean changing the container, wrapper, quantity, or label of a drug to further the distribution of the drug;
- “Repackager” to mean a person who owns or operates a facility that repackages;
- “Return” to mean 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” to mean 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;
- “Trading partner” to mean:
 - 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 would add new definitions for “FDA,” “label,” “labeling,” “long-term care facility,” and “transaction.”

The bill would amend definitions in the Act, including:

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

- “Co-licensee” changed to “co-licensed partner” to mean 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” to include 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” to include 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” to mean the sale, by a manufacturer, repackager, or exclusive distributor, of the manufacturer’s prescription drug, to a wholesale distributor whereby the wholesale distributor takes title but not possession of such prescription drug and the wholesale distributor invoices the dispenser, and the dispenser receives delivery of the prescription drug directly from the manufacturer, repackager, third-party logistics provider, or exclusive distributor, of such prescription drug;
- “Durable medical equipment” to remove references to specific types of equipment and to mean 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;
 - Generally is not useful to a person in the absence of an illness or injury;
 - Can withstand repeated use;
 - 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” to mean 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” to mean: (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” to mean 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” to mean 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” to mean 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 which would not be considered wholesale distribution.

Pharmacists

Licensure

The Board currently 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 would expand that authority to an application for licensure and add 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; and
- 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.

Email Requirement

The bill would require every pharmacist who changes an email address to notify the Secretary of the Board of such change on a form prescribed and furnished by the Board within 30 days.

Prescription Orders

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

Wholesale Distributors

Under the bill, it would be unlawful for any person to distribute at wholesale any drugs without first obtaining a registration as a wholesale distributor from the Board. The bill would remove the accreditation requirement for wholesale distributors. The authority for the Board to waive registration requirements for accredited wholesale distributors would be removed. The bill would allow the Board, by rules and

regulations, to implement laws related to wholesale distributors to conform with provisions of the DSCSA.

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

Automated Dispensing

The bill would require an automated dispensing system be under the supervision of a pharmacist licensed in Kansas, who would be responsible for record keeping and storage of all drugs, and verifying and documenting each prescription drug prepared or dispensed by the system. The Board would be required to adopt rules and regulations related to the control and operation of the system. It would be unlawful for any person to operate an automated dispensing system within Kansas without first obtaining a registration from the Board.

Registration Requirements

It would be 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 would allow 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, 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 would add to those findings a violation of the DSCSA or any rule or regulation adopted under the DSCSA.

Registration Fees

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

Third-party Logistics Provider

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

- The Board would require 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 would be required to consider certain factors, including criminal convictions of the applicant, applicant's experience in the manufacture or distribution of prescription drugs, furnishing false or fraudulent information on any related application provided by the applicant, 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 would have the authority to deny any application of a registration if the Board determines the granting of such registration would not be in the public interest;
- The Board would be required to adopt rules and regulations to implement the third-party logistics provider provisions;
- Each facility that operates as a third-party logistics provider would be 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 would be allowed to conduct the inspections but would be required to meet the standards set forth in the bill;
- Individual or third-party inspectors would be 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 would need to satisfy only the minimum federal requirements for licensure provided in applicable FDA regulations.

Outsourcing Facility

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

- The Board would require 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 would be 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 provided by the applicant; 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 would have the authority to deny any application for registration if the Board determines the granting of such registration would not be in the public interest;
- The Board would be 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 would be required to undergo an inspection prior to initial registration and not less than once every three years thereafter; and
- No outsourcing facility would be 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 would amend the law relating to pharmacy technicians as follows:

- Every person registered as a pharmacy technician would be 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 would be 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 would be 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 would be required to notify the Secretary within 30 days of ceasing employment as a pharmacy technician;
- Every pharmacist technician who changes residential address, email address, or legal name would be 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, would be required to wear a name badge with the pharmacy technician's name and designation as a pharmacy technician;
- Every registered pharmacy technician would be 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, would be required to pass a certified pharmacy technician examination approved by the Board.

Pharmacist Intern

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

Compounding

The bill would require the Board to adopt rules and regulations governing proper compounding practices and distribution of compounded drugs by pharmacists and pharmacies. Compounding would include the preparation of drugs or devices in anticipation of receiving prescription drug orders based on routine, regularly observed prescribing patterns. Compounding would 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.

Technical Amendments

Technical amendments would be made in Sections 18 through 23 of the bill to update terms and internal references.

Background

The bill was introduced by the House Committee on Health and Human Services at the request of the Board. At the House Committee hearing, representatives of the Board, the Kansas Association of Chain Drug Stores, and the Kansas Pharmacists Association testified as proponents of the bill. The proponents generally testified enactment of the bill would update the Act to change the pharmacy technician qualifications, comply and align with the federal DSCSA and emerging industry standards and trends as they relate to compounding and automation regulation, and improve the Board's function and protection of the public.

Written-only proponent testimony was provided by the Kansas Independent Pharmacy Service Corporation. No other testimony was provided.

According to the fiscal note prepared by the Division of the Budget, the Board indicates enactment of the bill would not affect agency revenue or expenditures.