SESSION OF 2016

SUPPLEMENTAL NOTE ON HOUSE BILL NO. 2614

As Amended by House Committee on Health and Human Services

Brief*

HB 2614 would amend the Pharmacy Practice Act (Act) by deleting, adding, and modifying definitions (the updated definitions are inserted throughout the bill); modifying the requirements for processing prescription orders; inserting provisions to bring the Act into compliance with the Federal Drug Supply Chain Security Act (FDSCSA); 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; and expanding the rules and regulations authority for the Board of Pharmacy (Board) in several areas.

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 which:
    - Performs operations or activities, other than compounding or administration, relative to

*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

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 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;

- "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;

- "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 FDSCSA;

- "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, or 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 would amend definitions in the Act including:

- "Co-licensee" changed to "co-licensed partner" to mean any person that has entered into an agreement with a pharmaceutical 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;

- "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);

- "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;

- "Wholesale distribution" to mean the distribution or receipt of prescription drugs to or by persons other than consumers or patients. The bill also defines what wholesale distribution would not include.

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.

Email Requirement

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

Prescription Orders

The bill would update the standards by which a pharmacist would be required to analyze and dispense any prescription order to include exercising professional judgment as it relates to the accuracy, validity, and authenticity of any prescription order consistent with federal and state laws and rules and regulations. A pharmacists would not be allowed to dispense a prescription drug if the pharmacist, in the exercise of professional judgment, determined the prescription is not a valid prescription order.

The prescriber would be allowed to authorize an agent to transmit to the pharmacy a prescription order orally, by facsimile, or by electronic transmission. A new written or electronically prepared and transmitted prescription order would be required to be signed manually or electronically by the prescriber. In the case of a controlled substance, if the prescription order is written or printed from an electronic prescription application, the prescription would require a manual signature prior to delivery to the patient or prior to facsimile transmission to the pharmacy. The Board would be authorized to conduct pilot projects related to new technology implementation; however, no state moneys would be allowed for such purpose. An authorization to refill a prescription order or to renew or continue an existing drug therapy would be

allowed to be transmitted to a pharmacist through oral communication, in writing, by facsimile, or by electronic transmission initiated by or directed by the prescriber. The authorization for a prescriber's agent to transmit a prescription order, whether new, refill, or renewal, would be allowed only under certain conditions.

The bill would authorize only a pharmacist or a pharmacist intern to receive a new prescription order; however, in addition to a pharmacist and a pharmacist intern, a registered pharmacy technician would be allowed to receive a renewal or refill order when authorized by the supervising pharmacist.

A pharmacist would not be allowed to exercise brand exchange with a view toward achieving a lesser cost to the purchaser if the prescription order is for biological product.

Wholesale Distributors

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 requirement for wholesale distributors to be accredited. The authority for the Board to waive registration requirements for wholesale distributors that are accredited 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 FDSCSA.

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 having first obtained 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, or an outsourcing facility in Kansas without first having obtained a registration from the Board. The bill would allow the Board to suspend, revoke, or place in a probationary status the registration or the renewal of such registration to be denied to manufacture or repackage drugs, to operate as a wholesale distributor, to operate an outsourcing facility, 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, upon specific findings. The bill would add to those findings a violation of the FDSCSA or any rule or regulation adopted under the FDSCSA.

Registration Fees

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

Compliance with the Federal Drug Supply Chain Security Act

The bill would require each pharmacy to comply with the FDSCSA 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 FDSCSA.

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 that 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 a third-party logistics provider;

- The Board would be required to adopt rules and regulations to implement the third-party logistics provider provisions; those rules and regulations could conform to any requirements of the FDSCSA;

- 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. The Board would be required to adopt rules and regulations to establish standards and requirements for the issuance and maintenance of a third-party logistics provider registration, including inspections;

- 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 the 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 that 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;

- Each outsourcing facility would be required to undergo an inspection prior to initial registration and not less than once every three years thereafter. The Board would be required to adopt rules and regulations to establish standards and requirements for the issuance and maintenance of an outsourcing facility registration, including inspections; 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;

- Every registered pharmacy technicians 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, 2016, 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, within 30 days, notify the Secretary of such change 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 routing, 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

At the House Committee on Health and Human Services hearing, representatives of the Board and Kansas Pharmacists Association testified as proponents of the bill. The proponents testified enactment of the bill would update the Pharmacy Practice Act to change the pharmacy technician qualifications, comply and align with the FDSCSA 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 Association of Chain Drugstores. There was no other testimony provided.

The House Committee amended the bill to modify the definitions of "co-licensed partner," "product," and "trading partner"; add the definition of "biological product"; exclude a pharmacist from exercising brand exchange for prescription orders for a biological product; and make a technical amendment.

According to the fiscal note prepared by the Division of the Budget on the original bill, the Board indicates there may be an increase in the number of registrations for new providers, and increased responsibilities for office staff

members, but states it is unknown how the increase would affect revenues or expenditures. The Board anticipates the increase in job duties would be offset by improved licensure software, and does not expect there to be any long-range fiscal effect if the bill is enacted.