SESSION OF 2017

SUPPLEMENTAL NOTE ON SENATE SUBSTITUTE FOR HOUSE BILL NO. 2055

As Amended by Senate Committee of the Whole

Brief*

Senate Sub. for HB 2055 would make several amendments to the Kansas Pharmacy Act (Act).

The bill would delete, add, and modify definitions to be consistent with federal standards (the updated definitions are inserted throughout the bill); modify the requirements for processing prescription orders to prohibit pharmacists from exercising brand exchange for a biological product; insert 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]; modify requirements for wholesale distributors; insert requirements for an automated dispensing system, a third-party logistics provider, and an outsourcing facility; change requirements for pharmacy technicians; set caps on registration fees for third-party logistics providers, outsourcing facilities, repackagers, and automated dispensing systems; and expand the rules and regulations authority for the Board of Pharmacy (Board) in several areas.

The bill would also consolidate provisions of KSA 2016 Supp. 65-1637b into KSA 2016 Supp. 65-1637 and repeal KSA 2016 Supp. 65-1637b. The bill would repeal an outdated statute requiring study results to be presented to the 2007 Legislature.

The bill would also amend the Act to allow a pharmacist to exercise brand exchange (substitution) of biological

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*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

products without prior approval from the prescriber, unless certain conditions exist. The bill would require pharmacists to notify the patient and prescriber of the substitution of a biological product after the exchange has occurred and would establish recording requirements for biological product substitutions. The bill would define a "biological product" and "interchangeable biological product" and clarify the definition of a "brand exchange" to distinguish between a brand exchange for a prescribed drug product and a prescribed biological product, provide for emergency refill of biological products, and address allowable charges for brand exchange of biological products.

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

- "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 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 would clarify what compounding would and would not include, as outlined below 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;

- "Interchangeable biological product" to mean a biological product the FDA has:

    - Licensed and determined meets the standards for "interchangeability" as the term is defined in federal law [42 USC §262(k)], as of January 1, 2017; or
    - Has 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" 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 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;
- “Brand exchange” to mean:
  - 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” 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 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" 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;
- 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" 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 would add 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;

- 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.

In-Person Examination or Encounter Not Required

The bill would state nothing in the Pharmacy 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 would consolidate two statutes regarding how a pharmacist receives, fills, and refills prescription orders, omitting outdated provisions, and would amend 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, 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 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, 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 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, the 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 pharmacy 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.

Pharmacist Prescription Fill Requirements for Biological Products

Exception to Prescription Fill in Strict Conformity with Prescriber Directions [Section 6]

The bill would add 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 would provide that a pharmacist who received a prescription order for a biological product could 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 would allow 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 currently applicable to prescription drugs not otherwise excluded would apply 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 would apply:

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

- A pharmacist would not be required to do an emergency refill; and
- Absent gross negligence or willful or wanton acts or omissions by a prescriber, the prescriber would not be subject to liability for any damages resulting from the emergency refilling of a prescription order by a pharmacist.

Allowable Charges for Brand Exchange [Section 6]

The bill would expand 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 [Section 6]

Notice to Patient or Patient's Representative

A pharmacist who selects an interchangeable biological product would be 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 would be required to make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication would be 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, would be presumed to provide notice to the prescriber. Otherwise, the pharmacist would be required to communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication would not be 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 would be required to maintain a record of the biological product dispensed for at least five years.

The Board would be 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.

Technical Amendments

Technical amendments would be made to update terms and internal references.

Effective Date

The bill would be effective upon publication in the *Kansas Register.*

Background

Senate Sub. for HB 2055

HB 2055 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.

In the Senate Committee on Public Health and Welfare hearing, representatives from the Board and Kansas Pharmacists Association testified in favor of the bill. Written-only proponent testimony was provided by the Kansas Association of Chain Drug Stores and the Kansas Independent Pharmacy Service Corporation. No other testimony was provided.

The Senate Committee incorporated HB 2107, as amended by the House Committee on Health and Human Services, portions of which amend statutes also amended by HB 2055, into HB 2055; inserted language to clarify the Act does not require an in-person examination between a person licensed to practice medicine and surgery and the patient prior to a pharmacist filling or refilling a prescription; amended the bill to make it effective upon publication in the *Kansas Register*; and recommended a substitute bill be adopted.

The Senate Committee of the Whole made two technical amendments to the substitute bill.

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

HB 2107

HB 2107 was introduced by the House Committee on Health and Human Services at the request of the Biotechnology Innovation Organization (BIO). In the House Committee hearing, a patient advocate for the Arthritis Foundation and representatives of the Alliance for Safe Biologic Medicines, Amgen, BIO, Express Scripts, the Midwest Rheumatology Society, and Pfizer testified in favor of the bill. The proponents generally stated current state substitution laws are silent on biologic substitutions, and the bill would establish a clear substitution process. At this time, the FDA has not determined any biosimilars are interchangeable. However, upon FDA approval of interchangeability, current Kansas law would require a pharmacist to obtain advanced approval from the prescriber before being allowed to substitute an interchangeable biologic for a brand name biologic; the bill would remove this requirement. The proponents also stated pharmacists would be required to notify the prescriber within five days of making the biologic substitution because the subtle difference in the biologics could lead to potentially life-threatening immune reactions or reduced efficacy.

Written-only proponent testimony was submitted by the Alliance of Specialty Medicine, the American Cancer Society Cancer Action Network (ACS CAN), the Arthritis and Rheumatology Clinics of Kansas, the Arthritis Foundation, the Coalition of State Rheumatology Organizations, the International Cancer Advocacy Network, the Kansas Chamber, and the Lupus and Allied Diseases Association, Inc.

Opponent testimony was provided by representatives of the Board and the Kansas Pharmacists Association. The opponents stated they generally supported incorporating biological products and the laws governing biosimilar and interchangeable products in Kansas, but could not support the bill because it would place a significant and unnecessary burden on the pharmacist to provide notice to the prescriber of the substitution of a biological product for an FDA-approved interchangeable biological product, presume communication from the pharmacist to the prescriber that may not be accessible to the prescriber, and make the rules for exchange inconsistent for pharmaceutical drugs and biological products. With regard to the reporting requirement, the opponents stated Kansas already has a model for substituting prescription drugs deemed to be equivalent by the FDA, which allows a pharmacist to exercise an exchange unless the prescriber expressly prohibits it by indicating the prescription be "dispensed as written." Written-only opponent testimony was submitted by the Kansas Independent Pharmacy Service Corporation.

Written-only neutral testimony was provided by representatives of the National Association of Chain Drug Stores and the Kansas Medical Society.

The House Committee amended the bill to change the citation to federal law in the bill to the definitions of a "biological product" and an "interchangeable biological product" in effect as of January 1, 2017; amend the definition of "brand exchange" and "interchangeable biological product"; clean up duplicative FDA language; clarify the bill requires notification of an exchange to the patient and physician; make a reference to an FDA list plural, as there are currently three such lists; and make technical amendments.

In the Senate Committee on Public Health and Welfare hearing, representatives from Amgen, the Arthritis Foundation, BIO, Pfizer, and Safe Biologic Medicines testified in favor of the bill.

Written-only proponent testimony was provided by representatives from the ACS CAN, Alliance for Safe Biologic Medicine, Arthritis Foundation, Express Scripts, Kansas Chamber of Commerce, and Kansas Rheumatology Alliance.

Opponent testimony was provided by the Board and the Kansas Independent Pharmacy Service Corporation.

Written-only neutral testimony was provided by a representative of the National Association of Chain Drug Stores.

The Senate Committee agreed to insert the contents of HB 2107, as amended by the House Committee on Health and Human Services, into HB 2055. HB 2107, as amended, would allow a pharmacist to exercise brand exchange (substitution) of biological products without prior approval from the prescriber, unless certain conditions exist; require pharmacists to notify the patient and prescriber of the substitution of a biological product after the exchange has occurred; and would establish recording requirements for biological product substitutions. According to the fiscal note prepared by the Division of the Budget on HB 2107, as introduced, enactment of the bill would have no fiscal effect for the Board.