SESSION OF 2017

SUPPLEMENTAL NOTE ON HOUSE BILL NO. 2107

As Amended by House Committee on Health and Human Services

Brief*

HB 2107, as amended, would amend the Kansas Pharmacy Act (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 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. The bill also would make technical amendments to the Act and to the Kansas Food, Drug and Cosmetic Act and delete outdated reporting requirements. Additional bill details follow.

Definitions

The bill would define and amend the following:

- "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;

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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

- "Brand exchange" would be amended 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;
- "Interchangeable biological product" would mean a biological product the federal Food and Drug Administration (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.

Pharmacist Prescription Fill Requirements for Biological Products

Exception to Prescription Fill in Strict Conformity with Prescriber Directions

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

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

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 federal 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 State Board of Pharmacy (Board) would be required to maintain a link on its website to the current lists of all biological products the federal FDA has determined to be interchangeable biological products.

Background

The bill 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 Action Network, 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.

According to the fiscal note prepared by the Division of the Budget on the bill as introduced, enactment of the bill would have no fiscal effect for the Board.