SUBJECT: Prescription and pharmaceutical substitution of biological products

COMMITTEE: Public Health — committee substitute recommended

VOTE: 10 ayes — Crownover, Naishtat, Blanco, Coleman, Collier, Guerra, R. Miller, Sheffield, Zedler, Zerwas

0 nays

1 absent — S. Davis

WITNESSES: For — Cam Scott, American Cancer Society Cancer Action Network; Thomas Felix, Amgen, Inc.; Chris Nieto, Arthritis Foundation; Chase Bearden, Coalition of Texans with Disabilities; Mark Godfrey, Eli Lilly and Company; Cindi Brannum, Global Healthy Living Foundation; Chuck Clayton, International Cancer Advocacy Network; Jim Mckay, Novartis; Tom Kowalski, Texas Healthcare and Bioscience Institute; Shannon Garrett; (*Registered, but did not testify*: John Robert Ball, AbbVie, Takeda Pharmaceuticals; Michelle Apodaca, Biotechnology Industries Organization; Kwame Walker, Boehringer Ingelheim Pharmaceuticals; Jesse Lewis, Bristol-Myers Squibb; Dennis Borel, Coalition of Texans with Disabilities; Juliana Kerker, Express Scripts; Brad Westmoreland, Genentech; Robert Culley, Generic Pharmaceutical Association; Myra Leo, GlaxoSmithKline; Richard Ponder, Johnson & Johnson; Rebecca Waldrop, Sanofi; Colin Parrish, Sullivan Public Affairs, Hospira; Dan Hinkle, Texas Academy of Family Physicians; Eric Woomer, Texas Dermatological Society; Darren Whitehurst, Texas Medical Association; Kevin Cooper, Texas Nurse Practitioners; Robert Peeler, UCB; Denise Berry)

Against — (*Registered, but did not testify*: Wendy Wilson, Prime Therapeutics)

On — Joe DaSilva, Texas Pharmacy Association; (*Registered, but did not testify*: Audra Conwell, Alliance of Independent Pharmacists of Texas; Bradford Shields, Texas Federation of Drug Stores; Michael Wright,

Texas Pharmacy Business Council; Gay Dodson, Texas State Board of Pharmacy)

BACKGROUND:

Federal law defines "biological product" under 42 USC sec. 262 to include a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or protein applicable to the prevention, treatment, or cure of a disease or condition of a human.

The same law defines "biosimilar" as a biological product that is highly similar to another biological product apart from minor differences in clinically inactive components and that has no clinically meaningful differences between the safety, purity, and potency of the two products. An application for federal license and evaluation of a biosimilar must include studies demonstrating that the biosimilar is highly similar to the biological product except for minor differences in clinically inactive components.

Federal law also defines the term "interchangeable" to mean a biological product that may be substituted for another biological product without the intervention of the health care provider who prescribed the product.

Occupations Code, ch. 562 regulates the prescription and dispensation of drugs that can be substituted for brand-name prescriptions, such as generic drugs.

DIGEST:

CSHB 751 would allow interchangeable biological products to be substituted for brand-name biological products under certain circumstances.

Definitions. CSHB 751 would define the term "biological product" in the state Occupations Code as it is defined by federal law, under 42 U.S.C. 262. It also would define the term "interchangeable" as it is defined in federal law or as a biological product that is designated as therapeutically equivalent to another product by the U.S. Food and Drug Administration (FDA) in the most recent edition or supplement of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as

the Orange Book.

Authorized substitution. If the price of a biological product was lower than a patient's copayment under the patient's prescription drug insurance plan, a pharmacist would have to offer the patient the option of paying for the lower-priced alternative instead of paying the amount of the copayment. The pharmacist would have to record on the prescription form the name, strength, and manufacturer or distributor of a dispensed biological product.

Physician notification by a pharmacist. The dispensing pharmacist or the pharmacist's designee would have to communicate to prescribing practitioners the name as well as the manufacturer or national drug code number of the specific biological product provided to the patient within three business days of dispensing the product. This notification would be made by entering the information, including information submitted for the claims payment, into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that a pharmacist reasonably concluded was electronically accessible by the prescribing practitioner. Otherwise, the pharmacist or a designee would have to communicate the dispensed biological product to the prescribing practitioner by fax, phone, electronic transmission, or other prevailing means. Communication would not be required if there were no interchangeable biological product approved by the FDA for the prescribed product or a refill prescription was not changed from the product dispensed on the prior filling of the prescription.

The notification requirements would expire September 1, 2019.

Labeling. Unless otherwise directed by the practitioner, the label on a biological product's dispensing container would have to indicate the actual product dispensed. The product dispensed would be indicated either by the brand name or, if there was not a brand name, by the drug's generic name or the name of the biological product, the strength of the biological product, and the name of the manufacturer or distributor of the biological product. The bill would require the same state labeling requirements for a

biological product as for another drug dispensed by a Class A or Class E pharmacy.

If a biological product has been selected other than the one prescribed, the pharmacist would have to label the container with the words "substituted for brand prescribed" or "substituted for 'brand name'" where "brand name" was the name of the biological product prescribed.

Interchangeable biological products. The bill would apply to interchangeable biological products the same requirements, other than signage requirements, that apply to generically equivalent drugs in Occupations Code, sec. 562.008-562.011, sec. 562.013, and sec. 562.015. These requirements would relate to:

- authorization to dispense an interchangeable biological product;
- selection of an interchangeable biological product to dispense;
- liability for selecting an interchangeable biological product to dispense; and
- restrictions on selecting interchangeable biological products and charging fees.

The new requirements would apply only to biological product prescriptions issued on or after December 1, 2015.

Rules. The Texas State Board of Pharmacy (TSBP) would have to adopt rules necessary to implement CSHB 751 by December 1, 2015, including rules to provide a dispensing directive to instruct pharmacists on the manner in which to dispense a biological product according to the contents of a prescription.

The board also would maintain on its website a link to the FDA's list of approved interchangeable biological products.

The bill would take effect September 1, 2015.

SUPPORTERS

CSHB 751 would update Texas pharmacy substitution laws for generic

SAY:

drugs so that patients would have access to interchangeable biological products, part of a category of drugs commonly known as biosimilars. The bill would extend the same labeling and patient notification requirements that apply to substituting generic medications to interchangeable biological products. It also would follow federal law that governs substitution, which authorizes substitution of a biosimilar only if it is determined to be interchangeable by the FDA.

Current substitution laws do not contemplate the existence of biosimilars, including interchangeables, although the FDA recently approved Zarxio, the first biosimilar product in the United States, which can be prescribed for patients with cancer, acute myeloid leukemia, and severe chronic neutropenia. Many other biosimilars are undergoing trial and will soon be available, with a host of interchangeable biological products to follow. CSHB 751 would allow greater access to new and less expensive treatment options for Texans who require a biologic medicine for their disease or condition.

Biosimilars, including interchangeables, are much more complex than regular generics, involving biologic molecules that are thousands of times larger and more complex than those in traditional drugs like aspirin or Claritin. The bill recognizes this difference by requiring communication between the pharmacist and prescribing physician as part of a complete treatment plan for patients who would use these drugs. The bill would allow a physician to have up-to-date information that reflected the specific product dispensed and would allow a physician to make changes accordingly. Due to their complexity, one biosimilar or interchangeable biological product might work better or worse for a patient than another, and the physician needs to know which one was dispensed to make the best decisions regarding the patient’s health.

The bill was amended in committee to account for concerns over notification requirements. In response to stakeholder concerns, the the communication requirements in CSHB 751 would expire four years after its effective date, which should give patients, doctors, and pharmacists enough time to fully realize the value of physician communication and

patient safety.

OPPONENTS SAY:

CSHB 751 would create cumbersome notification requirements for pharmacists. Pharmacies already are highly regulated, and an additional notification requirement would further burden the state's pharmacists.

NOTES:

CSHB 751 differs from the bill as introduced in that the substitute would:

- eliminate on September 1, 2019, the requirement for a pharmacist or pharmacist's designee to communicate to the prescribing practitioner the specific product provided to the patient;
- specify that a pharmacist or pharmacist's designee would have to communicate to the prescribing practitioner the specific product provided to the patient within three business days of dispensing the product;
- add "national drug code number" as information a pharmacist or designee could communicate to the prescribing practitioner;
- specify that communication to the prescribing practitioner would include information submitted for claims payment;
- add that a pharmacy record was one that a "pharmacist reasonably concludes" was electronically accessible by the prescribing practitioner;
- remove a provision that would have specified the wording of a sign that a pharmacist was required to display under Occupations Code, sec. 562.009;
- remove a provision regarding requirements for immunosuppressant drugs; and
- add a requirement that the board would have to maintain a website with a link to the FDA's list of approved interchangeable biological products.

The Senate companion bill, SB 542 by Kolkhorst, was considered in a public hearing of the Senate Health and Human Services Committee on April 1 and left pending.