First Regular Session
Sixty-ninth General Assembly
STATE OF COLORADO

ENGROSSED
This Version Includes All Amendments Adopted on Second Reading in the House of Introduction

LLS NO. 13-0189.01 Christy Chase x2008 **HOUSE BILL 13-1121**

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A BILL FOR AN ACT

CONCERNING THE ABILITY OF A PHARMACIST TO SUBSTITUTE A BIOSIMILAR PRODUCT FOR A PRESCRIBED BIOLOGICAL PRODUCT WHEN CERTAIN CONDITIONS ARE SATISFIED.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://www.leg.state.co.us/billsummaries.)

Current law permits a pharmacist to substitute an equivalent drug product for a prescribed drug if the substituted drug is the same generic drug type as the prescribed drug and the pharmacist determines that the substituted drug is therapeutically equivalent to and interchangeable with

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters indicate new material to be added to existing statute.
Dashes through the words indicate deletions from existing statute.

HOUSE
Amended 2nd Reading
February 22, 2013

the prescribed drug. While a pharmacist may substitute chemical drugs, current law does not allow a pharmacist to substitute biological drug products.

The bill allows a pharmacist to substitute a biosimilar product if the federal food and drug administration (FDA) has determined the biosimilar product to be interchangeable with a prescribed biological product for the indicated use and if the practitioner has not indicated that the prescription must be dispensed as written. Once a substitution occurs, the pharmacist must notify the practitioner of the substitution, and the pharmacy from which the biosimilar product was dispensed must retain a record of the substitution for at least 5 years. A pharmacist may comply with the notice requirement by entering the substitution information in an electronic system between the prescribing physician and the pharmacist, including an electronic medical record.

As with the substitution of a chemical drug, the pharmacist substituting a biosimilar product for a prescribed biological product must notify the purchaser orally and in writing and may only substitute a biosimilar product if the substituted product costs less than the prescribed biological product, unless the prescribed biological product is not in stock and the purchaser consents to the higher-priced biosimilar product.

The bill requires the state board of pharmacy to maintain a link on its web site to the FDA resource that identifies biosimilar products approved as interchangeable with specific biological products.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Legislative declaration. (1) The general assembly hereby finds and declares that:

(a) Today's biologic medicines are making a significant impact on the lives of patients with serious illnesses and have the potential to cure diseases like cancer, arthritis, and cardiovascular disorders;

(b) Biological products are often the best treatment for a patient with a serious illness but are complex medicines that are difficult and expensive to manufacture;

(c) Scientists have been developing and continue to develop what are known as "biosimilar" products that, if determined interchangeable by the federal food and drug administration, may be substituted for the

innovative biologic medicine;

(d) However, unlike brand-name and generic chemical drugs, biosimilars are not identical to their innovator counterparts, and since current state law only permits the substitution of a drug that is the same generic type as the prescribed drug, Colorado pharmacists currently cannot substitute a biosimilar product for a prescribed biologic medicine;

(e) The substitution of interchangeable biosimilars consistent with this act will provide patients access to additional treatment options for serious illnesses; and

(f) Because biologics and biosimilars are complex medicines used in patients with grievous illness, the need to identify the actual biological product dispensed is critical to patient safety; therefore, when interchangeable biosimilar products are substituted, communication among patients, pharmacists, and health care providers is essential to patient care.

SECTION 2. In Colorado Revised Statutes, 12-42.5-102, **add** (3.7), (3.8), (13.5), and (16.5) as follows:

12-42.5-102. Definitions. As used in this article, unless the context otherwise requires or the term is otherwise defined in another part of this article:

(3.7) "BIOLOGIC" OR "BIOLOGICAL PRODUCT" HAS THE SAME MEANING AS "BIOLOGICAL PRODUCT", AS DEFINED IN 42 U.S.C. SEC. 262 (i) (1).

(3.8) "BIOSIMILAR PRODUCT" HAS THE SAME MEANING AS "BIOSIMILAR" OR "BIOSIMILARITY", AS DEFINED IN 42 U.S.C. SEC. 262 (i) (2).

(13.5) "FDA" MEANS THE FEDERAL FOOD AND DRUG

ADMINISTRATION.

(16.5) "INTERCHANGEABLE", IN REFERENCE TO A BIOLOGICAL PRODUCT, HAS THE SAME MEANING AS "INTERCHANGEABLE" OR "INTERCHANGEABILITY", AS DEFINED IN 42 U.S.C. SEC. 262 (i) (3).

SECTION 3. In Colorado Revised Statutes, **amend** 12-42.5-122 as follows:

12-42.5-122. Substitution of prescribed drugs or biosimilar products authorized - when - conditions - repeal. (1) (a) A pharmacist filling a prescription order for a specific drug by brand or proprietary name may substitute an equivalent drug product if the substituted drug product is the same generic drug type and, in the pharmacist's professional judgment, the substituted drug product is therapeutically equivalent, is interchangeable with the prescribed drug, and is permitted to be moved in interstate commerce. A pharmacist making a substitution shall assume the same responsibility for selecting the dispensed drug product as he or she would incur in filling a prescription for a drug product prescribed by a generic name; except that the pharmacist is charged with notice and knowledge of the ~~federal food and drug administration~~ FDA list of approved drug substances and manufacturers that is published periodically.

(b) (I) A PHARMACIST FILLING A PRESCRIPTION ORDER FOR A SPECIFIC BIOLOGIC MAY SUBSTITUTE A BIOSIMILAR PRODUCT FOR THE PRESCRIBED BIOLOGIC ONLY IF:

(A) THE FDA HAS DETERMINED THAT THE BIOSIMILAR PRODUCT IS INTERCHANGEABLE WITH THE PRESCRIBED BIOLOGICAL PRODUCT; AND

(B) THE PRACTITIONER HAS NOT INDICATED, IN THE MANNER

DESCRIBED IN SUBSECTION (2) OF THIS SECTION, THAT THE PHARMACIST SHALL NOT SUBSTITUTE A BIOSIMILAR PRODUCT FOR THE PRESCRIBED BIOLOGIC.

(II) (A) WHEN A PHARMACIST SUBSTITUTES AN INTERCHANGEABLE BIOSIMILAR PRODUCT FOR A PRESCRIBED BIOLOGIC, THE PHARMACIST SHALL PROVIDE THE SUBSTITUTION INFORMATION IN WRITTEN, ORAL, OR ELECTRONIC FORM TO THE PRESCRIBING PRACTITIONER WITHIN THREE BUSINESS DAYS AFTER THE SUBSTITUTION TO ENABLE ACCURATE ATTRIBUTION OF ADVERSE EVENTS. ENTERING THE SUBSTITUTION INFORMATION INTO AN ELECTRONIC SYSTEM BETWEEN PRESCRIBING PHYSICIANS AND PHARMACISTS, INCLUDING ELECTRONIC MEDICAL RECORDS, SATISFIES THE REQUIREMENTS OF THIS SUB-SUBPARAGRAPH (A). THIS SUB-SUBPARAGRAPH (A) IS REPEALED, EFFECTIVE THREE YEARS AFTER THE DATE ON WHICH THE FDA FIRST APPROVES A BIOSIMILAR PRODUCT AS INTERCHANGEABLE WITH A SPECIFIC BIOLOGICAL PRODUCT. THE BOARD SHALL NOTIFY THE REVISOR OF STATUTES IN WRITING OF THE DATE ON WHICH FDA APPROVAL OCCURS.

(B) THE PHARMACY FROM WHICH THE SUBSTITUTED INTERCHANGEABLE BIOSIMILAR PRODUCT WAS DISPENSED MUST RETAIN A WRITTEN OR ELECTRONIC RECORD OF THE BIOSIMILAR SUBSTITUTION FOR AT LEAST FIVE YEARS AFTER THE SUBSTITUTION.

(III) THIS PARAGRAPH (b) DOES NOT APPLY TO THE ADMINISTRATION OF VACCINES AND IMMUNIZATIONS AS OUTLINED IN BOARD RULES.

(2) (a) If, in the opinion of the practitioner, it is in the best interest of the patient that the pharmacist not substitute an equivalent drug OR INTERCHANGEABLE BIOSIMILAR PRODUCT for the specific drug OR

BIOLOGIC he or she prescribed, the practitioner may convey this information to the pharmacist in any of the following manners:

(I) Initialing by hand or electronically a preprinted box that states "dispense as written" or "DAW";

(II) Signing by hand or electronically a preprinted box stating "do not substitute" or "dispense as written"; or

(III) Orally, if the practitioner communicates the prescription orally to the pharmacist.

(b) The practitioner shall not transmit by facsimile his or her handwritten signature, nor preprint his or her initials, to indicate "dispense as written".

(3) (a) If a pharmacist makes a substitution OF A DRUG PURSUANT TO PARAGRAPH (a) OF SUBSECTION (1) OF THIS SECTION, the pharmacist shall communicate the substitution to the purchaser in writing and orally, label the container with the name of the drug dispensed, and indicate on the file copy of the prescription both the name of the prescribed drug and the name of the drug dispensed in lieu of the prescribed drug.

(b) IF A PHARMACIST MAKES A SUBSTITUTION OF AN INTERCHANGEABLE BIOSIMILAR PRODUCT PURSUANT TO PARAGRAPH (b) OF SUBSECTION (1) OF THIS SECTION, THE PHARMACIST SHALL COMMUNICATE THE SUBSTITUTION TO THE PURCHASER IN WRITING AND ORALLY, LABEL THE CONTAINER WITH THE FULL NAME OF THE INTERCHANGEABLE BIOSIMILAR PRODUCT DISPENSED, AND INDICATE ON THE FILE COPY OF THE PRESCRIPTION BOTH THE NAME OF THE BIOLOGIC AND THE FULL NAME AND MANUFACTURER AND DISTRIBUTOR, IF AVAILABLE OF THE INTERCHANGEABLE BIOSIMILAR PRODUCT DISPENSED IN LIEU OF THE PRESCRIBED BIOLOGIC.

(c) The pharmacist is not required to communicate a substitution OF EITHER A PRESCRIBED DRUG OR BIOLOGIC to institutionalized patients.

(4) Except as provided in subsection (5) of this section, the pharmacist shall not substitute a drug OR INTERCHANGEABLE BIOSIMILAR product as provided in this section unless the drug OR INTERCHANGEABLE BIOSIMILAR product substituted costs the purchaser less than the drug OR BIOLOGICAL product prescribed. The prescription FOR A DRUG, OTHER THAN A BIOLOGICAL PRODUCT, shall be priced as if it had been prescribed generically.

(5) If a prescription drug outlet does not have in stock the prescribed drug OR BIOLOGICAL product and the only equivalent drug OR INTERCHANGEABLE BIOSIMILAR product in stock is higher priced, the pharmacist, with the consent of the purchaser, may substitute the higher-priced drug OR INTERCHANGEABLE BIOSIMILAR product. This subsection (5) applies only to a prescription drug outlet located in a town, as defined in section 31-1-101 (13), C.R.S.

(6) THE BOARD SHALL MAINTAIN ON ITS WEB SITE A LINK TO THE FDA RESOURCE, IF ONE IS AVAILABLE, THAT IDENTIFIES BIOSIMILAR PRODUCTS APPROVED AS INTERCHANGEABLE WITH SPECIFIC BIOLOGICAL PRODUCTS.

SECTION 4. Act subject to petition - effective date - applicability. (1) This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly (August 7, 2013, if adjournment sine die is on May 8, 2013); except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part

will not take effect unless approved by the people at the general election to be held in November 2014 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

(2) This act applies to prescriptions for biological products issued or ordered on or after the applicable effective date of this act.