**First Regular Session**
**Seventieth General Assembly**
**STATE OF COLORADO**

**INTRODUCED**

LLS NO. 15-0482.01 Christy Chase x2008 **SENATE BILL 15-071**

**SENATE SPONSORSHIP**

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## A BILL FOR AN ACT

**CONCERNING THE ABILITY OF A PHARMACIST TO SUBSTITUTE AN INTERCHANGEABLE BIOLOGICAL 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 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 biological product if the federal food and drug administration (FDA) has determined that the biological product is interchangeable with the prescribed biological product and if the practitioner has not indicated that the prescription must be dispensed as written.

Within a reasonable time after a pharmacist dispenses a biological product, the dispensing pharmacist or the pharmacist's designee must communicate to the prescribing practitioner the specific biological product dispensed to the patient, including the name of the product and manufacturer, through an electronic system. Otherwise, the communication can occur via facsimile, telephone, electronic transmission, or other prevailing means, but the pharmacist is not required to communicate with the prescribing practitioner when:

- No interchangeable biological product exists in the market; or
- The prescription is a refill that is unchanged from the prior filling.

As is required with substitutions of chemical drugs:

- The pharmacy from which an interchangeable biological product is dispensed must retain a record of the substitution for at least 2 years; and
- The pharmacist substituting an interchangeable biological product for a prescribed biological product must notify the purchaser orally and in writing and may only substitute a biological 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 product.

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

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

**SECTION 1.** In Colorado Revised Statutes, 12-42.5-102, **add** (3.7), (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) "BIOLOGICAL PRODUCT" HAS THE SAME MEANING AS "BIOLOGICAL PRODUCT", AS DEFINED IN 42 U.S.C. SEC. 262 (i) (1).

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

(16.5) "INTERCHANGEABLE", IN REFERENCE TO A BIOLOGICAL PRODUCT, MEANS:

(a) "INTERCHANGEABLE" OR "INTERCHANGEABILITY", AS DETERMINED BY THE FDA PURSUANT TO 42 U.S.C. SEC. 262 (k) (4); OR

(b) THAT THE FDA HAS DEEMED THE BIOLOGICAL PRODUCT THERAPEUTICALLY EQUIVALENT TO ANOTHER BIOLOGICAL PRODUCT, AS SET FORTH IN THE LATEST EDITION OR SUPPLEMENT OF THE FDA APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, ALSO REFERRED TO AS THE "ORANGE BOOK".

**SECTION 2.** In Colorado Revised Statutes, **amend** 12-42.5-122 as follows:

**12-42.5-122. Substitution of prescribed drugs authorized - when - conditions.** (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 BIOLOGICAL PRODUCT MAY SUBSTITUTE AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR THE PRESCRIBED BIOLOGIC ONLY IF:

(A) THE FDA HAS DETERMINED THAT THE BIOLOGICAL PRODUCT TO BE SUBSTITUTED 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 AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR THE PRESCRIBED BIOLOGICAL PRODUCT.

(II) WITHIN A REASONABLE TIME AFTER DISPENSING A BIOLOGICAL PRODUCT, THE DISPENSING PHARMACIST OR HIS OR HER DESIGNEE SHALL COMMUNICATE TO THE PRESCRIBING PRACTITIONER THE SPECIFIC BIOLOGICAL PRODUCT DISPENSED TO THE PATIENT, INCLUDING THE NAME AND MANUFACTURER OF THE BIOLOGICAL PRODUCT. THE PHARMACIST OR DESIGNEE SHALL COMMUNICATE THE INFORMATION TO THE PRESCRIBING PRACTITIONER BY MAKING AN ENTRY INTO AN INTEROPERABLE ELECTRONIC MEDICAL RECORDS SYSTEM, THROUGH ELECTRONIC PRESCRIBING TECHNOLOGY, OR THROUGH A PHARMACY RECORD THAT THE PRESCRIBING PRACTITIONER CAN ACCESS ELECTRONICALLY. OTHERWISE, THE PHARMACIST SHALL COMMUNICATE TO THE PRESCRIBING PRACTITIONER THE NAME AND MANUFACTURER OF THE BIOLOGICAL PRODUCT DISPENSED TO THE PATIENT USING FACSIMILE, TELEPHONE, ELECTRONIC TRANSMISSION, OR OTHER PREVAILING MEANS EXCEPT WHEN:

(A) THERE IS NO FDA-APPROVED INTERCHANGEABLE BIOLOGICAL

PRODUCT FOR THE PRESCRIBED BIOLOGICAL PRODUCT; OR

(B) A REFILL PRESCRIPTION IS NOT CHANGED FROM THE BIOLOGICAL PRODUCT DISPENSED ON THE PRIOR FILLING OF THE PRESCRIPTION.

(III) THE PHARMACY FROM WHICH THE BIOLOGICAL PRODUCT WAS DISPENSED MUST RETAIN A WRITTEN OR ELECTRONIC RECORD OF THE DISPENSED BIOLOGICAL PRODUCT FOR AT LEAST TWO YEARS AFTER THE SUBSTITUTION.

(IV) 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 BIOLOGICAL PRODUCT for the specific drug OR BIOLOGICAL PRODUCT 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 PURSUANT TO 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 OR BIOLOGICAL PRODUCT dispensed, and indicate on the file copy of the prescription both the name of the prescribed drug OR BIOLOGICAL PRODUCT and the name of the drug OR BIOLOGICAL PRODUCT dispensed in lieu of the prescribed drug OR PRESCRIBED BIOLOGICAL PRODUCT.

(b) The pharmacist is not required to communicate a substitution to institutionalized patients.

(4) Except as provided in subsection (5) of this section, the pharmacist shall not substitute a drug OR INTERCHANGEABLE BIOLOGICAL product as provided in this section unless the drug OR INTERCHANGEABLE BIOLOGICAL product substituted costs the purchaser less than the drug OR BIOLOGICAL product prescribed. The prescription shall be priced FOR A DRUG, OTHER THAN A BIOLOGICAL PRODUCT, 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 BIOLOGICAL product in stock is higher priced, the pharmacist, with the consent of the purchaser, may substitute the higher priced drug OR INTERCHANGEABLE BIOLOGICAL 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 ALL BIOLOGICAL PRODUCTS APPROVED AS INTERCHANGEABLE WITH SPECIFIC BIOLOGICAL PRODUCTS.

**SECTION 3. Safety clause.** The general assembly hereby finds,

determines, and declares that this act is necessary for the immediate preservation of the public peace, health, and safety.