

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

**PREAMENDED**

*This Unofficial Version Includes Committee  
Amendments Not Yet Adopted on Second Reading*

LLS NO. 15-0482.01 Christy Chase x2008

**SENATE BILL 15-071**

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**SENATE SPONSORSHIP**

**Jahn and Hill**, Aguilar, Scott, Newell, Guzman, Holbert, Johnston, Neville T., Todd

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**McCann and Landgraf**, Ginal

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**Senate Committees**  
Health & Human Services

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**A BILL FOR AN ACT**

101      **CONCERNING THE ABILITY OF A PHARMACIST TO SUBSTITUTE AN**  
102            **INTERCHANGEABLE BIOLOGICAL PRODUCT FOR A PRESCRIBED**  
103            **BIOLOGICAL PRODUCT WHEN CERTAIN CONDITIONS ARE**  
104            **SATISFIED.**

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**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

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.*

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

2 **SECTION 1.** In Colorado Revised Statutes, 12-42.5-102, **add**  
3 (3.7), (13.5), and (16.5) as follows:

4 **12-42.5-102. Definitions.** As used in this article, unless the  
5 context otherwise requires or the term is otherwise defined in another part

1 of this article:

2 (3.7) "BIOLOGICAL PRODUCT" HAS THE SAME MEANING AS  
3 "BIOLOGICAL PRODUCT", AS DEFINED IN 42 U.S.C. SEC. 262 (i) (1).

4 (13.5) "FDA" MEANS THE FEDERAL FOOD AND DRUG  
5 ADMINISTRATION.

6 (16.5) "INTERCHANGEABLE", IN REFERENCE TO A BIOLOGICAL  
7 PRODUCT, MEANS:

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

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

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

17 **12-42.5-122. Substitution of prescribed drugs authorized -**  
18 **when - conditions.** (1) (a) A pharmacist filling a prescription order for  
19 a specific drug by brand or proprietary name may substitute an equivalent  
20 drug product if the substituted drug product is the same generic drug type  
21 and, in the pharmacist's professional judgment, the substituted drug  
22 product is therapeutically equivalent, is interchangeable with the  
23 prescribed drug, and is permitted to be moved in interstate commerce. A  
24 pharmacist making a substitution shall assume the same responsibility for  
25 selecting the dispensed drug product as he or she would incur in filling a  
26 prescription for a drug product prescribed by a generic name; except that  
27 the pharmacist is charged with notice and knowledge of the ~~federal food~~

1 ~~and drug administration~~ FDA list of approved drug substances and  
2 manufacturers that is published periodically.

3 (b) (I) A PHARMACIST FILLING A PRESCRIPTION ORDER FOR A  
4 SPECIFIC BIOLOGICAL PRODUCT MAY SUBSTITUTE AN INTERCHANGEABLE  
5 BIOLOGICAL PRODUCT FOR THE PRESCRIBED BIOLOGIC ONLY IF:

6 (A) THE FDA HAS DETERMINED THAT THE BIOLOGICAL PRODUCT  
7 TO BE SUBSTITUTED IS INTERCHANGEABLE WITH THE PRESCRIBED  
8 BIOLOGICAL PRODUCT; AND

9 (B) THE PRACTITIONER HAS NOT INDICATED, IN THE MANNER  
10 DESCRIBED IN SUBSECTION (2) OF THIS SECTION, THAT THE PHARMACIST  
11 SHALL NOT SUBSTITUTE AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR  
12 THE PRESCRIBED BIOLOGICAL PRODUCT.

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

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

21 (2) (a) If, in the opinion of the practitioner, it is in the best interest  
22 of the patient that the pharmacist not substitute an equivalent drug OR  
23 INTERCHANGEABLE BIOLOGICAL PRODUCT for the specific drug OR  
24 BIOLOGICAL PRODUCT he or she prescribed, the practitioner may convey  
25 this information to the pharmacist in any of the following manners:

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

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

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

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

8 (3) (a) If a pharmacist makes a substitution PURSUANT TO  
9 SUBSECTION (1) OF THIS SECTION, the pharmacist shall communicate the  
10 substitution to the purchaser in writing and orally, label the container with  
11 the name of the drug OR BIOLOGICAL PRODUCT dispensed, and indicate on  
12 the file copy of the prescription both the name of the prescribed drug OR  
13 BIOLOGICAL PRODUCT and the name of the drug OR BIOLOGICAL PRODUCT  
14 dispensed in lieu of the prescribed drug OR PRESCRIBED BIOLOGICAL  
15 PRODUCT.

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

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

25 (5) If a prescription drug outlet does not have in stock the  
26 prescribed drug OR BIOLOGICAL product and the only equivalent drug OR  
27 INTERCHANGEABLE BIOLOGICAL product in stock is higher priced, the

1 pharmacist, with the consent of the purchaser, may substitute the higher  
2 priced drug OR INTERCHANGEABLE BIOLOGICAL product. This subsection  
3 (5) applies only to a prescription drug outlet located in a town, as defined  
4 in section 31-1-101 (13), C.R.S.

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

9 **SECTION 3. Safety clause.** The general assembly hereby finds,  
10 determines, and declares that this act is necessary for the immediate  
11 preservation of the public peace, health, and safety.