

First Regular Session
Seventieth General Assembly
STATE OF COLORADO

REENGROSSED

*This Version Includes All Amendments
Adopted in the House of Introduction*

LLS NO. 15-0482.01 Christy Chase x2008

SENATE BILL 15-071

SENATE SPONSORSHIP

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

HOUSE SPONSORSHIP

McCann and Landgraf, Ginal

Senate Committees
Health & Human Services

House Committees

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.**

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.

SENATE
3rd Reading Unamended
February 5, 2015

SENATE
Amended 2nd Reading
February 4, 2015

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.

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.

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

1 (A) THERE IS NO FDA-APPROVED INTERCHANGEABLE BIOLOGICAL
2 PRODUCT FOR THE PRESCRIBED BIOLOGICAL PRODUCT; OR

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

6 == ==
7 (III) THE PHARMACY FROM WHICH THE BIOLOGICAL PRODUCT WAS
8 DISPENSED MUST RETAIN A WRITTEN OR ELECTRONIC RECORD OF THE
9 DISPENSED BIOLOGICAL PRODUCT FOR AT LEAST TWO YEARS AFTER THE
10 SUBSTITUTION.

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

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

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

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

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

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

1 (3) (a) If a pharmacist makes a substitution PURSUANT TO
2 SUBSECTION (1) OF THIS SECTION, the pharmacist shall communicate the
3 substitution to the purchaser in writing and orally, label the container with
4 the name of the drug OR BIOLOGICAL PRODUCT dispensed, and indicate on
5 the file copy of the prescription both the name of the prescribed drug OR
6 BIOLOGICAL PRODUCT and the name of the drug OR BIOLOGICAL PRODUCT
7 dispensed in lieu of the prescribed drug OR PRESCRIBED BIOLOGICAL
8 PRODUCT.

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

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

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

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

1 PRODUCTS.

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