

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2015

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SENATE BILL 197\*

Short Title: Allow Substitution of Biosimilars. (Public)

Sponsors: Senators Apodaca, Hise (Primary Sponsors); Clark, Rabin, Van Duyn, and Woodard.

Referred to: Health Care.

March 9, 2015

1 A BILL TO BE ENTITLED  
2 AN ACT AMENDING THE NORTH CAROLINA PHARMACY PRACTICE ACT TO  
3 ALLOW FOR THE SUBSTITUTION OF AN INTERCHANGEABLE BIOLOGICAL  
4 PRODUCT.

5 The General Assembly of North Carolina enacts:

6 SECTION 1. G.S. 90-85.27 reads as rewritten:

7 "§ 90-85.27. Definitions.

8 As used in G.S. 90-85.28 through G.S. 90-85.31:

9 (1) Biological product. – As defined in section 351(i) of the Public Health  
10 Service Act, 42 U.S.C. § 262(i).

11 (1a) ~~"Equivalent drug product"~~ means Equivalent drug product. – A drug  
12 product which has the same established name, active ingredient, strength,  
13 quantity, and dosage form, and which is therapeutically equivalent to the  
14 drug product identified in the ~~prescription;~~prescription.

15 (2) ~~"Established name" has the meaning given~~Established name. – As defined in  
16 section 502(e)(3) of the Federal Food, Drug and Cosmetic Act, ~~21 U.S.C.~~  
17 ~~352(e)(3);~~21 U.S.C. § 352(e)(3).

18 (3) ~~"Good manufacturing practice" has the meaning given it~~Good manufacturing  
19 practice. – As defined in Part 211 of Chapter 1 of Title 21 of the Code of  
20 Federal ~~Regulations;~~Regulations.

21 (3a) Interchangeable biological product. – A biological product determined by  
22 the United States Food and Drug Administration to meet the standards set  
23 forth in 42 U.S.C. § 262(k)(4), or deemed therapeutically equivalent by the  
24 United States Food and Drug Administration.

25 (4) ~~"Manufacturer" means the~~Manufacturer. – The actual manufacturer of the  
26 finished dosage form of the ~~drug;~~drug.

27 (4a) ~~"Narrow therapeutic index drugs" means those~~Narrow therapeutic index  
28 drugs. – Those pharmaceuticals having a narrowly defined range between  
29 risk and benefit. Such drugs have less than a twofold difference in the  
30 minimum toxic concentration and minimum effective concentration in the  
31 blood or are those drug product formulations that exhibit limited or erratic  
32 absorption, formulation-dependent bioavailability, and wide inpatient  
33 pharmacokinetic variability that requires blood-level monitoring. Drugs  
34 identified as having narrow therapeutic indices shall be designated by the



North Carolina Secretary of Health and Human Services upon the advice of the State Health Director, North Carolina Board of Pharmacy, and North Carolina Medical Board, as narrow therapeutic index drugs and shall be subject to the provisions of G.S. 90-85.28(b1). The North Carolina Board of Pharmacy shall submit the list of narrow therapeutic index drugs to the Codifier of Rules, in a timely fashion for publication in January of each year in the North Carolina Register.

- (5) ~~"Prescriber" means anyone~~ Prescriber. – Anyone authorized to prescribe drugs pursuant to the laws of this State."

**SECTION 2.** G.S. 90-85.28 reads as rewritten:

**"§ 90-85.28. Selection by pharmacists permissible; prescriber may permit or prohibit selection; price limit on selected ~~drugs.~~ drugs; communication of dispensed biological products under specified circumstances.**

(a) A pharmacist dispensing a prescription for a drug product prescribed by its brand name may select any equivalent drug or interchangeable biological product which meets all of the following standards:

- (1) The manufacturer's name and the distributor's name, if different from the manufacturer's name, shall appear on the label of the stock ~~package;~~ package.
- (2) It shall be manufactured in accordance with current good manufacturing ~~practices;~~ practices.
- (3) ~~Effective January 1, 1982, all~~ All oral solid dosage forms shall have a logo, or other identification mark, or the product name to identify the manufacturer or ~~distributor;~~ distributor.
- (4) The manufacturer shall have adequate provisions for drug ~~recall;~~ and recall.
- (5) The manufacturer shall have adequate provisions for return of outdated drugs, through ~~his~~ the distributor or otherwise.

(b) The pharmacist shall not select an equivalent drug or interchangeable biological product if the prescriber instructs otherwise by one of the following methods:

- (1) A prescription form shall be preprinted or stamped with two signature lines at the bottom of the form which read:

" \_\_\_\_\_ Dispense as Written"  
 Product Selection Permitted

On this form, the prescriber shall communicate ~~his~~ instructions to the pharmacist by signing the appropriate line.

- (2) In the event the preprinted or stamped prescription form specified in ~~(b)(1)~~ subdivision (1) of subsection (b) of this section is not readily available, the prescriber may handwrite "Dispense as Written" or words or abbreviations of the same meaning on a prescription form.

- (3) When ordering a prescription orally, the prescriber shall specify either that the prescribed drug product be dispensed as written or that product selection is permitted. The pharmacist shall note the instructions on the file copy of the prescription and retain the prescription form for the period prescribed by law.

(b1) A prescription for a narrow therapeutic index drug shall be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless the prescriber is notified by the pharmacist prior to the dispensing of another manufacturer's product, and the prescriber and the patient give documented consent to the dispensing of the other manufacturer's product. For purposes of this subsection, the term "refilled" shall include a new prescription written at the expiration of a prescription which continues the patient's therapy on a narrow therapeutic index drug.

1       **(b2)** Within a reasonable time following the dispensing of a biological product, the  
2 pharmacist or a designee shall communicate to the prescriber the product name and  
3 manufacturer of the specific biological product dispensed to the patient. This required  
4 communication shall be through an interoperable electronic medical records system, electronic  
5 prescribing technology, or a pharmacy record that is electronically accessible by the prescriber.  
6 Otherwise, the pharmacist or a designee shall provide the required communication to the  
7 prescriber by facsimile, telephone, electronic transmission, or other prevailing means, provided  
8 that communication shall not be required under any of the following circumstances:

9           **(1)** There is no United States Food and Drug Administration-approved  
10 interchangeable biological product for the product prescribed.

11           **(2)** A refill prescription is not changed from the product dispensed on the prior  
12 filling of the prescription.

13       **(b3)** The Board of Pharmacy shall maintain a link on its Internet Web site to the current  
14 list of biological products determined by the United States Food and Drug Administration to be  
15 interchangeable with a specific biological product.

16       **(c)** The pharmacist shall not select an equivalent drug or interchangeable biological  
17 product unless its price to the purchaser is less than the price of the prescribed drug product."

18       **SECTION 3.** G.S. 90-85.31 reads as rewritten:

19       **"§ 90-85.31. Prescriber and pharmacist liability not extended.**

20       The selection of an equivalent drug or interchangeable biological product pursuant to this  
21 Article shall impose no greater liability upon the pharmacist for selecting the dispensed drug or  
22 biological product or upon the prescriber of the same than would be incurred by either for  
23 dispensing the drug or biological product specified in the prescription."

24       **SECTION 4.** G.S. 58-3-178(c)(4) reads as rewritten:

25       **"(4)** "Prescribed contraceptive drugs or devices" means drugs or devices that  
26 prevent pregnancy and that are approved by the United States Food and  
27 Drug Administration for use as contraceptives and obtained under a  
28 prescription written by a health care provider authorized to prescribe  
29 medications under the laws of this State. Prescription drugs or devices  
30 required to be covered under this section shall not include:

31       a. The prescription drug known as "RU-486" or any "equivalent drug  
32 product" as defined in ~~G.S. 90-85.27(1)~~.G.S. 90-85.27.

33       b. The prescription drug marketed under the name "Preven" or any  
34 "equivalent drug product" as defined in  
35 ~~G.S. 90-85.27(1)~~.G.S. 90-85.27."

36       **SECTION 5.** This act becomes effective October 1, 2015.