

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2015

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HOUSE BILL 195\*  
Committee Substitute Favorable 4/1/15

Short Title: Allow Substitution of Biosimilars.

(Public)

Sponsors:

Referred to:

March 11, 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 Manufacturer. – The actual manufacturer of the  
26 finished dosage form of the ~~drug;~~drug.

27 (4a) ~~"Narrow therapeutic index drugs"~~ means 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  
35 North Carolina Secretary of Health and Human Services upon the advice of  
36 the State Health Director, North Carolina Board of Pharmacy, and North





1 required communication shall be conveyed by making an entry into an interoperable electronic  
2 medical records system, or electronic prescribing technology, or a pharmacy benefit  
3 management system, or a pharmacy record that can be electronically accessible by the  
4 prescriber. Entry into one of the above referenced methods of communication is presumed to  
5 provide the required communication. Otherwise, the pharmacist or a designee shall provide the  
6 required communication to the prescriber by facsimile, telephone, electronic transmission, or  
7 other prevailing means, provided that communication shall not be required under any of the  
8 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 (b4) If the State mandates electronic medical records between a pharmacist and a  
17 prescriber as described in subsection (b2) of this section, then the pharmacist shall only be  
18 required to communicate the biological product dispensed through an electronic medical  
19 records system when such a system is in place and the information is accessible by the  
20 prescriber.

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

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

24 **"§ 90-85.31. Prescriber and pharmacist liability not extended.**

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

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

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

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

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

41 **SECTION 5.** This act becomes effective October 1, 2015. G.S. 90-85.28(b2) and  
42 G.S. 90-85.28(b4) as enacted by Section 2 of this act shall expire on October 1, 2020.