GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2015

H **D**

HOUSE BILL 195*
PROPOSED COMMITTEE SUBSTITUTE H195-PCS20173-TK-3

Short Title: Allow Substitution of Biosimilars. (Public)

Sponsors:

Referred to:

March 11, 2015

A BILL TO BE ENTITLED

AN ACT AMENDING THE NORTH CAROLINA PHARMACY PRACTICE ACT TO ALLOW FOR THE SUBSTITUTION OF AN INTERCHANGEABLE BIOLOGICAL PRODUCT.

The General Assembly of North Carolina enacts:

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

"**§ 90-85.27. Definitions.**

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

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

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

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

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

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

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

(4a) ~~"Narrow therapeutic index drugs" means those~~Narrow therapeutic index drugs. – Those pharmaceuticals having a narrowly defined range between risk and benefit. Such drugs have less than a twofold difference in the minimum toxic concentration and minimum effective concentration in the blood or are those drug product formulations that exhibit limited or erratic absorption, formulation-dependent bioavailability, and wide intrapatient pharmacokinetic variability that requires blood-level monitoring. Drugs 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:

" _____ _____

Product Selection Permitted Dispense as Written"

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.

(b2) Within a reasonable time following the dispensing of a biological product requiring a prescription, the pharmacist or a designee shall communicate to the prescriber the product name and manufacturer of the specific biological product dispensed to the patient. This

required communication shall be conveyed by making an entry into an interoperable electronic medical records system, or electronic prescribing technology, or a pharmacy benefit management system, or a pharmacy record that can be electronically accessible by the prescriber. Entry into one of the above referenced methods of communication is presumed to provide the required communication. Otherwise, the pharmacist or a designee shall provide the required communication to the prescriber by facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required under any of the following circumstances:

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

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

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

(b4) If the State mandates electronic medical records between a pharmacist and a prescriber as described in subsection (b2) of this section, then the pharmacist shall only be required to communicate the biological product dispensed through an electronic medical records system when such a system is in place and the information is accessible by the prescriber.

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

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

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

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

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

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

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

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

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