HOUSE BILL 195:
Allow Substitution of Biosimilars

2015-2016 General Assembly

Committee:	Senate Health Care	**Date:**	May 12, 2015
Introduced by:	Reps. Dollar, S. Martin, Avila, Lambeth	**Prepared by:**	Theresa Matula Kristen Harris Committee Counsel
Analysis of:	Second Edition		

SUMMARY: House Bill 195 would amend the NC Pharmacy Practice Act. The bill would provide definitions for biological and interchangeable products; allow for the substitution of an interchangeable biological product for a prescribed drug product; require communication between a pharmacist and prescriber under certain circumstances when a biological product is dispensed; and require the Board of Pharmacy to maintain a list of biological products determined by the FDA to be interchangeable with a specific biological product. The bill would extend the liability protection a pharmacist currently has for substituting a generic drug product for a prescribed drug product to the substitution of an interchangeable drug product for a prescribed drug product.

[As introduced, this bill was identical to S197, as introduced by Senators Apodaca and Hise which is currently in Senate Health Care.]

CURRENT LAW: The NC Pharmacy Practice Act allows a pharmacist to dispense an equivalent drug product (typically referred to as a generic) when a brand name drug is prescribed, provided that certain standards are met. Under 90-85.28, the prescriber may specify that an equivalent drug product is not to be used by utilizing one of three methods:

- By selecting on the prescription form whether product selection is permitted or whether the pharmacist must dispense as written.
- Notating "dispense as written" on the prescription.
- When ordering a prescription orally, specifying that the product be dispensed as written or allowing for product selection.

With regard to refills, a narrow therapeutic index drug (a drug having a narrowly defined range between risk and benefit) must be refilled using the same drug product by the same manufacturer that the pharmacist last dispensed, unless the pharmacist notifies the prescriber prior to dispensing another manufacturer's product and the patient consents.

Pharmacists are not allowed to select an equivalent drug product unless its cost to the purchaser is less than the price of the prescribed drug.

BACKGROUND:

The Patient Protection and Affordable Care Act (ACA) created an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-approved biological product. A "biosimilar" is a biological product that is highly similar to a U.S.-licensed reference biological product notwithstanding minor differences in the clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product. A healthcare provider

has to write the specific name of the biosimilar on the prescription to prescribe it. An interchangeable biological product is biosimilar to an FDA-approved reference product and can be expected to produce the same clinical result and may be substituted without the intervention of a healthcare provider who prescribed the reference product.[1] The first biosimilar was approved on March 6, 2015.[2] At this time, there are no approved interchangeable biological products.

BILL ANALYSIS:

Section 1 would add the terms biological product and interchangeable biological product to the definitions found in G.S. 90-85.27 which is part of the North Carolina Pharmacy Practice Act. Both definitions reference those found in the federal regulations under 42 USC 262.

Section 2 would make conforming changes to allow for interchangeable biological products to be treated the same as equivalent drug products when a pharmacist is making a substitution. **Section 2** would also add these new subsections to G.S. 90-85.28.

- Subsection (b2) would require a pharmacist or a designee to communicate to the prescriber of a biological product the name and manufacturer of the product dispensed to the patient. The communication would have to be done by making an entry into one of the following: 1) an interoperable electronic medical records system, 2) an electronic prescribing technology, 3) a pharmacy benefit management system, or 4) or pharmacy record that could be electronically accessed by the provider. If no such communication method is available, then the pharmacist or designee has to provide the product name and manufacturer by fax, phone, email or other means, except no communication is required if there was no FDA-approved interchangeable biological product for the product prescribed or the refill prescription was not changed from the product dispensed on the prior filling of the prescription.
- Subsection (b3) would require the North Carolina Board of Pharmacy to maintain a link on its website to the current list of biological products determined by the FDA to be interchangeable with a specific biological product.
- Subsection (b4) would direct that if the State mandates electronic medical records between a pharmacist and a prescriber as described in subsection (b2), then the pharmacist would 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.

Section 3 would amend G.S. 90-85.31 by extending the protections from liability that a pharmacist or prescriber has when selecting an equivalent drug product to the selection of an interchangeable biological product. The selection of an equivalent drug product or an interchangeable drug product would not impose a greater liability upon the pharmacist or the prescriber than if they had dispensed the drug product specified in the prescription.

Section 4 would make a technical change to conform to changes made to the definitions in **Section 1** of the bill.

EFFECTIVE DATE: 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 expire on October 1, 2020.

Amy Jo Johnson, former Committee Counsel to Senate Health Care, substantially contributed to this summary.

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[1] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm

[2] Zarxio is used to prevent infections in cancer patients receiving chemotherapy.