HOUSE BILL 195:
Allow Substitution of Biosimilars

2015-2016 General Assembly

Committee:	House Health	**Date:**	April 1, 2015
Introduced by:	Reps. Dollar, S. Martin, Avila, Lambeth	**Prepared by:**	Amy Jo Johnson Committee Counsel
Analysis of:	Second Edition		

SUMMARY: House Bill 195 amends the NC Pharmacy Practice Act to provide for a definition of biological products and interchangeable biological products and allow for the substitution of interchangeable biological products. The bill also requires pharmacist communication with the prescriber under specified circumstances when a biological product is dispensed. House Bill 195 requires the Board of Pharmacy to maintain a list of biological products determined by the US FDA to be interchangeable with a specific biological product. The bill also makes conforming statutory changes.

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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 regards 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 it's 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 determined to be "biosimilar" to an already-approved biological product. According to the US Food and Drug Administration, 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."[1] The first biosimilar was approved on March 6, 2015. At this time, there are no approved interchangeable biological products.

BILL ANALYSIS:

Section 1 of H195 adds 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 352.

Section 2 of H195 makes some 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** also adds two new subsections to G.S. 90-85.28.

The new subsection (b2) requires that a pharmacist or a designee communicate to the prescriber the product name and manufacturer of a biological product dispensed to a patient. If available, the communication must be done by making an entry into an interoperable electronic medical records system, electronic prescribing technology, a pharmacy benefit management system or a pharmacy record that can be electronically accessed by the provider. If no such communication method is available, then the pharmacist or designee must provide the product name and manufacturer of a biological product dispensed to a patient using fax, phone, email or other means. Additionally, if an interoperable electronic medical records system, electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record that can be electronically accessed by the provider is not available, the pharmacist or designee will not be required to send the communication via fax, phone, email or other means if there is no interchangeable biological product approved by the FDA for the product prescribed or a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

The new subsection (b3) requires 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.

The bill adds a new subsection (b4) which directs that if the State mandates electronic medical records between a pharmacist and a prescriber as described in subsection (b2), then the pharmacist is 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 extends the same 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 upon the prescriber would have by either dispensing the drug or biological product specified in the prescription.

Section 4 makes a technical change.

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.

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