The Senate Committee on Health and Human Services offers the following substitute to SB 51:

A BILL TO BE ENTITLED
AN ACT

To amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, so as to provide for substitutions of interchangeable biological products; to define certain terms; to provide for requirements and limitations; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, is amended by revising Code Section 26-4-5, relating to definitions, by adding new paragraphs to read as follows:

"(1.1) 'Biological product' means a biological product as defined in subsection (i) of Section 351 of the Public Health Service Act, 42 U.S.C. Section 262."

"(18.2) 'Interchangeable biological product' means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in subsection (k)(4) of 42 U.S.C. Section 262 or has been deemed therapeutically equivalent by the federal Food and Drug Administration."

SECTION 2.

Said chapter is further amended by revising Code Section 26-4-81, relating to substitution of generic drugs for brand name drugs, as follows:

"26-4-81.

(a) In accordance with this Code section, a pharmacist may substitute:

(1) A ~~a~~ drug with the same generic name in the same strength, quantity, dose, and dosage form as the prescribed brand name drug product which is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent; or

(2) A biological product with an interchangeable biological product.

(b) If a practitioner of the healing arts prescribes:

(1) A ~~a~~ drug by its generic name, the pharmacist shall dispense the lowest retail priced drug product which is in stock and which is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent; or

(2) A biological product by its nonproprietary name, the pharmacist shall dispense the lowest retail priced interchangeable biological product which is in stock.

(c) Substitutions as provided for in subsections (a) and (b) of this Code section are authorized for the express purpose of making available to the consumer the lowest retail priced:

(1) Drug ~~drug~~ product which is in stock and which is, in the pharmacist's reasonable professional opinion, both therapeutically equivalent and pharmaceutically equivalent; or

(2) Interchangeable biological product which is in stock.

(d)(1) Whenever a substitution is made, the pharmacist shall record on the original prescription the fact that there has been a substitution and the identity of the dispensed drug product or interchangeable biological product and its manufacturer. Such prescription shall be made available for inspection by the board or its representative in accordance with the rules of the board.

(2) If a pharmacist substitutes a generic drug product for a brand name prescribed drug product when dispensing a prescribed medication, the brand name and the generic name of the drug product, with an explanation of 'generic for (insert name of brand name prescribed drug product)' or similar language to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the drug may not appear upon the prescription label; provided, however, that this paragraph shall not apply to medication dispensed for in-patient hospital services or to medications in specialty packaging for dosing purposes as defined by the board.

(3) If a pharmacist substitutes an interchangeable biological product for a prescribed biological product when dispensing a prescribed medication, the name of the interchangeable biological product, with an explanation of 'interchangeable biological product for (insert name of prescribed biological product)' or similar language to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the biological product may not appear upon the prescription label; provided, however, that this paragraph shall not apply to biological products dispensed for in-patient hospital services or to biological products in specialty packaging for dosing purposes as defined by the board.

(e) The substitution of any drug or biological product by a registered pharmacist pursuant to this Code section does not constitute the practice of medicine.

(f) A patient for whom a prescription drug or biological product order is intended may instruct a pharmacist not to substitute a generic name drug in lieu of a brand name drug or an interchangeable biological product in lieu of a prescribed biological product.

(g) A practitioner of the healing arts may instruct the pharmacist not to substitute a generic name drug in lieu of a brand name drug or an interchangeable biological product in lieu of a prescribed biological product by including the words 'brand necessary' in the body of the prescription. When a prescription is a hard copy prescription drug or biological product order, such indication of brand necessary must be in the practitioner's own handwriting and shall not be printed, applied by rubber stamp, or any such similar means. When the prescription is an electronic prescription drug or biological product order, the words 'brand necessary' are not required to be in the practitioner's own handwriting and may be included on the prescription in any manner or by any method. When a practitioner has designated 'brand necessary' on an electronic prescription drug or biological product order, a generic drug or interchangeable biological product shall not be substituted without the practitioner's express consent, which shall be documented by the pharmacist on the prescription and by the practitioner in the patient's medical record.

(h) Within 48 hours, excluding weekends and holidays, following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

(1) There is no federal Food and Drug Administration approved interchangeable biological product for the prescribed product; or

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

(i) The State Board of Pharmacy shall maintain a link on its website to the current list of all biological products determined by the federal Food and Drug Administration to be interchangeable with a specific biological product.″

SECTION 3.

All laws and parts of laws in conflict with this Act are repealed.