Senate Bill 370

By: Senator Carter of the 1st

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 define certain terms; to provide for substitutions of interchangeable biological products; 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 in Code Section 26-4-5, relating to definitions, by adding new paragraphs to read as follows:

"(1.1) 'Biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide) or analogous product, or arsphenamine, derivative of arsphenamine, or any other trivalent organic arsenic compound applicable to the prevention, treatment, or cure of a disease or condition of human beings."

"(18.2) 'Interchangeable biological product' means a biological product that the United States Food and Drug Administration has determined meets the safety standards set forth in 42 U.S.C. Section 262(k)(4) and may be substituted for the referenced product without the intervention of the health care provider who prescribed the referenced product."

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 a drug with the same generic name in the same strength, quantity, dose, and dosage form as the prescribed brand name drug product or an interchangeable biological product where the route of

administration, dosage form, and strength of the interchangeable biological product are the same as those of the prescribed biological product, which is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent.

(b) If a practitioner of the healing arts prescribes a drug by its generic name or prescribes an interchangeable biological product by its nonproprietary 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.

(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 drug product or biological product which is in stock and which is, in the pharmacist's reasonable professional opinion, both therapeutically equivalent and pharmaceutically equivalent.

(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 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 brand name prescribed biological product when dispensing a prescribed medication, the brand name and the nonproprietary name of the interchangeable biological product, with an explanation of 'interchangeable biological product for (insert name of brand name 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 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.

(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."

SECTION 3.

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