

The House Committee on Health and Human Services offers the following substitute to HB 195:

A BILL TO BE ENTITLED  
AN ACT

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

5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

6 **SECTION 1.**

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

10 "(1.1) 'Biological product' means a biological product as defined in subsection (i) of  
11 section 351 of the Public Health Service Act, 42 U.S.C. Section 262."

12 "(18.2) 'Interchangeable biological product' means a biological product that the federal  
13 Food and Drug Administration has determined meets the standards set forth in subsection  
14 (k)(4) of 42 U.S.C. Section 262 or has been deemed therapeutically equivalent by the  
15 federal Food and Drug Administration."

16 **SECTION 2.**

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

19 "26-4-81.

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

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

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

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

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

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

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

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

37 (2) Interchangeable biological product which is in stock.

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

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

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

62 paragraph shall apply to hospital retail pharmacies and to any biological products  
63 dispensed by a hospital for a patient's use or administration at home.

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

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

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

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

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

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

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

98 (j) Code Section 26-4-118, 'The Pharmacy Audit Bill of Rights,' shall apply to biological  
99 products and interchangeable biological products dispensed pursuant to this Code section.'

100

**SECTION 3.**

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