

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

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:

SECTION 1.

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

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."

SECTION 2.

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

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.