

House Bill 681

By: Representatives Byrd of the 20<sup>th</sup>, Lunsford of the 110<sup>th</sup>, Shipp of the 58<sup>th</sup>, Hill of the 21<sup>st</sup>,  
Cheokas of the 134<sup>th</sup>, and others

A BILL TO BE ENTITLED

AN ACT

1 To amend Article 5 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated,  
2 relating to prescription drugs, so as to change certain provisions relating to the substitution  
3 of generic drugs; to provide legislative findings; to eliminate redundant language relating to  
4 the practice of medicine; to prohibit the substitution of anti-epileptic drugs except under  
5 certain conditions; to provide for related matters; to repeal conflicting laws; and for other  
6 purposes.

7 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

8 **SECTION 1.**

9 The General Assembly finds that epileptic children and adults are entering clinics and  
10 emergency rooms with life-threatening seizures due to the undisclosed substitution of generic  
11 drugs for their prescribed drugs. While the Food and Drug Administration is investigating  
12 whether an extended release generic drug provides less active drug effects than the  
13 comparable brand name, leading to increased risk of severe and life-threatening seizures,  
14 Georgia continues to authorize the substitution of generic drugs without patient or physician  
15 consent. This undisclosed generic drug substitution has resulted in medical complications,  
16 severe injuries, seizure-related automobile accidents, and even death of epileptic patients,  
17 including many epileptic children. Experts in epilepsy and its treatment have routinely  
18 advised against switching among different versions of the same drug without physician  
19 guidance, monitoring, and oversight. The General Assembly further finds that the potential  
20 for increased profits to pharmacies or cost savings to medical insurance companies resulting  
21 from the use of generic drugs does not outweigh the substantial risk of permitting drug  
22 substitution without informed consent. No one should have to risk a seizure because of a  
23 flawed formulation of their medication.

24 **SECTION 2.**

25 Article 5 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to  
 26 prescription drugs, is amended by revising Code Section 26-4-81, relating to substitution of  
 27 generic drugs for brand name drugs, as follows:

28 "26-4-81.

29 (a) In accordance with this Code section and except as otherwise provided in Code Section  
 30 26-4-81.1, a pharmacist may substitute a drug with the same generic name in the same  
 31 strength, quantity, dose, and dosage form as the prescribed brand name drug product which  
 32 is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent.

33 (b) If a practitioner of the healing arts prescribes a drug by its generic name, the  
 34 pharmacist shall dispense the lowest retail priced drug product which is in stock and which  
 35 is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent.

36 (c) Substitutions as provided for in subsections (a) and (b) of this Code section are  
 37 authorized for the express purpose of making available to the consumer the lowest retail  
 38 priced drug product which is in stock and which is, in the pharmacist's reasonable  
 39 professional opinion, both therapeutically equivalent and pharmaceutically equivalent.

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

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

46 (f) A patient for whom a prescription drug order is intended may instruct a pharmacist not  
 47 to substitute a generic name drug in lieu of a brand name drug.

48 (g) A practitioner of the healing arts may instruct the pharmacist not to substitute a generic  
 49 name drug in lieu of a brand name drug by including the words 'brand necessary' in the  
 50 body of the prescription. When a prescription is a hard copy prescription drug order, such  
 51 indication of brand necessary must be in the practitioner's own handwriting and shall not  
 52 be printed, applied by rubber stamp, or any such similar means.

53 ~~(h) The substitution of any drug by a registered pharmacist pursuant to this Code section~~  
 54 ~~does not constitute the practice of medicine."~~

55 **SECTION 3.**

56 Said article is further amended by adding a new Code section to read as follows:

57 "26-4-81.1.

58 (a) As used in this Code section, the term:

59 (1) 'Anti-epileptic drug' means:

60 (A) Any drug prescribed for the treatment of epilepsy; and

61 (B) A drug used to treat or prevent seizures.

62 (2) 'Epilepsy' means a neurological condition characterized by recurrent seizures.

63 (3) 'Interchange' means the substitution of one version of a drug for another, including  
64 a generic version for the prescribed brand version, a brand version for the prescribed  
65 generic version, a generic version by one manufacturer for a generic version by another  
66 manufacturer, a different formulation of the prescribed version, and a different drug for  
67 the product prescribed.

68 (4) 'Seizure' means an acute clinical change secondary to a brief disturbance in the  
69 electrical activity of the brain.

70 (b) A pharmacist shall not interchange an anti-epileptic drug or formulation of an  
71 anti-epileptic drug without prior approval from the prescribing physician."

72 **SECTION 4.**

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