

The House Committee on Health and Human Services offers the following substitute to HB 952:

A BILL TO BE ENTITLED
AN ACT

1 To amend Code Section 26-4-5 of the Official Code of Georgia Annotated, relating to
2 definitions applicable to pharmacists and pharmacies, so as to provide for definitions of
3 certain opioid drugs; to amend Code Section 26-4-28 of the Official Code of Georgia
4 Annotated, relating to powers, duties, and authority of the State Board of Pharmacy, so as
5 to authorize the State Board of Pharmacy to approve and designate certain opioid products
6 that utilize tamper resistance technologies; to amend Code Section 26-4-81 of the Official
7 Code of Georgia Annotated, relating to substitution of generic drugs for brand name drugs,
8 so as to provide for instructions from physicians to pharmacists relating to the use of tamper
9 resistant technologies; to provide for related matters; to provide an effective date; to repeal
10 conflicting laws; and for other purposes.

11 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

12 style="text-align:center">**SECTION 1.**

13 Code Section 26-4-5 of the Official Code of Georgia Annotated, relating to definitions
14 applicable to pharmacists and pharmacies, is revised by adding two new paragraphs to read
15 as follows:

16 "(24.1) 'Opioid drug' means a drug in the opioid drug class prescribed to treat moderate
17 to severe pain or other conditions, whether in immediate release or extended release form
18 and whether combined with other drug substances to form a single tablet or other dosage
19 form.

20 (24.2) 'Opioid drug incorporating tamper resistant technology' means an opioid drug
21 listed by the State Board of Pharmacy based upon a submission of evidence by the drug
22 manufacturer or distributor that the drug:

23 (A) Incorporates a tamper resistance technology; and

24 (B) Has been approved by the United States Food and Drug Administration pursuant
25 to an application that includes:

26 (i) At least one human tampering or abuse potential study; or

27 (ii) A laboratory study comparing the tamper or abuse resistance properties of the
 28 drug to one or more opioid drugs that have previously been approved by the United
 29 States Food and Drug Administration as a positive control."

30 **SECTION 2.**

31 Code Section 26-4-28 of the Official Code of Georgia Annotated, relating to powers, duties,
 32 and authority of the State Board of Pharmacy, is amended by revising subsection (a) by
 33 deleting "and" at the end of paragraph (20), by replacing the period with "; and" at the end
 34 of paragraph (21), and by adding a new paragraph to read as follows:

35 "(22) The designation of certain opioid products as opioid drugs incorporating tamper
 36 resistant technology."

37 **SECTION 3.**

38 Code Section 26-4-81 of the Official Code of Georgia Annotated, relating to substitution of
 39 generic drugs for brand name drugs, is amended by revising subsection (g) and by adding a
 40 new subsection to read as follows:

41 "(g) A practitioner of the healing arts may ~~instruct~~:

42 (1) ~~Instruct~~ the pharmacist not to substitute a generic name drug in lieu of a brand name
 43 drug by including the words 'brand necessary' in the body of the prescription. When a
 44 prescription is a hard copy prescription drug order, such indication of brand necessary
 45 must be in the practitioner's own handwriting and shall not be printed, applied by rubber
 46 stamp, or any such similar means. When the prescription is an electronic prescription
 47 drug order, the words 'brand necessary' are not required to be in the practitioner's own
 48 handwriting and may be included on the prescription in any manner or by any method.
 49 When a practitioner has designated 'brand necessary' on an electronic prescription drug
 50 order, a generic drug shall not be substituted without the practitioner's express consent,
 51 which shall be documented by the pharmacist on the prescription and by the practitioner
 52 in the patient's medical record.

53 (2) Require a pharmacist dispensing an opioid drug to incorporate tamper resistant
 54 technology by:

55 (A) Writing the words 'TRF necessary' in the body of the prescription; or

56 (B) Checking a box on the prescription with the designation 'tamper resistant
 57 formulation required.'

58 (h) The State Board of Pharmacy shall identify a list of opioid drugs incorporating tamper
 59 resistant technology. Inclusion of a drug on such list shall not require that the drug bear
 60 a label purporting to reduce tampering abuse or abuse potential at the time of listing. Such

61 list shall also indicate which opioid drugs are listed as opioid drugs incorporating tamper
62 resistant technology based solely upon evidence submitted by the drug manufacturer.
63 (i) Nothing in this Code section shall be interpreted to require a hospital pharmacy to
64 dispense medications according to brand necessary restrictions or to require a hospital
65 pharmacy to utilize tamper resistant formulations. A hospital pharmacy shall be authorized
66 to dispense medications according to the established drug formulary policy of the hospital
67 in which the pharmacy is located."

68 **SECTION 4.**

69 This Act shall become effective upon its approval by the Governor or upon its becoming law
70 without such approval.

71 **SECTION 5.**

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