

Bill No. HB 2125, 2nd Eng.

Amendment No.

	<u>Senate</u>	CHAMBER ACTION	<u>House</u>
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11	Senator Silver moved the following amendment:		
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13	Senate Amendment (with title amendment)		
14	On page 68, between lines 27 and 28,		
15			
16	insert:		
17	Section 57. Subsection (6) of section 465.025, Florida		
18	Statutes, is amended to read:		
19	465.025 Substitution of drugs.--		
20	(6) The Board of Pharmacy and the Board of Medicine		
21	shall establish by rule a formulary of generic drug type and		
22	brand name drug products which <u>have not been rated as</u>		
23	<u>therapeutically equivalent in "Approved Drug Products with</u>		
24	<u>Therapeutic Equivalence Evaluations" (Orange Book) published</u>		
25	<u>by the Federal Food and Drug Administration, and were not</u>		
26	<u>eligible for generic substitution for brand name drug products</u>		
27	<u>in at least 40 other states on January 1, 1999</u> are determined		
28	by the boards to demonstrate clinically significant biological		
29	or therapeutic inequivalence and which, if substituted, would		
30	pose a threat to the health and safety of patients receiving		
31	prescription medication.		

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1 (a) The formulary may be added to or deleted from as
 2 the Board of Pharmacy and the Board of Medicine deem
 3 appropriate. Any person who requests any inclusion, addition,
 4 or deletion of a generic drug type or brand name drug product
 5 to the formulary shall have the burden of proof to show cause
 6 why such inclusion, addition, or deletion should be made.

7 (b) Upon adoption of the formulary required by this
 8 subsection, and upon each addition, deletion, or modification
 9 to the formulary, the Board of Pharmacy shall mail a copy to
 10 each manager of the prescription department of each community
 11 pharmacy licensed by the state, each nonresident pharmacy
 12 registered in the state, and each board regulating
 13 practitioners licensed by the laws of the state to prescribe
 14 drugs shall incorporate such formulary into its rules. No
 15 pharmacist shall substitute a generically equivalent drug
 16 product for a prescribed brand name drug product if the brand
 17 name drug product or the generic drug type drug product is
 18 included in the said formulary, unless the generically
 19 equivalent drug product has been rated as therapeutically
 20 equivalent in the Orange Book.

21
22 (Redesignate subsequent sections.)

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24
25 ===== T I T L E A M E N D M E N T =====

26 And the title is amended as follows:

27 On page 5, line 10, after the semicolon,

28
29 and insert:

30 amending s. 465.025, F.S.; revising
31 requirements for the Board of Pharmacy and the

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1 Board of Medicine in adopting a formulary of
2 generic drugs and brand name drugs;
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