Bill No. SB 370

Amendment No. ___

CHAMBER ACTION

Senate	House
.	
.	
.	
.	
.	
.	

Senator Myers moved the following amendment:

Senate Amendment (with title amendment)

On page 1, between lines 25 and 26,

insert:

Section 2. Subsection (6) of section 465.025, Florida Statutes, is amended to read:

465.025 Substitution of drugs.--

(6) The Board of Pharmacy and the Board of Medicine shall establish by rule a formulary of generic drug type and brand name drug products as defined in 21 C.F.R. section 320.33 which meet all of the following criteria: the drug product requires careful patient titration under the supervision of a physician to establish the proper patient dose; the drug product requires routine laboratory monitoring of the patient to maintain the proper patient dose; improper patient dosing can lead to life-threatening adverse events; and the drug is a chronic-care medication involving therapy beyond 30 days ~~which are determined by the boards to demonstrate clinically significant biological or therapeutic~~

~~inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication~~.

(a) The formulary may be added to or deleted from as the Board of Pharmacy and the Board of Medicine deem appropriate; however, the Board of Pharmacy and the Board of Medicine shall jointly review the formulary not less than once every 2 years to determine whether each of the individual drug products on the formulary continues to meet the criteria established in this subsection. Any person who requests any inclusion, addition, or deletion of a generic drug type or brand name drug product to the formulary shall have the burden of proof to show cause why such inclusion, addition, or deletion should be made.

(b) Upon adoption of the formulary required by this subsection, and upon each addition, deletion, or modification to the formulary, the Board of Pharmacy shall mail a copy to each manager of the prescription department of each community pharmacy licensed by the state, each nonresident pharmacy registered in the state, and each board regulating practitioners licensed by the laws of the state to prescribe drugs shall incorporate such formulary into its rules. No pharmacist shall substitute a generically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type drug product is included in the the ~~said~~ formulary, unless the prescriber authorizes substitution in advance of dispensing such substitute drug product.

(Redesignate subsequent sections.)

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

And the title is amended as follows:

On page 1, line 6, after the semicolon,

insert:

amending s. 465.025, F,S.; prescribing criteria for inclusion of drugs on the formulary; requiring periodic review of drugs on the formulary; requiring prior physician authorization for substitution of drugs;